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federal register

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday). This is a voluntary program. (See OFR NOTICE 41 FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/SECRETARY	USDA/ASCS		DOT/SECRETARY	USDA/ASCS
DOT/COAST GUARD	USDA/FNS		DOT/COAST GUARD	USDA/FNS
DOT/FAA	USDA/FSQS		DOT/FAA	USDA/FSQS
DOT/FHWA	USDA/REA		DOT/FHWA	USDA/REA
DOT/FRA	MSPB/OPM		DOT/FRA	MSPB/OPM
DOT/NHTSA	LABOR		DOT/NHTSA	LABOR
DOT/RSPA	HHS/FDA		DOT/RSPA	HHS/FDA
DOT/SLSDC			DOT/SLSDC	
DOT/UMTA			DOT/UMTA	
CSA			CSA	

Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday.
Comments on this program are still invited.
Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408

NOTE: As of September 2, 1980, documents from the Animal and Plant Health Inspection Service, Department of Agriculture, will no longer be assigned to the Tuesday/Friday publication schedule.

REMINDERS

The "reminders" below identify documents that appeared in issues of the **Federal Register** 15 days or more ago. Inclusion or exclusion from this list has no legal significance.

Rules Going Into Effect Today

Note: There were no items eligible for inclusion in the list of **Rules Going Into Effect Today.**

List of Public Laws

Last Listing December 30, 1980

This is a continuing listing of public bills from the current session of Congress which have become Federal laws. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (telephone 202-275-3030).

H.J. Res. 615 / Pub. L. 96-563 Providing for appointment of David C. Acheson as a citizen regent of the Board of Regents of the Smithsonian Institution (December 22, 1980; 94 Stat. 3304) Price $1.

S. 2227 / Pub. L. 96-564 To grant the consent of the United States to the Red River Compact among the States of Arkansas, Louisiana, Oklahoma, and Texas (December 22, 1980; 94 Stat. 3305) Price $1.25.

H.R. 7217 / Pub. L. 96-565 To establish the Kalaupapa National Historical Park in the State of Hawaii, and for other purposes (December 22, 1980; 94 Stat. 3321) Price $1.

H.J. Res. 642 / Pub. L. 96-566 Providing for convening of the first regular session of the Ninety-seventh Congress on January 5, 1981, and for other purposes (December 22, 1980; 94 Stat. 3328) Price $1.

H.R. 7865 / Pub. L. 96-567 Nuclear Safety Research, Development, and Demonstration Act of 1980 (December 22, 1980; 94 Stat. 3329) Price $1.

S. 3027 / Pub. L. 96-568 Disaster Relief Act Amendments of 1980 (December 22, 1980; 94 Stat. 3334) Price $1.

S. 2726 / Pub. L. 96-569 Environmental Research, Development, and Demonstration Authorization Act of 1981 (December 22, 1980; 94 Stat. 3335) Price $1.

H.R. 2111 / Pub. L. 96-570 To extend the service area for the Sacramento Valley Canals, Central Valley project, California, and for other purposes (December 22, 1980; 94 Stat. 3339) Price $1.

S. 1784 / Pub. L. 96-571 Alaska Federal-Civilian Energy Efficiency Swap Act of 1980 (December 22, 1980; 94 Stat. 3341) Price $1.

S. 1148 / Pub. L. 96-572 To reauthorize title I of the Marine Protection, Research, and Sanctuaries Act, and for other purposes (December 22, 1980; 94 Stat. 3344) Price $1.

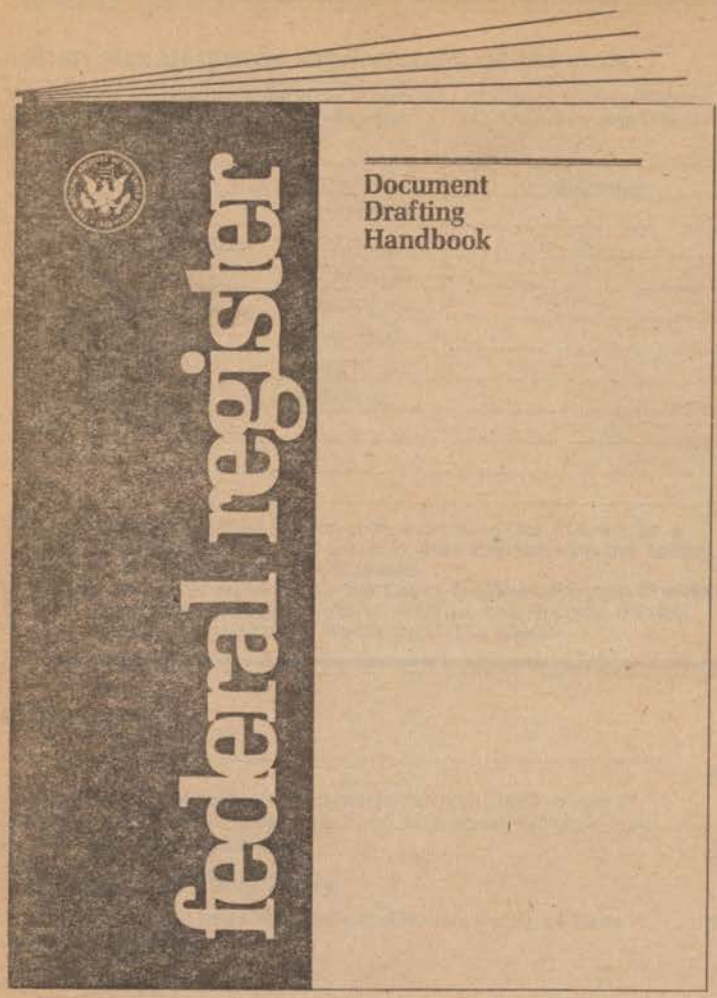
S. 2189 / Pub. L. 96-573 Low-Level Radioactive Waste Policy Act (December 22, 1980; 94 Stat. 3347) Price $1.

H.R. 999 / Pub. L. 96-574 To amend the Plant Variety Protection Act (7 U.S.C. 2321 et seq.) to clarify its provisions, and for other purposes (December 22, 1980; 94 Stat. 3350) Price $1.

H.R. 4941 / Pub. L. 96-575 To name a dam and reservoir on the San Gabriel River, Texas, as the "North San Gabriel Dam" and "Lake Georgetown", respectively (December 22, 1980; 94 Stat. 3353) Price $1.

H.R. 8345 / Pub. L. 96-576 To name the United States Customs House in Ogdensburg, New York, the "Robert C. McEwen United States Customs House" (December 22, 1980; 94 Stat. 3355) Price $1.

H. J. Res. 337 / Pub. L. 96-577 Designating February 11, 1981, "National Inventors' Day" (December 22, 1980; 94 Stat. 3357) Price $1.



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Tuesday, December 30, 1980

MEETINGS ANNOUNCED IN THIS ISSUE

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
Vol. 45, No. 251
Tuesday, December 30, 1980

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 330 and 351

Recruitment, Selection, and Placement (General); Reduction in Force

AGENCY: Office of Personnel Management.

ACTION: Final regulations.

SUMMARY: These regulations clarify OPM's policies concerning the establishment and maintenance of reemployment priority lists. Also, these regulations clarify how agencies make appointments from reemployment priority lists. These changes were developed in response to requests by agencies that OPM clarify its material covering the operation of agency reemployment priority lists.

EFFECTIVE DATE: January 29, 1981.

FOR FURTHER INFORMATION CONTACT: Ted Dow or Tom Glennon, (202) 632–4422.

SUPPLEMENTARY INFORMATION:

Background

On July 22, 1980, OPM published proposed regulations in the **Federal Register** (45 FR 48904) that would amend Parts 330 and 351 of this title to clarify how agencies establish, maintain, and make appointments from reemployment priority lists. The proposed regulations were derived from Section 15 of the Veterans Preference Act of 1944, as presently codified in 5 U.S.C. 3315. Subpart J of Part 351 of this title covers the establishment and maintenance of reemployment priority lists, while Subpart B of Part 330 of this title covers appointment from reemployment priority lists. Additional material that implements the reemployment priority list is contained in Federal Personnel Manual (FPM) Chapters 330 and 351.

The 60-day period for interested parties to submit written comments ended on September 22, 1980.

Discussion of Comments

Fourteen comments were received concerning the proposed regulations: twelve from agencies and two from unions. Five agencies had no objection to the proposed regulations while the other seven agencies and both of the unions suggested specific revisions to the material.

One agency suggested that we clarify in Part 330 of this title that appointments from the reemployment priority list are made in subgroup order. We agree that this revision would be helpful in explaining how agencies make appointments from the reemployment priority list. Accordingly, we have revised § 330.201(c) to explain that, in selecting persons from a reemployment priority list, an appointing officer follows subgroup order without regard to the order of retention standing within the subgroup.

Three agencies and one of the unions were concerned that proposed § 330.201(f) might unnecessarily limit agency efforts to reemploy persons who were separated because of reduction in force. For reference, proposed § 330.201(f) provided that agencies, in making appointments from reemployment priority lists, would consider full-time employees for full-time positions, and other-than-full-time employees for other-than-full-time positions. Specifically, these respondents believed that agencies should be able to have increased flexibility in making appointments from reemployment priority lists and to thus minimize any hardship to separated employees.

Our purpose in drafting § 330.201(f) was to ensure that other-than-full-time employees who have received reduction in force separation notices must receive first consideration for appointment from the reemployment priority list to other-than-full-time positions. After consideration of these comments, we have revised § 330.201(f) to include provisions which permit an agency, at its discretion, to consider full-time employees for appointment from the reemployment priority list to other-than-full-time positions if there are no other-than-full-time employees on the list who are qualified and available for the positions. Similarly, we have revised § 330.201(f) to also provide that an agency, again at its discretion, may consider other-than-full-time employees for appointment from the reemployment priority list to full-time positions if there are no full-time employees on the list who are qualified and available for the positions. We believe that the revised § 330.201(f) will achieve our original goal while allowing agencies additional flexibility in making appointments from the reemployment priority list and improving reemployment opportunities for separated employees.

In a further effort to clarify how the reemployment priority list operates, we have included new § 330.201(g) in the final regulations. Specifically, § 330.201(g) states, for reference, that Subpart J of Part 351 of this title covers the establishment and maintenance of the reemployment priority list. New § 330.201(g) is intended to serve the same purpose as proposed § 351.1002(c) which states, for reference, that Subpart B of Part 330 of this title covers appointment from the reemployment priority list.

Although we did not receive any specific written comments on the subject, we did receive several telephone inquiries asking about the relationship of the reemployment priority list to mandatory material presently contained in Section B–2a of Appendix B of FPM Chapter 351. Specifically, Section B–2a of Appendix B, in part, contains longstanding provisions that require agencies to advise employees who have received specific reduction in force notices of their right to priority consideration under the reemployment priority list and the Displaced Employee Program. (For reference, the Displaced Employee Program is covered in Subpart C of Part 330 of this title.)

After consideration of the material in Section B–2a of Appendix B, we found that there was a need to properly implement these mandatory provisions through Part 351 of this title. Accordingly, we have added a new § 351.808 which provides that each employee who receives a specific notice of separation under Part 351 of this title must be given information concerning his or her right to priority consideration for reemployment under the provisions of Subparts B and C of Part 330 of this title.

Two agencies suggested that we further clarify the conditions under which employees become eligible to be entered on the reemployment priority list. We agree that further clarification would be useful since we generally receive a significant number of inquiries asking for this information. Accordingly, we have revised proposed § 351.1002(a) to state that each group I or group II employee who receives a specific notice of separation from a competitive position under Part 351 of this title is entered on the reemployment priority list. We also clarify that the reemployment priority list only includes employees separated from competitive, as distinguished from excepted, positions. To further clarify the conditions under which the names of employees are entered on the reemployment priority list, we subdivided certain material set forth in proposed § 351.1003 (a) and (b) into new paragraphs § 351.1003(a)(1)–(4) and § 351.1003(b)(1)–(5).

One agency suggested that we revise proposed § 351.1003(b) to provide that an other-than-full-time employee would be entered on the reemployment priority list if the employee declined assignment under Subpart G of Part 351 of this title to a position with the same type of work schedule (e.g., part-time, intermittent, or seasonal). The same agency recommended that we revise proposed §§ 351.1003(b) and 351.1004(d)(2) to provide that the eligibility of an other-than-full-time employee to be entered or maintained on the reemployment priority list would not be based upon the employee's regularly scheduled administrative workweek. For reference, our proposed §§ 351.1003(b) and 351.1004(b)(2) both made reference to the regularly scheduled administrative workweek, but not the type of work schedule, of an other-than-full-time employee.

After consideration of the agency's suggestions, we have revised § 351.1003(b) to provide, in § 351.1003(b)(1), that a group I or group II other-than-full-time employee is entered on the reemployment priority list unless he or she has declined assignment to a position that is of the same type work schedule as the position from which the employee was separated. However, we also believe that the reemployment priority list should include an other-than-full-time employee who has declined assignment to a position with a regularly scheduled administrative workweek that is lower than that of the position from which the employee was separated. Therefore, we did not delete the references to "regularly scheduled administrative workweek" that were set forth in §§ 351.1003(b) and 351.1004(b)(2).

One agency suggested that we revise proposed § 351.1005(a) to clarify that the name of a group I or group II employee who receives a notice of separation under Part 351 of this title from a competitive position located in Alaska or overseas, except in certain circumstances, is entered on the reemployment priority list for the area in which the position from which the employee was separated is located. We agree that a further revision of this material would be useful and have accordingly clarified the material.

One union suggested that we revise proposed § 351.1004(a) to provide that a group II employee remains on the reemployment priority list for two years from the date he or she is separated under Part 351 of this title. For reference, OPM's present provisions in § 351.1001(a) covering the establishment and maintenance of the reemployment priority list provide that the name of a group I employee remains on the reemployment priority list for two years, and the name of a group II employee remains on the list for one year.

After consideration of this union's suggestion, we have decided not to revise § 351.1004(a) to change the duration of eligibility for an employee in group II. The provisions in proposed § 351.1004(a) reflect longstanding OPM policy, and are based upon the principle that an employee in group I has permanent status and is thus entitled to additional consideration for reemployment over that given to an employee in group II.

The same union and one agency also noted that the reemployment priority list only covers positions in any agency within a particularly commuting area. The union suggested that OPM develop regulations providing for an agency-wide reemployment priority list while the agency suggested that OPM permit agencies to place employees on the reemployment priority list in any locations for which the employee is available.

At present we see no need to require agencies to extend the coverage of the reemployment priority list beyond the commuting area of a particular agency. However, certain agencies, such as the Department of Defense, have developed extensive placement programs and systems. OPM is available to assist any agencies who wish to extend the scope of their placement programs beyond that required under Subparts B and C of Part 330 of this title, and Subpart J of Part 351 of this title.

Explanation of Final Regulations

The following changes in Title 5, Code of Federal Regulations, are now made final:

(1) Section 330.201(c) is revised to clarify that, in making appointments from the reemployment priority list, the appointing officer may select persons in a subgroup without regard to the order of retention standing within the subgroup.

(2) Section 330.201(f) is added. Section 330.201(f)(1) provides that, in making appointments from the reemployment priority list, an agency considers full-time employees only for full-time positions, and other-than-full-time employees only for other-than-full-time positions, except as provided in § 330.201(f)(2).

Section 330.201(f)(2) provides that an agency, at its discretion, may adopt administrative assignment provisions to consider employees for selection from the reemployment priority list under the following conditions:

(a) Full-time employees may be considered for other-than-full-time positions if there are no other-than-full-time employees on the reemployment priority list who are qualified and available; and

(b) Other-than-full-time employees may be considered for full-time positions if there are no full-time employees on the reemployment priority list who are qualified and available.

(3) Section 330.201(g) is added for reference. Specifically, § 330.201(g) explains that Subpart J of Part 351 of this title covers the establishment and maintenance of the reemployment priority list.

(4) Section 351.808 is added. Section 351.808 provides that an employee who receives a specific notice of separation under Part 351 of this title must be given information concerning his or her right to consideration for reemployment under the provisions of Subparts B and C of Part 330 of this title. The information concerning consideration for reemployment should be included in or with the specific reduction in force notice; otherwise, a separate supplemental notice containing this information is given to the employee.

(5) Subpart J of Part 351 is revised. Subpart J formerly consisted of § 351.1001 (a) and (b). The new § 351.1001 reorganizes material formerly contained in § 351.1001(a) to clarify agency responsibility for the establishment and maintenance of the reemployment priority list.

(6) Section 351.1002 (a), (b), and (c) are added. Section 351.1002 (a) and (b)

reorganize and clarify material formerly contained in § 351.1001(a). In addition, § 351.1002(a) now clearly provides that the name of each group I and group II employee who receives a specific reduction in force notice of separation from a competitive service position is entered on the reemployment priority list.

Section 351.1002(c) explains that Subpart B of Part 330 of this title covers appointment from the reemployment priority list. This change is being proposed in response to requests by agencies that OPM provide a reference to Subpart B of Part 330 of this title in Subpart I of Part 351.

(7) Section 351.1003 (a) and (b) are added. Section 351.1003(a) reorganizes and clarifies material formerly contained in § 351.1001(a). In addition, § 351.1003(a) contains new material clarifying that an employee's eligibility to be placed on the reemployment priority list is, in part, based upon an offer of assignment under Subpart G of this part. This proposed change reflects present policy, and clarifies the purpose and applicability of the reemployment priority list.

Section 351.1003(b) contains new material clarifying that an other-than-full-time employee's eligibility to be placed on the reemployment priority list is also, in part, based upon an offer of assignment under Subpart G of this part. Again, this proposed change reflects current policy, and clarifies the purpose and applicability of the reemployment priority list.

Final § 351.1003(b) also provides that the name of an other-than-full-time employee is entered on the reemployment priority list unless the employee, in part, declined assignment to an other-than-full-time position that is of the same type work schedule (i.e., part-time, intermittent, or seasonal) as the position from which the employee was separated. This provision was developed from comments received concerning the proposed regulations published on July 22, 1980, and is another effort to ensure that other-than-full-time employees have the same rights under Part 351 as full-time employees.

(8) Section 351.1004 (a), (b), (c), and (d) are added. Section 351.1004 reorganizes and clarifies material formerly contained in § 351.1001(a).

(9) Section 351.1005 (a), (b), and (c) are added. Section 351.1005 reorganizes and clarifies material formerly contained in § 351.1001(b).

Information Concerning Other Recent Changes to Part 351 of This Title

On August 27, 1980, OPM issued FPM Bulletin 351–18, which listed all of the proposed and final changes to the regulations in Part 351 of this title that were published in the **Federal Register** in 1979 and to that date in 1980. As noted in the FPM Bulletin, OPM plans to publish the revised Part 351 of this title in the **Federal Register** after these regulations covering the reemployment priority list become final. Agencies will then have access to all of the substantive changes in Part 351 of this title with a minimum of delay.

OPM has determined that this is a significant regulation for the purposes of E.O. 12044.

Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

Accordingly, Title 5, Code of Federal Regulations, is amended as follows:

PART 330 RECRUITMENT, SELECTION, AND PLACEMENT (GENERAL)

1) In § 330.201 paragraph (c) is revised and paragraphs (f) and (g) added to read as follows:

§ 330.201 Priority in filling vacancies.

* * * * *

(c) In selection from a reemployment priority list, an agency shall give preference to tenure group I employees over tenure group II employees, and to qualified preference eligibles over nonpreference eligibles within each tenure group. An appointing officer may select persons in a subgroup without regard to order of retention standing within the subgroup.

* * * * *

(f)(1) In selection from a reemployment priority list, an agency considers full-time employees only for full-time positions, and other-than-full-time employees only for other-than-full-time positions, except as provided in subparagraph (2) of this section.

(2) An agency, at its discretion, may adopt administrative provisions to consider employees for selection from a reemployment priority list under the following conditions:

(i) Full-time employees may be considered for other-than-full-time positions if there are no other-than-full-time employees on the reemployment priority list who are qualified and available; and

(ii) Other-than-full-time employees may be considered for full-time positions if there are no full-time employees on the reemployment priority list who are qualified and available.

(g) Subpart J of Part 351 of this title covers the establishment and maintenance of the reemployment priority list.

(5 U.S.C. 3315)

2) Section 351.808 is added to read as follows:

§ 351.808 Notice concerning consideration for reemployment.

An employee who recieves a specific notice of separation under this part must be given information concerning his or her right to consideration for reemployment under the provisions of Subparts B and C of Part 330 of this title. This information is in addition to that specified in § 351.802. The information concerning consideration for reemployment should be included in or with the specific reduction in force notice; otherwise, a separate supplemental notice covering this information must be given to the employee.

PART 351—REDUCTION IN FORCE

3) Subpart J of Part 351 is revised to read as follows:

Subpart J—Reemployment Priority List

Sec.

Authority: 5 U.S.C. 1302, 3315.

Subpart J—Reemployment Priority List

§ 351.1001 Establishment and maintenance of the reemployment priority list.

Each agency shall establish and maintain a reemployment priority list for each commuting area in which it separates group I or group II employees from competitive positions under this part.

§ 351.1002 Persons covered.

(a) The name of each group I or group II employee who receives a specific notice of separation from a competitive position (as distinguished from an excepted position) under this part is entered on the reemployment priority list.

(b) This priority extends to all competitive positions in the commuting area for which the employee is qualified and available, except as provided in § 351.1005.

(c) Subpart B of Part 330 of this title covers appointment from the reemployment priority list.

§ 351.1003 Employee eligibility.

(a) A full-time group I or group II employee is entered on the

reemployment priority list unless he or she has declined assignment under Subpart G of this part to a position that:

(1) Is full-time;

(2) Is competitive;

(3) Is nontemporary; and

(4) Has a representative rate no lower than that of the position from which the employee was separated.

(b) An other-than-full-time group I or group II employee is entered on the reemployment priority list unless he or she has declined assignment under Subpart G of this part to an other-than-full-time position that:

(1) Is of the same type work schedule (i.e., part-time, intermittent, or seasonal) as the position from which the employee was separated;

(2) Is competitive;

(3) Is nontemporary;

(4) Has a representative rate no lower than that of the position from which the employee was separated; and

(5) Has a regularly scheduled administrative workweek no lower than that or the position from which the employee was separated.

§ 351.1004 Duration of eligibility.

(a) The name of a group I employee remains on the reemployment priority list for 2 years, and a group II employee's name for 1 year, from the date he or she was separated.

(b) An employee's name is deleted from the reemployment priority list when the employee submits a written request to the agency asking that his or her name be deleted.

(c) A full-time employee's name is also deleted from the reemployment priority list when the employee:

(1) Accepts a non-temporary, full-time, competitive position; or

(2) Declines under this subpart a full-time, nontemporary, competitive position with a representative rate the same as, or higher than, that of the position from which he or she was separated under this part.

(d) An other-than-full-time employee's name is also deleted from the reemployment priority list when the employee:

(1) Accepts a nontemporary competitive position; or

(2) Declines under this subpart a nontemporary, competitive position with a representative rate, and regularly scheduled administrative workweek, the same as or higher than that of the position from which the employee was separated under this part.

§ 351.1005 Operation of the list in Alaska and overseas.

(a) The name of each group I or group II employee who receives a notice of separation under this part from a competitive position in Alsaka or overseas is entered on the reemployment priority list for the area in which the position from which separated is located, except when:

(1) The employee leaves that area; or

(2) The agency has a general program for rotating employees between overseas areas and the United States and the employee's immediately preceding overseas services or residence, combined with prospective overseas service under available appointments, exceeds the maximum duration of an overseas duty tour in the agency's rotation program.

(b) Upon his or her written request, the name of an employee who leaves the area is entered on the agency's reemployment priority list for:

(1) The commuting area from which he or she was employed for Alaskan or overseas service; or

(2) Another area, except in Alaska or overseas, that is mutually acceptable to the employee and the agency.

(c) In addition to any of the reasons, as appropriate, in § 351.1004(b), (c), or (d), for deleting an employee's name from the reemployment priority list, the name of an employee is deleted from an Alaskan or overseas reemployment priority list when the employee:

(1) Leaves the area covered by that list; or

(2) Becomes disqualified for overseas appointment because of his or her previous service or residence.

(5 U.S.C. 1902, 3315)

[FR Doc. 80-40492 Filed 12-29-80; 8:45 am]

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5 CFR Part 536

Grade and Pay Retention

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing final regulations to implement the grade and pay retention provisions of the Civil Service Reform Act of 1978.

EFFECTIVE DATE: January 29, 1981.

FOR FURTHER INFORMATION CONTACT: Larry Holman, 202-632-6127, or Jan Karicher, 202-632-4634.

SUPPLEMENTARY INFORMATION: Interim regulations, effective on the first day of the first applicable pay period beginning on or after January 11, 1979, were published in the **Federal Register** on March 2, 1979 (44 FR 117741). OPM proposed final regulations in this area which were published in the **Federal Register** for a 60-day comment period on June 17, 1980 (45 FR 40990). Based on comments received from Federal agencies, several labor organization representatives and individuals, OPM has made several revisions to the proposed regulations.

Subpart A

With only two exceptions, the intent of the proposed regulations to redelegate authority to agency heads to determine circumstances under which grade or pay retention should be extended was acceptable to the respondents. Those opposed felt the redelegation was too vague and open to inconsistent application. We have clarified the language pertinent to the redelegation. The term, "management-initiated action," has been dropped from § 536.102, 536.103, and 536.206. With regard to grade retention, the language was simplified to show that management's authority is limited to downgrades during reorganizations and reclassifications. The term, "reorganization," has been defined to further identify the bounds of the redelegation. More important, the redelegation still better recognizes the necessity for agency heads to decide what circumstances, outside those prescribed by the law, warrant grade or pay retention in order to promote the efficiency of their operations.

In response to several separate comments, § 536.104 has been extended to include several specific circumstances warranting pay retention. The first calls for pay retention when an employee is downgraded in a reduction in force or reclassification but does not meet the eligibility requirements for grade retention. This extension was included in the interim rgulations. The second extends pay retention to an employee whose basic pay is a special rate moved by management to a lesser special rate position or to a non-special rate position. This circumstance was covered in the interim regulations under § 536.212(a)(2), "* * * reassignment to a position in a different pay schedule."

Some concern was expressed with the term "placement" in the extension of pay retention. The concern was that any movement by an employee in the specified circumstances would warrant coverage. In fact, in any potential entitlement to grade or pay retention, the limitations of the exclusions in § 536.105, especially, "is reduced in grade or pay . . . at the employee's request," means that the placement must be caused or influenced by management. This implies that the movement is beyond the employee's control and/or to further the mission of the agency.

Similarly an individual commented that OPM should not extend pay retention to prevailing rate employees who move from a high to lower wage area. This extension, like the others, is generally for an action which is caused or influenced by management and is not strictly "at the employee's request." Furthermore, it recognizes the needs of management to sometimes move employees to promote an efficient organziation without adversely affecting employees. The extension is, therefore, still included.

Several changes or additions have been made to § 536.102 other than the addition of "reorganization." "Rate of basic pay" has been amended to show that the night and environmental differentials for prevailing rate employees are not included in basic pay protected by grade or pay retention. "Representative rate" now includes the representative rate for a Senior Executive Service employee. "Rate schedule" has been added here and where appropriate throughout Part 536 for use in situations where the movement is not between pay schedules but between rates within a schedule, e.g., special rate movement.

"Temporary reassignment" in both § 536.102 and 536.105 was questioned by a commenter as unnecessary because reassignment implies no promotion or demotion. While this is generally correct, these reassignments can result in pay adjustments, e.g., reassignment to a special rate position or to a higher or lower wage area. The result could be a pay discrepancy which might raise questions of entitlement and, therefore, create the necessity for its use. A suggestion to define "covered pay system" was not adopted because the term was not used in these regulations.

In § 536.105, the most significant change was the altering of the exclusion of non-appropriated fund employees. The only non-appropriated fund employees now excluded are those covered under § 2105(c) of title 5, United States Code, i.e., those in Department of Defense and Coast Guard nonprevailing rate positions. Non-appropriated fund employees, other than those in DOD and the Coast Guard, are covered for most benefit purposes. It is, therefore, consistent to cover them for grade and pay retention.

Several comments suggested we increase the scope of coverage beyond reorganizations and reclassifications for grade retention and to change eligibility requirements from the position being classified for 1 year to the employee being in the position for 1 year. OPM has not adopted these because our ability to regulate this benefit does not allow us to change the intent of the law. We have also not included a restatement of the law or of sections 5337 and 5345 of title 5, which were repealed, because we feel the soon to be released Federal Personnel Manual guidance on grade and pay retention will provide the necessary background. This guidance should also provide information on movements between agencies creating grade retention entitlements and further explain the 52-week/1 year eligibility requirements, both of which raised questions.

A significant question was raised regarding potential entitlement to pay retention when an employee waives grade retention or when an employee requests a demotion for ill health or similar circumstances. In the former case, OPM's position is that once an employee waives grade retention, the employee removes management's influence over the particular action against the employee. Any ensuing loss of pay would be as a result of an employee request and no pay retention could be granted even under the agency's authority. In the latter case these demotions are also at the employee's request unless the agency has already informed the employee that action to downgrade will be taken for non-disciplinary reasons of ill health and the agency offers another position. The agency could then grant pay retention under its authority.

Subpart B

Section 536.202(a) of the proposed regulations has been made a separate section, § 536.201. This reflects the fact that this method of comparing grades and rates is necessary not only for determining grade retention entitlement but also whether the 52-week/1 year at a higher grade requirement has been met, whether a demotion has occurred, or whether an employee has declined an offer at, or been placed in, a grade equal to or greater than the retained grade. This change required renumbering the sections of the entire subpart.

Several changes were made to the section on determining the rate of basic pay. The language of the section was clarified to show what rate of basic pay, including a special rate under 5 U.S.C. 5303, is used to determine pay retention entitlement. The language change also reflects the fact that we will issue regulations shortly as Part 532 for setting pay in the Federal Wage System, when grade and pay retention entitlement terminates.

A paragraph has been added to show that any employee on pay retention receives only 50 percent of the annual comparability increase. This paragraph also demonstrates that this rule only applied to employees on pay retention and only affects increases in the scheduled rates of a position.

Section 536.204(c) of the proposed regulations has been changed as the result of several comments to place an employee who is on pay retention at the maximum rate of the range of the new position when, after receiving only 50 percent of increases in scheduled rates, the employee's pay can be found within the rate range of the new position. This was the rule of the interim regulations. This 50 percent rule is designed only to move the employee into the rate range of the new position and not to adversely affect the employee any more than is necessary.

Several changes have been made to the section describing the criteria for a reasonable offer. The employee must now be informed of his or her right to appeal to OPM the reasonableness of the offer. This provision is similar to other regulations which require an agency to inform employees of their appeal rights. The language has also been changed to show that the offered position must be at least equal in tenure to the position the grade or pay of which is being protected. This change protects the employee who moves during a period of grade or pay retention but is not offered a position whose tenure is equal to or higher than the position which created the entitlement.

OPM has removed the necessity that the employee meets the qualification requirements of the offered position. This is in keeping with regulations regarding reductions in force which allow agencies to waive qualifications in order to place employees. Staffing guidance in the Federal Personnel Manual will reflect the fact that qualifications may be waived when grade or pay retention is involved.

"Commuting area" was not defined because we believe that the current language allows the affected employee the maximum possible protection in an appeal. Designating a specific radius does not fully take into account other transportation circumstances which may affect the reasonableness of an offer.

Several issues were raised concerning the factors for terminating eligibility and/or entitlement to grade and pay retention. Specifically at issue was the extent of the priority placement program provision in grade retention situations. The provision has been extended to include an employee who does not fully comply with written agency requirements of a priority placement program. These requirements can range from formally placing one's name in the program to actively participating in the

program, e.g., filing SF–171's. This ensures maximum effort by the employee to return as quickly as possible to a proper grade or pay level position. This balances management's requirement under § 536.301 to establish placement and classification plans. This prompt return to the proper level recognizes the intent of the law. A similar provision was not added to pay retention situations because of OPM's lack of authority in this area, e.g., restrictions imposed by the statutory construction of section 5363 of title 5, U.S. Code. These restrictions also prevent significant changes in the cessation factors imposed by the law.

These cessation factors for grade retention have also been amended to show that an employee is not declining a reasonable offer when the employee requests a lower graded position than the reduction-in-force position rather than displace another employee. This change avoids harmful and widespread displacement and is in keeping with the intent of the delegation of this authority to agency heads.

Subpart C

The section reserved for grade and pay retention under the merit pay system was determined unnecessary because merit pay employees will be treated the same as General Schedule employees for grade and pay retention purposes. In its place is a section establishing a legal basis for OPM requiring agencies with affected employees to have classification and placement plans. Again, these plans promote the intent of the law, i.e., to return the employee to the proper grade or pay level as quickly as possible.

OPM has adjusted the time period for filing an appeal of the termination of benefits because of the employee's declination of a reasonable offer. It will now be 20 calendar days to conform to the appeal period used by the Merit Systems Protection Board. We decided not to include under this appeal right the termination of benefits due to an employee's failure to fully participate in a priority placement program. These disputes will be based on detailed agency policy and can be better settled within the affected agency through the internal agency grievance procedures or procedures negotiated in labor contracts.

Throughout the regulations several small nonsubstantive changes were made in language to clarify issues and alleviate confusion raised in the comments. Several comments were not accepted for changes in the regulations themselves because we feel the guidance soon to be issued in the Federal Personnel Manual will take these comments into account and clarify issues in this area.

OPM has determined that these are significant regulations for the purposes of E.O. 12044.

Office of Personnel Management.

JoAnn B. Platter,

Assistant Issuance System Manager.

Accordingly, the Office of Personnel Management is revising Part 536 of Title 5, Code of Federal Regulations, to read as follows:

PART 536—GRADE AND PAY RETENTION

Subpart A—Definitions, Coverage and Applicability

Sec.

Subpart B—Determination of Retained Grade and Rate of Basic Pay; Loss of, or Termination of Eligibility

Subpart C—Miscellaneous Provisions

Authority: 5 U.S.C. 5361–5366, Pub. L. 95–454.

Subpart A—Definitions; Coverage and Applicability

§ 536.101 General.

(a) Title VIII of Pub. L. 95–454 (The Civil Service Reform Act of 1978) provides that an employee who is placed in a lower grade as a result of reduction-in-force procedures, or whose position is reduced in grade as a result of reclassification of the position, is entitled to retain for a period of 2 years the grade held immediately before that placement or reduction. It also provides the authority for granting an employee indefinite pay retention. In addition to specifying criteria and conditions for the application of the grade and pay retention provisions, the law authorizes the Office of Personnel Management to extend the application of these provisions to other individuals and situations to which they would not otherwise apply.

(b) This part contains the regulations—including extensions, conditions, criteria, and procedures—which the Office of Personnel Management has prescribed for the administration of grade and pay retention. This part supplements and implements the provisions of 5 U.S.C. 5361–5366, and section 801(b) of Pub. L. 95–454, and must be read together with those sections of law.

§ 536.102 Definitions.

For the purposes of this part:

"Demotion at an employee's request" means a reduction in grade:

(1) Which is initiated by the employee for his or her benefit, convenience or personal advantage, including consent to a demotion in lieu of one for personal cause, and

(2) Which is not caused or influenced by a management action.

"Demotion for personal cause" means a reduction in grade based on the conduct, character, or unacceptable performance of an employee.

"Employee" means an employee as defined in 5 U.S.C. 5361 and also an individual who is moved from a position which is not under a covered pay schedule to a position which is under a covered pay schedule provided that the individual's employment immediately prior to the move was on other than a temporary or term basis.

"Employment on a temporary or term basis" means employment under an appointment having a definite time limitation or designated as temporary or term.

"Rate of basic pay" means, for any pay system, the rate of pay fixed by law or administrative action for the position held by an employee before any deductions and exclusive of additional pay or any kind such as night or environmental differentials in the case of a prevailing rate employee.

"Rate schedule" means a specific set of rates within a pay schedule.

"Reorganization" means the planned elimination, addition or redistribution of functions or duties either wholly within an agency or between agencies.

"Representative rate" means:

(1) The fourth rate of the grade in the case of a position under the General Schedule including the fourth rate of the corresponding grade of the General

Schedule in the case of a position under the merit pay system established by chapter 54 of title 5, United States Code, the single rate of GS–18; or the individual's rate under the Senior Executive Service;

(2) The second rate of the grade of a position under a regular prevailing rate schedule established under subchapter IV of chapter 53 of title 5, United States Code, or in the case of a position with a single rate, the single rate of that position; or

(3) The rate designated as representative of the position by the agency responsible for establishing and adjusting the schedule in the case of a position under a schedule different from those covered in paragraph (1) or (2) of this section.

"Temporary promotion" means a promotion with a definite time limitation, and one which the individual is informed in advance is temporary and would normally require that the individual return to his or her permanent position at the expiration of that promotion.

"Temporary reassignment" means a reassignment with a definite time limitation, and one which the individual is informed in advance is temporary and would normally require that the individual return to his or her permanent position at the expiration of that reassignment.

§ 536.103 Coverage and applicability of grade retention.

(a) Grade retention shall apply to an employee who moves to a position in a covered pay schedule which is lower graded than the position held immediately prior to the demotion in the following circumstances:

(1) As a result of reduction-in-force procedures; or

(2) As a result of a reclassification process.

(b) Except as otherwise covered in paragraph (a) of this section, the head of the agency may offer grade retention to eligible employees who are or might be reduced in grade as the result of a reorganization or reclassification decision announced by management in writing. When an employee is offered a position with grade retention in anticipation of a reduction in grade, the agency shall inform the employee in writing that acceptance of the position is not required and that declination of the offer has no effect on the employee's entitlement to grade retention under paragraph (a) of this section if he or she is actually moved to a lower graded position.

(c)(1) An employee who, immediately prior to being placed in a lower graded position as a result of reduction-in-force procedures, is in a position under a covered pay schedule, is eligible for grade retention only if the employee has served for 52 consecutive weeks or more in position(s) under a covered pay schedule at a grade(s) higher than the position in which the employee is placed.

(2) An employee is eligible for grade retention when his or her position has been reclassified at a lower grade only if the position which is being reduced had been classified at a higher grade(s) for a continuous period of at least 1 year immediately before the reduction.

(3) In situations other than those covered in paragraphs (c)(1) and (c)(2) of this section, an employee is eligible for grade retention if he or she, immediately prior to being placed in the lower grade, has served in a position in any pay schedule for 52 consecutive weeks or more provided that the service was in an agency as defined in 5 U.S.C. 5102 at a grade(s) higher than the position in which the employee is placed.

§ 536.104 Coverage and applicability of pay retention.

(a) Pay retention shall apply to any employee whose rate of basic pay would otherwise be reduced:

(1) As the result of the expiration of the 2-year period of grade retention; or

(2) As a result of reduction-in-force or reclassification when the employee does not meet the eligibility requirement for grade retention; or

(3) As a result of the reduction or elimination of scheduled rates, except those reflecting a decrease in the level of prevailing rates as determined by a wage survey, or as a result of the reduction or elimination of special schedules or special rates; or

(4) As a result of the placement of an employee into a non-special rate position or into a lower special rate position from a special rate position; or

(5) As a result of the placement of an employee in a position in a lower wage area or in a position in a different pay schedule; or

(6) As a result of the placement of the employee in a formal employee development program generally utilized Governmentwide: Upward Mobility, Apprenticeship, and Career Intern Programs.

(b) Except as otherwise covered in paragraph (a) of this section, the head of the agency may provide pay retention to eligible employees whose rates of basic pay would otherwise be reduced as the result of a management action.

§ 536.105 Exclusions

(a) Grade and pay retention shall not apply to an employee who:

(1) Moves from a position which is not in an agency as defined in 5 U.S.C. 5102; or

(2) Is identified under 5 U.S.C. 2105(c) except prevailing rate employees included under 5 U.S.C. 5361; or

(3) Is reduced in grade or pay for personal cause or at the employee's request; or

(4) Does not satisfactorily complete the probationary period prescribed by 5 U.S.C. 3321(a)(2), and, as a result, is removed from a supervisory or managerial position.

(b) An employee's entitlement to grade or pay retention is not affected by a temporary promotion or temporary reassignment. However, an employee serving under a temporary promotion or temporary reassignment may not retain a grade or rate of basic pay held during the temporary promotion or temporary reassignment.

Subpart B—Determination of Retained Grade and Rate of Basic Pay; Loss of, or Termination of Eligibility

§ 536.201 Comparison of grades in different pay schedules or pay systems.

For the purpose of determining whether the grade of a position is equal to, higher than, or lower than the grade of another position in movements between pay schedules or pay systems, the representative rates of the positions will be compared.

§ 536.202 Period of grade retention.

(a) An employee entitled to grade retention is entitled to retain that grade for 2 years beginning on the date the employee is placed in the lower graded position.

(b) If, during a 2-year period of grade retention, an employee is further reduced in grade under circumstances also entitling the employee to grade retention, the employee shall continue to retain the previous retained grade for the remainder of the previous 2-year retention period. At the end of that period, the employee shall be entitled to retain the grade of the position from which the further reduction in grade was made, until 2 years have passed from the date of the further reduction in grade.

§ 536.203 Determination of retained graded.

(a) An employee who is in a position under a covered pay schedule immediately prior to the action which gives entitlement to grade retention shall retain the grade held immediately prior to the action.

(b) An employee who is in a position not under a covered pay schedule immediatley prior to the action which gives entitlement to grade retention shall retain:

(1) The lowest grade of the covered pay schedule in which placed which has a representative rate equal to or higher than the representative rate of the grade held immediately prior to that placement; or

(2) The highest grade of the covered pay schedule in which placed, if there is no grade in the covered pay schedule with a representative rate equal to or higher than the representative rate held immediately prior to that placement.

§ 536.204 Determination of applicable rate schedule.

(a) When an employee entitled to grade retention is placed in a position in a different geographical area, the rate schedule which applies to the employee is the rate schedule in the new geographical area.

(b) When an employee entitled to grade retention is placed in a position in, or his or her position is changed to, a different occupational series, the rate schedule which applies to the individual is the rate schedule for the new occupational series.

§ 536.205 Determination of rate of basic pay.

(a) When an employee becomes entitled to grade retention, or moves to another position during a period of grade retention under conditions which permit continuation of the grade retention entitlement, the employee is entitled to the greatest of:

(1) His or her rate of basic pay before the movement, or

(2) The rate of basic pay from the applicable rate schedule for the grade and step (or relative position within a range of rates under the merit pay system) held by the employee before the movement, or

(3) The lowest rate of basic pay from the applicable rate schedule for the retained grade which equals or exceeds the employee's rate of basic pay before the movement.

(b)(1) When an employee becomes entitled to pay retention, or moves to another position while receiving pay retention, the employee's rate of basic pay immediately prior to eligibility or movement shall be compared with the range of rates of basic pay for the position to be occupied by the employee upon this eligibility or movement.

(2) The employee is entitled to the lowest rate of basic pay in the position to be occupied upon the eligibility or movement which equals or exceeds his or her rate of basic pay immediately prior to the eligibility or movement. If the rate of basic pay can be accommodated in the rate range of the latter position, pay retention does not apply.

(3) If the employee's rate of basic pay immediately prior to the pay retention exceeds the maximum rate of the position to be occupied when he or she becomes entitled to pay retention, the employee is entitled to the lower of:

(i) The rate of basic pay payable to the employee immediately before the reduction in pay; or

(ii) 150 percent of the maximum rate of basic pay payable for the new grade.

(c) When an increase in the scheduled rates of the grade of the employee's position occurs while the employee is under pay retention, the employee is entitled to 50 percent of the amount of the increase in the maximum rate of basic pay payable for the grade of the employee's current position.

(d) When, as a result of an increase in the scheduled rate(s) of the grade of the employee's position, an employee's retained rate of basic pay becomes equal to or lower than the maximum rate of that grade, the employee is entitled to the maximum rate of that grade and pay retention ceases.

(e) An employee who is serving on a temporary promotion at the time he or she becomes eligible for pay retention is entitled to retain the rate of basic pay which he or she would have been receiving at that time had the temporary promotion not occurred.

(f) When an employee's entitlement to grade or pay retention terminates, the employee's rate of basic pay shall be set in accordance with the provisions of Parts 531 and 532 of this title unless:

(1) Grade retention is being terminated as a result of the expiration of the 2-year retention period; or

(2) The employee is moved to a grade equal to or greater than the retained grade; or

(3) The employee is entitled to a higher rate of basic pay under paragraphs (b) or (d) of this section.

§ 536.206 Criteria for a "reasonable offer".

For the purposes of this part, an offer of a position, in order to be considered a reasonable one, must fulfill the following conditions:

(1) The offer must be in writing, and must include an official position description of the offered position; and

(2) The offer must inform the employee that an entitlement to grade or pay retention will be terminated if the offer is declined and that the employee may appeal the reasonableness of the offer as provided in § 536.302; and

(3) The offered position must be of tenure equal to or greater than that of the position creating the grade or pay retention entitlement; and

(4) The offered position must be in an agency, as defined in 5 U.S.C. 5102, although not necessarily in the same agency in which the employee is serving at the time of the offer; and

(5) The offered position must be full-time, unless the employee's position immediately before the change creating entitlement to grade or pay retention was less than full-time, in which case the offered position must have a work schedule of no less time than that of the position held before the change; and

(6) The offered position must be in the same commuting area as the employee's position immediately before the offer, unless the employee is subject to a mobility agreement or a published agency policy which requires employee mobility.

§ 536.207 Loss of eligibility for grade retention.

(a) Eligibility for grade retention as a result of entitlement under § 536.103(a) of this part ceases if any of the following conditions occurs at any time after the employee receives written notice of the reduction in grade action, but before the commencement of the 2-year period of grade retention:

(1) The employee has a break in service of 1 workday or more; or

(2) The employee is demoted for personal cause or at the employee's request; or

(3) The employee is placed in, or declines a reasonable offer of, a position the grade of which is equal to or higher than the retained grade; or

(4) The employee elects in writing to terminate the benefits of grade retention.

(b) Eligibility for grade retention as a result of entitlement under § 536.103(b) of this part ceases if any of the following conditions occurs at any time after the employee is informed by management of an impending reorganization or reclassification which will or could result in reduction in grade, but before the commencement of the 2-year period of grade retention:

(1) Any of the conditions listed in paragraph (a) of this section except that an employee's request for placement in a lower graded position, in lieu of displacing an employee at his or her grade under reduction-in-force procedures, is not a declination of a reasonable offer for grade retention purposes; or

(2) The employee fails to enroll in, or to comply with reasonable written requirements established to assure full

consideration under, a program providing priority consideration for placement.

§ 536.208 Termination of grade retention.

(a) Grade retention terminates if any of the conditions listed in § 536.207(a) occurs after commencement of the 2-year period of grade retention.

(b) Grade retention as provided by § 536.103(b) also terminates if any of the conditions listed in § 536.207(b) occur after the commencement of the 2-year period of grade retention.

(c) The effective date of termination of grade retention benefits is:

(1) The day before placement if the termination is the result of the employee's placement in another position; or

(2) At the end of the last day of the pay period which the employee:

(i) Declines a reasonable offer; or

(ii) Elects to waive grade retention benefits; or

(iii) Fails to enroll in, or comply with reasonable written requirements established to assure full consideration under, a program providing priority consideration for placement.

§ 536.209 Loss of eligibility for, or termination of, pay retention.

(a) Eligibility for pay retention, or actual retention of pay, ceases if any of the following conditions occurs at any time after the employee had received written notification that his or her pay is to be reduced:

(1) The employee has a break in service of 1 workday or more; or

(2) The employee is entitled to a rate of basic pay which is equal to or higher than, or declines a reasonable offer of a position the rate of basic pay for which is equal to or higher than, the rate to which the employee is entitled under pay retention; or

(3) The employee is demoted for personal cause or at the employee's request.

(b) The effective date of termination of pay retention benefits is:

(1) The day before placement if the termination is the result of the employee's placement in another position; or

(2) The end of the last day of the pay period in which the employee declines a reasonable offer.

Subpart C—Miscellaneous Provisions

§ 536.301 Placement and classification plans.

(a) Agencies which employ individuals subject to this part are required to establish in writing placement and classification plans.

(b) The placement and classification plans must commit the agency to:

(1) Identify and correct classification errors; and

(2) Correct position management problems; and

(3) Carry out specific planned efforts to place employees subject to this part; and

(4) Pursue placement efforts that do not adversely affect affirmative action goals.

§ 536.302 Appeal of termination of benefits because of reasonable offer.

(a) Except as provided for in paragraph (e) of this section, an employee whose grade or pay retention benefits are terminated on the grounds the employee declined a reasonable offer of a position the grade or pay of which is equal to or greater than his or her retained grade or pay may appeal the termination to the Office of Personnel Management.

(b) An employee who appeals under this section shall file the appeal in writing with the Office of Personnel Management not later than 20 calendar days after being notified that his or her grade of pay retention benefits have been terminated, and shall state in the appeal the reasons why the employee believes the offer of a position was not a reasonable offer.

(c) The Office of Personnel Management may conduct any investigation or hearing it determines necessary to ascertain the facts of the case.

(d) If a decision by the Office of Personnel Management on an appeal under this section requires corrective action by an agency, including the retroactive or prospective restoration of grade or pay retention benefits, the agency shall take that corrective action.

(e) Termination of benefits based on a declination of a reasonable offer by an employee in an exclusively recognized bargaining unit may be reviewed under negotiated grievance and arbitration procedures in accordance with chapter 71 of title 5, United States Code, and the terms of any applicable collective bargaining agreement. An employee in an exclusively recognized bargaining unit may not appeal a termination of benefits to the Office of Personnel Management if the grievance procedure of the agreement by which he or she is covered provides for this review.

(f) Decisions issued by the Office of Personnel Management shall be considered final decisions. OPM may, at its discretion, reconsider an original appellate decision when new and material information is presented, in writing, by the employee or the agency, which establishes a reasonable doubt as to the appropriateness of the original decision. The request must show that the information was not readily available when the decision was issued. A request for reconsideration of an original appeal decision must be submitted to OPM within 30 calendar days of the date of the original decision.

§ 536.303 Documentation.

The application of the provisions of this part shall be documented in writing as a permanent part of the employee's Official Personnel Folder. As a minimum this documentation will include a copy of the letter described in § 536.304.

§ 536.304 Issuance of employee letters.

When an employee is entitled to grade and/or pay retention, the employing agency shall give to the employee, with a copy of the Notification of Personnel Action (SF–50) documenting entitlement to grade and/or pay retention, a letter describing the circumstances warranting grade and/or pay retention, and the nature of that entitlement.

§ 536.305 Effect of grade retention on quota spaces.

To determine the number of positions at GS–16, –17 and –18, or the equivalent, including positions in the Senior Executive Service, authorized by an Act of Congress, the grades (or SES levels) of the positions occupied, rather than the retained grades, are to be used.

§ 536.306 Retroactive entitlement.

Employees who are eligible for grade retention as provided by § 536.103(a) except that the reduction in grade took place on or after January 1, 1977, and before the first day of the first pay period beginning on or after January 11, 1979, shall be entitled to pay and benefits as provided in section 801(b) of the Civil Service Reform Act of 1978 under procedures and instructions issued by the Office of Personnel Management.

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5 CFR Part 551

Federal Pay Administration Under the Fair Labor Standards Act

AGENCY: Office of Personnel Management.

ACTION: Final rule

SUMMARY: The Fair Labor Standards Act was amended by the Fair Labor Standards Amendments of 1974 to include Federal employees under its coverage effective May 1, 1974. The

legislation authorized the Office of Personnel Management to administer the provisions of the Act for Federal employees. This document contains regulations that supplement and implement the Act.

EFFECTIVE DATE: January 29, 1981.

FOR FURTHER INFORMATION CONTACT: Dwight W. Brown, [202] 632–4634.

SUPPLEMENTARY INFORMATION: The Fair Labor Standards Act of 1938, as amended, provides for minimum standards for both wages and overtime entitlements, and delineates administrative procedures by which covered worktime must be compensated. Section 4(f) of the Act authorizes the Office of Personnel Management to administer the provisions of the Act for all employees of the United States, except for those who are employed by the Library of Congress, United States Postal Service, Postal Rate Commission, or the Tennessee Valley Authority; such employees are specifically covered by the Department of Labor's administration of the Act. In addition to this authority, the legislative history of Pub. L. 93–259 further authorizes the Office of Personnel Management to resolve conflicts between the Act and other statutory provisions entitling employees to overtime pay (120 Cong. Rec. 7335).

These regulations establish the rules and guidelines by which Federal administration of the Act is to be effected. In addition to specifying OPM's authority and agencies' responsibilities, they provide definitions, rules, and guidelines by which determinations are to be made as to what time constitutes "hours or work," and, therefore, as to what time is compensable. Futhermore, they provide the methodology by which precise overtime pay entitlements under the Act shall be computed. Finally, they provide special overtime provisions for employees engaged in fire protection activities or law enforcement activities.

On July 25, 1980, OPM published proposed regulations [45 FR 49580] for its administration of the Act in the Federal sector and invited written comments from the public. Comments were received from 24 Federal agencies and four labor organizations representing Federal employees. These comments, and OPM's action on these comments, are summarized as follows:

General

Numerous comments cited the need for supplemental guidance or examples to further clarify the regulations in this part. Numerous other comments referred to the more complete instructions contained in FPM letters in the 551 series and asked what effect the regulations had on this material.

The regulations in this part create rights in or impose obligations upon employees or agencies for compliance with the Act. The more comprehensive instructions and examples contained in FPM letters in the 551 series provide supplemental instructions and continue in effect, with the exception of FPM Letter 551–3. OPM is issuing an FMP letter which rescinds FPM Letter 551–3 and provides instructions for the treatment of time spent in training as modified in § 551.423 of ths part. The instructions in this new letter are effective on the effective date of these regulations.

In addition, OPM is completing a new book 551 to FPM Supplement 990–2. It will incorporate the instructions and examples contained in existing FPM letters. When completed, Book 551 will supplement and augment the requirements of the Act and this part. Until that time, the instructions and guidelines contained in FPM letters in the 551 series (with the exception of FPM Letter 551–3) are still appropriate.

Suffered or Permitted Work

Two agencies recommended transferring the definition of suffered or permitted work from subpart D, Hours of Work, to the definitions section in subpart A. This recommendation was adopted.

In addition, at the recommendation of several agencies, this definition has been modified to emphasize that the employee's supervisor (1) must have knowledge of such work and (2) must have an opportunity to prevent such work from being performed. It follows that if the supervisor did not know the work was being performed, he or she had no opportunity to prevent the work, and, therefore, the supervisor did not suffer or permit the work. Of course, once the supervisor knows work is being performed and does nothing to prevent it, he or she has suffered or permitted the work.

Trainees

With the change in OPM position concerning time spent in training under the Act, it was necessary to define the term "trainee" in § 551.102 and to exclude those persons meeting this definition from coverage under OPM's administration of the Act in § 551.103. Trainees who are assigned or attached to a Federal activity primarily for training are not employees of the Government of the United States for purposes of the Act. These include persons employed by a state or local government under a CETA or WIN Program, persons employed by a college or university under a College Work Study Program, student-employees assigned or attached to a government hospital primarily for training (5 CFR Part 534), and any other person who attends a training program that meets the six conditions outlined in § 551.102.

Volunteers

Numerous comments were received recommending that persons who perform volunteer services for a Federal activity be excluded specifically from coverage under the Act. We have included a new definition of "volunteer" in § 551.102.

In addition, in § 551.103 we have excluded persons whose appointment authority specifically states that they are to be employed without compensation, and persons who meet the definition of volunteer in § 551.102. These include student volunteers (5 CFR Part 308), VISTA and Peace Corps volunteers, and persons who perform personal services primarily for their own benefit or for the benefit of other persons—e.g., volunteers in a Federal hospital who write letters for patients or perform other personal amenities for patients. The one group that does not meet the definition of volunteer in § 551.102 and, therefore, is not excluded from coverage by § 551.103, is that made up of individuals who perform services of economic benefit for a Federal agency. Persons in this group meet the "economic realities" test for employment. For example, they may perform services for a Federal activity to free Federal employees for other duties. If they did not perform such services, Federal employees would have to. Therefore, their services are of economic benefit to the Federal activity. However, acceptance of such services is subject to the restriction in section 665(b) of title 31, United States Code (the Anti-Deficiency Act), against accepting voluntary services.

Subminimum Wage

One labor organization recommended that the criteria for compliance with the subminimum wage authority be spelled out. OPM is issuing a separate FPM letter on this subject at this time. While the subminimum wage authority of the Act permits the employment of students, learners, apprentices, and handicapped workers, OPM has determined that use of this authority by Federal agencies will be limited to handicapped patients who are receiving treatment or care in a Federal hospital or institution and who are permitted to perform work of a

consequential economic benefit for the hospital or institution.

Records Keeping

Numerous comments addressed the proposed OPM requirement to keep records for a period of six years. The Office of Financial Management, GAO, advised that the present records retention schedule of three years at the agency level and 56 years at the National Personnel Records Center is sufficient for its use to settle pay claims. Therefore, we have removed the reference to six years. Agencies will continue to follow the GAO schedule.

Rest Periods and Meal Periods.

In numerous comments it was requested that OPM specify how many rest periods are allowed in a workday. Agencies are responsible for scheduling the work of their employees. This includes scheduling authorized rest periods during the workday. We have modified the language in § 551.411 to clarify that any authorized rest period is worktime.

One agency had a problem with the term "bona fide meal periods." We do not specify a specific scheduled meal period, nor do we authorize a deduction from hours worked when an employee works and does not take an authorized meal period. This term simply means that, when an employee has an authorized meal period and does, in fact, take the meal period off, the employee is off duty during this period and is not paid for it.

Time Spent Traveling

Numerous comments questioned the specific rules for compensable travel time under the Act. These rules are presently contained in FPM Letters 551–10 and 11. The letters also include in depth instructions, with examples, on how the rules are to be applied under the Act. The rules are consistent with the rulings, interpretations, and opinions of the Department of Labor and the courts in the private sector. We recognize that the rules for compensable travel time under title 5, United States Code, differ considerably from those under FLSA. This area is one of the most difficult in premium pay administration because of the dual administrations of title 5 and the FLSA. The rules for compensable travel time must be applied separately under each law, title 5 and FLSA, and nonexempt employees are to be paid under whichever law provides them the greater overtime pay benefit.

Time Spent in Training

Numerous comments recommended that we retain the prohibition currently contained in FPM Letter 551–3 on the payment of overtime pay for a period of training under the Act. The change in OPM determination concerning time spent in training was brought about by (1) a better understanding of the differences between title 5, United States Code, and the FLSA, and (2) other relevant decisions by OPM in its experience in resolving conflicts between the two laws. It has been OPM's position, endorsed by GAO, that the two laws are to be administered separately and independently, with nonexempt employees being paid under whichever law provides them the greater overtime pay benefit. Consistent with this position, we have modified our original determination to provide that time spent in training outside regular working hours is compensable as hours of work under the FLSA if certain specific criteria are met. This change will bring OPM's administration of the FLSA into line with that of the Department of Labor in the private sector and will produce consistency in OPM's administration of the Act.

We have modified the language in § 551.423, and have prepared an FPM letter to provide supplemental instructions in response to the myriad of comments received on this section. The new FPM letter rescinds FPM Letter 551–3 and is to be effective on the effective date of the regulations. Together the regulations in § 551.423 and the supplemental instructions in the FPM letter clearly outline those situations when time spent in training is hours of work and those situations when time spent in training is not hours of work. A summary of the changes in language in § 551.423 and the instructions contained in the FPM letter follows:

A paragraph was added in this section to clarify further the phrases, "directed to participate," and "to improve the employee's performance * * * of his or her current position." The FPM letter provides specific instructions on what training meets these criteria.

A paragraph was added in this section to address preparatory time for attendance at training. The FPM letter provides additional instructions on how an agency may determine the appropriate allowance for preparatory time and when such preparatory time is hours of work.

A special provision was added in this section to address employees engaged in an apprenticeship program or other entry level training programs, employees engaged in an internship program or other career related work study programs, and employees appointed under the Veterans Readjustment Act (5 CFR Part 307). The FPM letter contains special instructions for the treatment of training time for employees in these programs. Furthermore, OPM will issue Federal Personnel Manual guidance reflecting this change in its chapter 410 on training.

Time Spent Adjusting Grievances or Performing Representational Functions

Numerous comments expressed a need to distinguish clearly between time spent by a grievant adjusting his or her grievance and "official time" spent by an employee representative performing representational functions. The language in § 551.424 has been revised to clarify (1) that any time spent by a grievant in the settlement of his or her grievance while the grievant is required to be on the agency's premises is worktime, and (2) that any "offficial time" granted by an agency and used by an employee representative in the performance of representational functions is worktime.

One agency expressed concern over the meaning of the phrase, "while otherwise in a duty status." The key to whether time spent performing representational functions outside regular working hours is overtime work is that the employee representative must already have been in an overtime duty status at the direction of the agency at the time an event arises which calls for the performance of representational functions. The employee representative cannot extend his or her duty hours (including overtime hours) solely for the purpose of extending representational functions into overtime hours.

Time Spent Receiving Medical Attention

Three agencies recommended that the time spent receiving medical attention should be limited to job-related illnesses or injuries, and another agency recommended that such time be limited to one hour. It must be emphasized that § 551.425 addresses only a situation where an employee has already reported to work and subsequently becomes ill or injured, and, further, it only applies to that specific workday. This provision cannot be limited to a job-related illness or injury, and it cannot be limited to a specific period of time. However, it is limited to situations when an employee is receiving medical attention at the direction and under the control of the agency. When these criteria are met, the employee is on duty during the time he or she receives medical attention.

Two agencies recommended that this section be expanded to include time spent by an employee taking a physical examination that is required for continued employment with the agency. This recommendation was adopted.

Time Spent in Charitable Activities

The comments of a few agencies expressed some confusion concerning the treatment of time spent by volunteers in charitable activities. It must be emphasized that the rules for the treatment of such time contained in § 551.426 apply only to employees of an agency. Volunteers, as defined in § 551.102, are not employees under the Act, and, therefore, this section is not applicable to such individuals.

Time Spent on Standby Duty or in an On-Call Status

Two agencies recommended that § 551.431 be revised to distinguish clearly between (1) standby duty and (2) time spent in an on-call status. This recommendation was adopted.

In addition, one labor organization recommended that time spent in on-call status be compensable. Under the Act, an employee is either on duty or off duty. There is no provision for a semi-duty status such as standby duty or on-call status. Therefore, OPM was faced with the task of determining whether standby duty and time spent in an on-call status are properly worktime under the Act. OPM determined that the severe restrictions placed on an employee's whereabouts and time to qualify for standby duty pay under title 5, United States Code, make such duty worktime under the Act. However, the Department of Labor and the courts have not seen fit to consider time spent in an on-call status a severe enough limitation on an employee's off duty time to require compensation for such status. Therefore, we determined that time spent in an on-call status is not worktime. This policy determination was promulgated in FPM Letter 551–14, dated May 15, 1978. The feasibility of a premium or a differential to ensure an employee's availability during a period of on-call status is currently being reviewed by the Compensation Program Development Division, OPM.

Maximum Earnings Limitation

One agency recommended the inclusion of a statement that the maximum limitation on an employee's aggregate pay (basic pay and premium pay) under title 5, United States Code, does not apply to overtime pay under the Act. This recommendation was adopted.

Fractional Hours of Work

Numerous agencies questioned the requirements to pay for irregular, unscheduled overtime work in fractions of a quarter of an hour or less, and to pay for every minute of regularly scheduled overtime work. They indicated that it would be administratively burdensome to comply with these requirements. The requirements contained in § 551.521 are not a change in policy, but merely express in regulatory language the procedures currently prescribed in FPM Letter 551–6, dated June 12, 1975.

Recently, the Comptroller General concurred in an OPM proposal to provide for rounding of odd minutes of irregular, unscheduled overtime work under title 5, United States Code. For example, if an agency is paying for such overtime work in increments of 15 minutes, seven minutes or less may be rounded down to zero and eight minutes or more may be rounded up to 15 minutes. OPM is currently amending 5 CFR Part 550 to provide for the rounding of odd minutes under title 5. This section has been revised to provide for the rounding of odd minutes of irregular, unscheduled overtime work on the same basis. The revision will provide agencies four possible administrative procedures for the treatment of irregular, unscheduled overtime work: (1) Restrict the performance of overtime work to the full fraction used to account for overtime work, (2) pay for every minute of irregular, unscheduled overtime work, (3) round odd minutes of irregular, unscheduled overtime work on a daily basis, or (4) accumulate odd minutes of irregular, unscheduled overtime work and round on a workweek basis. Agencies are encouraged to adopt the same administrative procedure under both title 5 and the FLSA.

Compensatory Time Off

Two agencies and one labor organization commented on the seemingly limited use of compensatory time off under this part—i.e., that compensatory time off may be taken only in the same workweek. The rules contained in § 551.531, which are consistent with instructions contained in FPM Letter 551–6, dated June 12, 1975, allow for the use of compensatory time off in subsequent workweeks, provided the employee's overtime pay entitlement under title 5, United States Code, is equal to or greater than his or her overtime pay entitlement under the FLSA, and the employee makes a written requests for such compensatory time off.

We acknowledge the position expressed by the Wage and Hour Division, Department of Labor, that an employee is entitled to overtime pay for overtime work and that overtime payments must be made within the regular pay periods. This is the basis for the Wage and Hour Division's position that an employer may not credit an employee with compensatory time off for overtime work to be used in subsequent pay periods. The Wage and Hour Divisions, at the same time, expressed its awareness of the statutory conflict between the FLSA and title 5. OPM has addressed this conflict by administering both laws concurrently and requiring compensation under whichever law provides the greater overtime pay benefit. When an employee's entitlement to overtime pay under title 5 is equal to or greater than his or her entitlement to overtime pay under the FLSA, the employee may excercise his or her statutory entitlement to request compensatory time off in lieu of overtime pay under title 5.

OPM has determined that this is a significant regulation for the purposes of E.O. 12044.

Office of Personnel Management.

JoAnn B. Platter,

Assistant Issuance System Manager.

Accordingly, OPM is adding Subparts A, C, D, and E to 5 CFR Part 551, to read as follows:

PART 551—PAY ADMINISTRATION UNDER THE FAIR LABOR STANDARDS ACT

Subpart A—General Provisions

Sec.

* * * * *

Subpart C—Minimum Wage Provisions

Basic Provision

Subminimum Wage

Subpart D—Hours of Work

General Provisions

Application of Principles in Relation to Normal Workday

Application of Principles in Relation to Other Activities

Authority: Pub. L. 93-259; 29 U.S.C. 204f.

Subpart A—General Provisions

§ 551.101 General.

(a) Section 3(e)(2) of the Fair Labor Standards Act of 1938, as amended, authorizes the application of the provisions of the Act to any person employed by the Government of the United States, as specified in that section. Section 4(f) of the Act authorizes the Office of Personnel Management to administer the provisions of the Act for all such employees, except for those who are employed by the Library of Congress, United States Postal Service, Postal Rate Commission, or the Tennessee Valley Authority; the named groups of employees are specifically excluded from the Office of Personnel Management's administration.

(b) The Act provides for minimum standards for both wages and overtime entitlements, and delineates administrative procedures by which covered worktime must be compensated. Included in the Act are provisions related to child labor, equal pay, and portal-to-portal activities. In addition, the Act exempts specified employees or groups of employees from the application of certain of its provisions. It prescribes penalties for the commission of specifically prohibited acts.

(c) This part contains the regulations, criteria, and conditions that the Office of Personnel Management has prescribed for the administration of the Act. This part supplements and implements the Act, and must be read in conjunction with it.

§ 551.102 Definitions.

In this part:

(a) "Act" means the Fair Labor Standards Act of 1938, as amended (29 U.S.C. 201 et seq.);

(b) "Agency", for purposes of the Office of Personnel Management's administration of the Act, means any instrumentality of the United States Government, or any constituent element thereof acting directly or indirectly as an employer, as this term is defined in section 3(d) of the Act; but does not include:

(1) The Library of Congress;

(2) The United States Postal Service;

(3) The Postal Rate Commission; or

(4) The Tennessee Valley Authority;

all of which are subject to the administration of the Act by the Department of Labor, under Title 29, Code of Federal Regulations.

(c) "Employ" means to engage a person in an activity that is for the benefit of an agency, as defined for this part, and includes any hours of work that are suffered or permitted.

(d) "Employee" means a person who is employed:

(1) In an executive agency;

(2) As a civilian in a military department;

(3) In a nonappropriated fund instrumentality of an executive agency or a military department; or

(4) In a unit of the legislative or judicial branch of the Government that has positions in the competitive service.

(e) "Suffered or permitted" work means any work performed by an employee for the benefit of an agency, whether requested or not, provided the employee's supervisor knows or has reason to believe that the work is being performed and has an opportunity to prevent the work from being performed.

(f) "Trainee" means a person who does not meet the definition of "employee" in (d), above, and who is assigned or attached to a Federal activity primarily for training. A person who attends a training program under the following conditions is considered a "trainee" and, therefore, is not an "employee" of the Government of the United States for purposes of the Act:

(1) The training, even though it includes actual operation of the facilities of the Federal activity, is similar to that given in a vocational school or other institution of learning;

(2) The training is for the benefit of the individual;

(3) The trainee does not displace regular employees, but, rather, is supervised by them;

(4) The Federal activity which provides the training derives no immediate advantage from the activities of the trainee; on occasion its operations may actually be impeded;

(5) The trainee is not necessarily entitled to a job with the Federal activity at the completion of the training period; and

(6) The agency and the trainee understand that the trainee is not entitled to the payment of wages from the agency for the time spent in training.

(g) "Volunteer" means a person who does not meet the definition of "employee" in (d), above, and who volunteers or donates his or her service the primary benefit of which accrues to the performer of the service or to someone other than the agency. Under such circumstances there is neither an expressed nor an implied compensation agreement. Services performed by such a volunteer include personal services that, if left unperformed, would not necessitate the assignment of an employee to perform them.

§ 551.103 Coverage.

(a) Any employee of an agency who is not specifically excluded by another statute is covered by the Act. This includes any person who is:

(1) Defined as an employee under section 2105 of title 5, United States Code;

(2) Appointed under other appropriate authority; or

(3) Suffered or permitted to work by an agency whether or not formally appointed.

(b) The following persons are not covered under the Act:

(1) A person appointed under appropriate authority without compensation;

(2) A trainee as defined in § 551.102(f); or

(3) A volunteer as defined in § 551.102(g).

§ 551.104 Administrative authority.

The Office of Personnel Management is the administrator of the provisions of the Act with respect to any person employed by an agency, except for the equal pay provisions contained in section 6(d) of the Act, which are administered by the Equal Employment Opportunity Commission.

* * * * *

Subpart C—Minimum Wage Provisions

Basic Provision

§ 551.301 Minimum wage.

(a) Except as provided in § 551.311, an agency shall pay each of its employees wages at rates not less than the minimum wage specified in section 6(a)(1) of the Act for all hours of work as defined in subpart D of this part.

(b) An employee has been paid in compliance with the minimum wage provisions of this subpart if the employee's hourly regular rate of pay, as defined in § 551.511(a) of this part, for the workweek is equal to or in excess of the rate specified in section 6(a)(1) of the Act.

Subminimum Wage

§ 551.311 Subminimum wage.

An agency may, if it meets certain criteria published by the Office of Personnel Management, employ certain groups of less than fully productive employees (e.g., handicapped patient workers) at rates less than the minimum wage specified in section 6(a)(1) of the Act.

Subpart D—Hours of Work

General Provisions

§551.401 Basic principles.

(a) All time spent by an employee performing an activity for the benefit of an agency and under the control or direction of the agency is "hours of work." Such time includes:

(1) Time during which an employee is required to be on duty;

(2) Time during which an employee is suffered or permitted to work; and

(3) Waiting time or idle time which is under the control of an agency and which is for the benefit of an agency.

(b) Paid periods of nonwork (e.g., leave, holidays, or excused absences) are not hours of work for the proposes of this part.

(c) Time that is considered hours of work under this part shall be used only to determine an employee's entitlement to minimum wages or overtime pay under the Act, and shall not be used to determine hours of work for pay administration under title 5, United States Code, or any other authority.

551.402 Agency responsibility.

(a) An agency is responsible for exercising appropriate controls to assure that only that work for which it intends to make payment is performed.

(b) An agency shall keep complete and accurate records of all hours worked by its employees.

Application of Principles in Relation to Normal Workday

§ 551.411 Workday.

(a) For the purposes of this part, "workday" means the period between the commencement of the principal activity(s) that an employee is engaged to perform on a given day, and the cessation of the principal activity(s) for that day. All time spent by an employee in the performance of such activity(s) is hours of work. The workday is not limited to a calendar day or any other 24-hour period.

(b) Any rest period authorized by an agency that does not exeed 20 minutes and that is within the workday shall be considered hours of work.

(c) *Bona fide* meal periods shall not be considered hours of work.

§ 551.412 Preparatory or concluding activities.

(a) A preparatory or concluding activity that is closely related to the principal activity, and is indispensable to its performance, is an integral part of the principal activity and is, therefore, a part of the workday and shall be considered hours of work.

(b) A preparatory or concluding activity that is not an integral part of the performance of the principal activity is not a part of the workday. Such an activity is a preliminary or postliminary activity and is not considered hours of work.

Application of Principles in Relation to Other Activities

§ 551.421 Regular working hours.

(a) Under the Act there is no requirement that a Federal employee have a regularly scheduled administrative workweek. However, under title 5 United States Code, and Part 610 of this chapter, the head of an agency is required to establish work schedules for his or her employees. In determining what activities constitute hours of work under the Act, there is generally a distinction based on whether the activity is performed by an employee during regular working hours or outside regular working hours. For purposes of this part, "regular working hours" means the hours and days during which an employee is normally scheduled to be on duty.

§ 551.422 Time spent traveling.

(a) Time spent traveling shall be considered hours of work if:

(1) An employee is required to travel during regular working hours;

(2) An employee is required to drive a vehicle or perform other work while traveling;

(3) An employee is required to travel as a passenger on a one-day assignment away from the official duty station; or

(4) An employee is required to travel as a passenger on an overnight assignment away from the official duty station during hours on nonworkdays that correspond to the employee's regular working hours.

(b) An employee who travels from home before the regular workday begins and returns home at the end of the workday is engaged in normal "home to work" travel; such travel is not hours of work. When an employee travels directly from home to a temporary duty location outside the limits of his or her official duty station, the time the employee would have spent in normal home to work travel shall be deducted from hours of work as specified in paragraphs (a)(2) and (a)(3) of this section.

(c) An employee who is offered one mode of transportation, and who is permitted to use an alternative mode of transportation, or an employee who travels at a time other than that selected by the agency, shall be credited with the lesser of:

(1) The actual travel time which is hours of work under this section; or

(2) The estimated travel time which would have been considered hours of work under this section had the employee used the mode of transportation offered by the agency, or traveled at the time selected by the agency.

§ 551.423 Time spent on training or attending a lecture, meeting, or conference.

(a) Time spent in training, whether or not it is under the purview of Part 410 of this chapter, shall be administered as follows:

(1) Time spent in training during regular working hours shall be considered hours of work.

(2) Time spent in training outside regular working hours shall be considered hours of work if:

(i) The employee is directed to participate in the training by his or her employing agency; and

(ii) The purpose of the training is to improve the employee's performance of the duties and responsibilities of his or her current position.

(3) Time spent in apprenticeship or other entry level training, or internship or other career related work study training, or training under the Veterans Readjustment Act (5 CFR Part 307) outside regular working hours shall not be considered hours of work, provided no productive work is performed during such periods.

(4) Time spent by an employee performing work for the agency during a period of training shall be considered hours of work.

(b) The following phrases contained in (a), above, are further clarified:

(1) "Directed to participate" means that the training is required by the agency and the employee's performance or continued retention in his or her current position will be adversely affected by nonenrollment in such training.

(2) Training "to improve the employee's performance . . . of his or her current position" is distinguished from upward mobility training or developmental training to provide an employee the knowledge or skills needed for a subsequent position in the same career field.

(c) Time spent by an employee within an agency's allowance of preparatory time for attendance at training shall be considered hours of work if such preparatory time is:

(1) During an employee's regular working hours; or

(2) Outside the employee's regular working hours, and the purpose of the training meets the requirements of (a)(2), above.

(d) Time spent attending a lecture, meeting, or conference shall be considered hours of work if attendance is:

(1) During an employee's regular working hours; or

(2) Outside an employee's regular working hours, and

(i) The employee is directed by an agency to attend such an event; or

(ii) The employee performs work for the benefit of the agency during such attendance.

§ 551.424 Time spent adjusting grievances or performing representational functions.

(a) Time spent by an employee adjusting his or her grievance (or any appealable action) with an agency during the time the employee is required to be on the agency's premises shall be considered hours of work.

(b) "Official time" granted an employee by an agency to perform representational functions during those hours when the employee is otherwise in a duty status shall be considered hours of work. This includes time spent by an employee performing such functions during regular working hours (including regularly scheduled overtime hours), or during a period of irregular, unscheduled overtime work, provided an event arises incident to representational functions that must be dealt with during the irregular, unscheduled overtime period.

§ 551.425 Time spent receiving medical attention.

(a) Time spent waiting for and receiving medical attention for illness or injury shall be considered hours of work if:

(1) The medical attention is required on a workday an employee reported for duty and subsequently became ill or was injured;

(2) The time spent receiving medical attention occurs during the employee's regular working hours; and

(3) The employee receives the medical attention on the agency's premises, or at the direction of the agency at a medical facility away from the agency's premises.

(b) Time spent taking a physical examination that is required for the employee's continued employment with the agency shall be considered hours of work.

§ 551.426 Time spent in charitable activities.

Time spent working for public or charitable purposes at an agency's request, or under an agency's direction or control, shall be considered hours of work. However, time spent voluntarily in such activities outside an employee's regular working hours is not hours of work.

Special Situations

§ 551.431 Time spent on standby duty or in an on-call status.

(a) An employee will be considered on duty and time spent on standby duty shall be considered hours of work if:

(1) The employee is restricted to an agency's premises, or so close thereto that the employee cannot use the time effectively for his or her own purposes; or

(2) The employee, although not restricted to the agency's premises:

(i) Is restricted to his or her living quarters or designated post of duty;

(ii) Has his or her activities substantially limited; and

(iii) Is required to remain in a state of readiness to perform work.

(b) An employee will be considered off duty and time spent in an on-call status shall not be considered hours of work if:

(1) The employee is allowed to leave a telephone number or to carry an electronic device for the purpose of being contacted, even though the employee is required to remain within a reasonable call-back radius; or

(2) The employee is allowed to make arrangements such that any work which may arise during the on-call period will be performed by another person.

§ 551.432 Sleep time.

(a) Except as provided in paragraph (b) of this section, *bona fide* sleep time that fulfills the following conditions shall not be considered hours of work if:

(1) The tour of duty is *24 hours or more;*

(2) During such time there are adequate facilities such that an employee may usually enjoy an uninterrupted period of sleep; and

(3) There are at least 5 hours available for such time during the sleep period.

(b) For employees engaged in fire protection activities or law enforcement activities, the exclusion of sleep time is appropriate for tours of duty *of more than 24 hours* only. However, paragraphs (a)(2) and (a)(3) of this section still apply to employees in these activities.

(c) Not more than 8 hours in a 24-hour period shall be considered sleep time.

(d) If sleep time is interrupted by a call to duty, the time spent on duty is considered hours of work.

Subpart E—Overtime Pay Provisions

Basic Provisions

§ 551.501 Overtime pay.

(a) Except as otherwise provided in this subpart, an agency shall compensate an employee who is not exempt under subpart B of this part for all hours of work in excess of 40 in a workweek at a rate equal to one and one-half times the employee's hourly regular rate of pay.

(b) An employee's "workweek" is a fixed and recurring period of 168 hours—seven consecutive 24-hour periods. It need not coincide with the calendar week but may begin on any day and at any hour of a day. For employees subject to Part 610 of this chapter, the workweek shall be the same as the administrative workweek defined in § 610.102 of this chapter.

(c) The maximum limitation on an employee's aggregate rate of pay under § 550.105 of this chapter does not apply to overtime pay due the employee under this subpart.

Overtime Pay Computations

§ 551.511 Hourly regular rate of pay.

(a) An employee's "hourly regular rate" is computed by dividing the total remuneration paid to an employee in the workweek by the total number of hours of work in the workweek for which such compensation was paid.

(b) "Total remuneration" includes all remuneration for employment paid to, or on behalf of, an employee except:

(1) Payments as rewards for service the amount of which is not measured by

or dependent on hours of work, production, or efficiency (e.g., a cash award for a suggestion made by an employee and adopted by an agency);

(2) Payments for periods during which no work is performed (e.g., leave, holidays, or excused absences), or reimbursements for travel expenses, or other similar expenses, incurred by an employee in furtherance of an agency's interest, which are not related to hours of work;

(3) Payments made in recognition of services performed during a given period, if both the fact that payment is to be made and the amount of the payment are determined at the sole discretion of the agency (e.g., incentive awards for outstandingly high-quality work);

(4) Contributions by an agency to a fund for retirement, insurance, or similar benefits;

(5) Extra compensation provided by a premium rate paid for hours of work performed by an employee in excess of eight in a day, or in excess of the normal workweek applicable to the employee;

(6) Extra compensation provided by a premium rate paid for hours of work performed by an employee on a Sunday or a holiday where such premium rate is at least one and one-half times the employee's rate of pay for work performed in nonovertime hours on other days; or

(7) Extra compensation provided by a premium rate paid for hours of work performed by an employee outside his or her regular working hours, where such premium rate is at least one and one-half times the employee's rate of pay for work performed in nonovertime hours.

§ 551.512 Overtime pay entitlement.

(a) An employee's overtime entitlement under this subpart includes:

(1) The straight time rate of pay times all overtime hours worked; plus

(2) One-half times the employee's hourly regular rate of pay times all overtime hours worked.

(b) An employee's "straight time rate of pay" is equal to the employee's rate of pay for his or her position (exclusive of any premiums or differentials) except for an employee who is authorized annual premium pay under §§ 550.141 or 550.151 of this chapter. For an employee who is authorized annual premium pay, straight time rate of pay is equal to basic pay plus annual premium pay divided by the hours for which the basic pay plus annual premium pay are intended.

(c) An employee has been paid in compliance with the overtime pay provisions of this subpart only if the employee has received pay at a rate at least equal to the employee's straight time rate of pay for all nonovertime hours of work in the workweek.

§ 551.513 Payment of greater overtime pay entitlement.

An employee entitled to overtime pay under this subpart and overtime pay under § 550.113 of this chapter, or under any other authority, shall be paid under whichever authority provides the greater overtime entitlement in the workweek. This overtime pay shall be paid in addition to all pay, other than overtime pay, to which the employee is entitled under title 5, United States Code, or any other authority.

Fractional Hours of Work

§551.521 Fractional hours of work.

(a) A quarter of an hour shall be the largest fraction of an hour used for crediting irregular, unscheduled overtime work under this subpart. Odd minutes or irregular, unscheduled overtime work shall be rounded up or rounded down to the nearest full fraction of an hour being used to account for overtime work.

(b) An employee shall be compensated for every minute of regularly scheduled overtime work.

Compensatory Time Off

§ 551.531 Compensatory time off.

(a) An agency may grant an employee compensatory time off in lieu of overtime pay under appropriate statutory authority, to be taken during the same workweek in which the overtime work was performed.

(b) An employee who earns an overtime pay entitlement under this subpart may be granted compensatory time off in a subsequent workweek provided:

(1) The employee earns overtime entitlement under § 550.113 of this chapter that is equal to or greater than the employee's overtime entitlement under this subpart; and

(2) The employee makes a written request to substitute compensatory time off for overtime payment.

Special Overtime Pay Provisions

§ 551.541 Employees engaged in fire protection activities or law enforcement activities.

(a) An employee engaged in fire protection activities or law enforcement activities shall be paid at a rate equal to one and one-half times the employee's hourly regular rate of pay for those hours in a tour of duty which exceed the overtime standard for a work period specified in section 7(k) of the Act.

(b) The "tour of duty" of an employee engaged in these activities shall include all time the employee is on duty. Meal periods and sleep periods are included in the tour of duty except as otherwise provided in § 551.432 of this part.

(c) Each agency shall establish the "work period" to be used for application of section 7(k) of the Act. The work period shall be at least seven days and not more than 28 days.

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5 CFR Part 581

Processing Garnishment Orders for Child Support and/or Alimony

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: This document revises and updates the entire appendix to the garnishment regulations which lists agents who are designated to accept legal process for garnishment for child support and/or alimony.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: Murray Meeker, Office of the General Counsel, (202) 632-5524.

SUPPLEMENTARY INFORMATION: Appendix A was originally published in the **Federal Register** on July 22, 1980 (45 FR 48853-48864). On July 22, 1980, OPM published final garnishment regulations for the executive branch. The regulations were in compliance with Executive Order 12105 which expressly directed OPM to promulgate such regulations. Included with the regulations was an appendix which listed designated agents to accept service of process in garnishment actions.

On September 3, 1980, OPM issued FPM Bulletin 581-3 which requested additional agents from agencies which had not responded previously. FPM Bulletin 581-3 was directly responsible for the majority of the new designations published herein. The entire Appendix is reprinted below as a service to the reader.

OPM has determined that this is a nonsignificant regulation for the purposes of E.O. 12044.

Office of Personnel Management.

JoAnn B. Platter,

Assistant Issuance System Manager.

Accordingly, OPM is revising Part 581 to read as follows:

PART 581—PROCESSING GARNISHMENT ORDERS FOR CHILD SUPPORT AND/OR ALIMONY

Subpart A—Purpose and Definitions

Subpart B—Service of Process

Subpart C—Compliance with Process

Subpart D—Consumer Credit Protection Act Restrictions

Subpart E—Implementation by Governmental Entities

Authority: 42 U.S.C. 659, 661–662; 15 U.S.C. 1673; E.O. 12105.

Subpart A—Purpose and Definitions

§ 581.101 Purpose.

Section 659 of title 42 of the United States Code, as amended, provides that moneys, the entitlement to which is based upon remuneration for employment, due from, or payable by, the United States or the District of Columbia to any individual, shall be subject, as if the United States or the District of Columbia were a private person, to legal process brought for the enforcement of such individual's legal obligations to provide child support and/or make alimony payments. The purpose of this part is to implement the objectives of section 659 as it pertains to the executive branch of the Government of the United States.

§ 581.102 Definitions.

In this part: (a) "The executive branch of the Government of the United States" means all "governmental entities" as defined in this section, including therein the territories and possessions of the United States, the United States Postal Service, the Postal Rate Commission, any wholly owned Federal corporation created by an Act of Congress, and the government of the District of Columbia.

(b) "Governmental entity" means each department, both civilian and military, agency, independent establishment, or instrumentality of the executive branch, including the United States Postal Service, the Postal Rate Commission, any wholly owned Federal corporation created by an Act of Congress, any office, commission, bureau, or other administrative subdivision or creature of the executive branch, and the governments of the District of Columbia and of the territories and possessions of the United States.

(c) "Private person" means a person who does not have sovereign or other special immunity or privilege which causes that person not be be subject to legal process.

(d) "Child support" means periodic payments of funds for the support and maintenance of a child or children, and, subject to and in accordance with State or local law, includes, but is not limited to, payments to provide for health care, education, recreation, clothing, or to meet other specific needs of such a child or children; the term also includes attorney's fees, interest, and court costs, if they are expressly made recoverable under a decree, order, or judgment issued in accordance with applicable State or local law by a court of competent jurisdiction.

(e) "Alimony" means periodic payments of funds for the support and maintenance of a spouse or former spouse, and, subject to and in accordance with State or local law, includes, but is not limited to, separate maintenance, alimony pendente lite, maintenance, and spousal support. Alimony also includes attorney's fees, interest, and court costs, if they are expressly made recoverable under a decree, order, or judgment issued in accordance with applicable State or local law by a court of competent jurisdiction. This term does not include any payment or transfer of property or its value by an individual to his/her spouse or former spouse in compliance with any community property settlement, equitable distribution of property, or other division of property between spouses or former spouses. (See instead 5 U.S.C. 8345(j).)

(f) "Legal process" means any writ, order, summons, or other similar process in the nature of garnishment, which may include an attachment, writ of execution, or court ordered wage assignment, which—

(1) Is issued by: (i) A court of competent jurisdiction, including Indian tribal courts, within any State, territory, or possession of the United States, or the District of Columbia;

(ii) A court of competent jurisdiction in any foreign country with which the United States has entered into an agreement which requires the United States to honor the process; or

(iii) An authorized official pursuant to an order of a court of competent jurisdiction or pursuant to State or local law, and

(2) Is directed to, and the purpose of which is to compel, a governmental entity, to make a payment from moneys otherwise payable to an individual, to another party to satisfy a legal obligation of the individual to provide child support and/or make alimony payments.

(g) "Legal obligation" means an obligation to pay alimony and/or child support which is enforceable under appropriate State or local law.

(h) "Obligor" means an individual having a legal obligation to pay alimony and/or child support.

(i) "Remuneration for employment" means compensation paid or payable for personal services, whether such compensation is denominated as wages, salary, commission, bonus, pay, or otherwise, and includes, but is not limited to, those items set forth in § 581.103.

(j) "Party" means the person or persons to whom alimony and/or child support payments should be made, or, in the case of an agency established by State or local law, the agency which has been assigned, by law or by agreement, the right to receive such payment or payments.

§ 581.103 Moneys which are subject to garnishment.

(a) For the personal service of a civilian employee obligor:

(1) Saved pay;
(2) Retained pay;
(3) Night differentials;
(4) Sunday and holiday premium pay;
(5) Overtime pay;
(6) Standby pay;
(7) Environmental differentials;
(8) Hazardous duty pay;
(9) Tropical differentials;
(10) Recruitment incentives;
(11) Equalization allowance;
(12) Any payment in consideration of accrued leave;
(13) Severance pay;
(14) Sick pay;
(15) Physicians comparability allowances;
(16) Special pay for physicians and dentists;

(17) Amounts paid pursuant to a personal services contract where the contractor recipient performed the services and received the payments in the capacity as a Federal employee;
(18) Merit pay;
(19) Incentive pay;
(20) Cash awards;
(21) Agency and Presidential incentive awards (except where such award is for making a suggestion); and
(22) Senior Executive Service rank and performance awards.

(b) For the personal service of an obligor in the uniformed services of the United States: (1) Basic pay (including service academy cadet and midshipmen pay);
(2) Special pay (including enlistment and re-enlistment bonuses);
(3) Lump sum reserve bonus;
(4) Continuation pay for physicians and dentists;
(5) Special pay for physicians, dentists, optometrists, and veterinarians;
(6) Incentive pay;
(7) Variable incentive pay;
(8) Inactive duty training pay;
(9) Administrative duty pay;
(10) Academy official pay (other than personal money allowances);
(11) Any payments made in consideration of accrued leave (basic pay portion only);
(12) Readjustment pay;
(13) Disability retired pay;
(14) Severance pay (including disability severance pay); and
(15) Cash awards (NOAA Corps).

(c) For obligors generally: (1) Periodic benefits, including a periodic benefit as defined in section 428(h)(3) of title 42 of the United States Code, title II of the Social Security Act, to include a benefit payable in a lump sum if it is commutation of, or a substitute for, periodic payments; or other payments to these individuals under the programs established by subchapter II of chapter 7 of title 42 of the United States Code (Social Security Act) and by chapter 9 of title 45 of the United States Code (Railroad Retirement Act) or any other system or fund established by the United States (as defined in section 662(a) of title 42 of the United States Code) which provides for the payment of:
(i) Pensions;
(ii) Retirement;
(iii) Retired/retainer pay;
(iv) Annuities;
(v) Refunds of retirement contributions where an application has been filed; and
(vi) Dependents' or survivors' benefits when payable to the obligor.
(2) Amounts received under any Federal program for compensation for work injuries; and
(3) Benefits received under the Longshoremen's and Harbor Workers' Compensation Act.
(4) Exceptions. Remuneration would not include: (i) Any payment as compensation for death, including any lump sum death benefit under any Federal program;
(ii) Any payment under any Federal program established to provide "black lung" benefits;
(iii) Any payment by the Veterans Administration as pension; or
(iv) Any payments by the Veterans Administration as compensation for a service-connected disability or death, except any compensation paid by the Veterans Administration to a former member of the Armed Forces who is in receipt of retired or retainer pay if such former member has waived a portion of his/her retired pay in order to receive such compensation. In this case, only that part of the Veterans Administration payment which is in lieu of the waived retired/retainer pay, is subject to garnishment.

§ 581.104 Moneys which are not subject to garnishment.

(a) Payments made pursuant to the provisions of the Federal Tort Claims Act, as amended, sections 1346(b) and 2671 *et seq.*, of title 28 of the United States Code;
(b) Payments or portions of payments made by the Veterans Administration pursuant to sections 501–562 of title 38 of the United States Code, in which the entitlement of the payee is based on non-service-connected disability or death, age and need;
(c) Refunds and other payments made in connection with overpayments or erroneous payments of income tax and other taxes levied under Title 26 of the United States Code;
(d) Grants;
(e) Fellowships;
(f) Veterans' educational assistance payments under sections 1651 *et seq.*, of Title 38 of the United States Code;
(g) Contracts, except where the contractor recipient performed personal services and received payments in his/her capacity as an employee of a governmental entity; and
(h) Reimbursement for expenses incurred by an indivudal in connection with his/her employment, or allowances in lieu thereof, and other payments and allowances, including, but not limited to:
(1) In the case of civilian employees:
(i) Uniform allowances;
(ii) Travel and transportation expenses (including mileage allowances);
(iii) Relocation expenses;
(iv) Storage expenses;
(v) Post differentials;
(vi) Foreign areas allowances;
(vii) Education allowances for dependents;
(viii) Separate maintenance allowances;
(ix) Post allowances and supplementary post allowances;
(x) Home service transfer allowances;
(xi) Quarters allowances;
(xii) Cost-of-living allowances (COLA), when applicable to an employee in a foreign area or an employee stationed outside of the continental United States or in Alaska;
(xiii) Remote worksite allowance; and
(xiv) Per diem allowances.
(2) In the case of members of the uniformed services: (i) Position pay (Navy only);
(ii) Basic allowance for quarters;
(iii) Basic allowance for subsistence;
(iv) Station allowances;
(v) Armed Forces health professions scholarship stipends;
(vi) Public Health Service scholarship stipends;
(vii) Travel and transportation allowances;
(viii) Dislocation allowances;
(ix) Family separation allowances;
(x) ROTC subsistence allowance;
(xi) Allowance for recruiting expenses;
(xii) Education allowances for dependents;
(xiii) Clothing allowances for enlisted personnel; and
(xiv) Uniform allowances for General and Flag officers, and for the Surgeon General and other employees of the Public Health Service.
(3) In the case of volunteers serving under either the Domestic Volunteer Service Act or the Peace Corps Act, all allowances, including, but not limited to, readjustment allowances, stipends, and reimbursements for out-of-pocket expenses.

§ 581.105 Exclusions.

In determining the amount of any "moneys due from or payable by, the United States" to any individual, there shall be excluded amounts which:
(a) Are owed by the individual to the United States;
(b) Are required by law to be deducted from the remuneration or other payment involved, including, but not limited to:
(1) Amounts withheld from benefits payable under title II of the Social Security Act where the withholding is required by law;

(2) Federal employment taxes;
(3) Amounts mandatorily withheld for the U.S. Soldiers' and Airmen's Home; and
(4) Fines and forfeitures ordered by a court-martial or by a commanding officer;
(c) Are properly withheld for Federal, State, or local income tax purposes, if the withholding of the amounts is authorized or required by law and if amounts withheld are not greater than would be the case if the individual claimed all dependents to which he/she were entitled. The withholding of additional amounts pursuant to section 3402(i) of title 26 of the United States Code may be permitted only when the individual presents evidence of a tax obligation which supports the additional withholding;
(d) Are deducted as health insurance premiums, including, but not limited to, amounts deducted from civil service annuities for Medicare where such deductions are requested by the Health Care Financing Administration;
(e) Are deducted as normal retirement contributions, not including amounts deducted for supplementary coverage. Amounts withheld as Survivor Benefit Plan or Retired Serviceman's Family Protection Plan payments are considered to be normal retirement contributions. Amounts voluntarily contributed toward additional civil service annuity benefits are considered to be supplementary; or
(f) Are deducted as normal life insurance premiums from salary or other remuneration for employment, not including amounts deducted for supplementary coverage. Both Servicemen's Group Life Insurance and "regular" Federal Employees' Group Life Insurance premiums are considered to be normal life insurance premiums; "optional" Federal Employees' Group Life Insurance premiums and life insurance premiums paid for by allotment, such as National Service Insurance, are considered to be supplementary.

§ 581.106 Future payments.

Moneys paid by a governmental entity which may be due and payable to an individual at some future date, shall not be considered due the individual unless and until all of the conditions necessary for payment of the moneys to the individual have been met, including, but not limited to, the following conditions which might apply:
(a) Retirement;
(b) Resignation from a position in the Federal service; or
(c) Application for payment of moneys by the individual.

Subpart B—Service of Process

§ 581.201 Agent to receive process.

(a) Appendix A to this part lists agents designated to accept service of process.
(b) The head of each governmental entity shall submit to the Office of the General Counsel, Room 5H30, Office of Personnel Management, 1900 E Street, NW., Washington, D.C. 20415, for publication in Appendix A to this part, the following information concerning the agent(s) designated to accept service of process:
(1) Title;
(2) Mailing address;
(3) Telephone number; and
(4) Geographical area or region, if applicable.
(c) United States Attorneys are not considered appropriate agents to accept service of process.

§ 581.202 Service of process.

(a) A party using this part shall serve on the designated agent of the governmental entity which has moneys due and payable to the obligor, legal process which names the governmental entity as the garnishee.
(b) Service of legal process brought for the enforcement of an obligation to provide child support and/or alimony shall be accomplished by certified or registered mail, return receipt requested, or by personal service, upon the appropriate agent designated in Appendix A to this part, or if no agent has been designated for the governmental entity having payment responsibility for the moneys involved, then upon the head of that governmental entity. The designated agent shall note the date and time of receipt on the legal process. The governmental entity shall make every reasonable effort to facilitate proper service of process on its designated agent(s). If legal process is not directed to any particular official within the entity, or if it is addressed to the wrong individual, the recipient shall, nonetheless, forward the legal process to the designated agent. However, valid service is not accomplished until the legal process is received in the office of the designated agent.
(c) Where it does not appear from the face of the process that it has been brought to enforce the legal obligation(s) defined in § 581.102(d) and/or (e), the process must be accompanied by a certified copy of the court order establishing such legal obligation(s).
(d) Where the State or local law provides for the issuance of legal process without a support order, such other documentation establishing that it was brought to enforce legal obligation(s) defined in § 581.102(d) and/or (e) must be submitted.
(e) In order for the party who caused the legal process to be served to receive the additional five (5) percent provided for in either § 581.402(a) or (b), it must appear on the face of the legal process that the process was brought for the enforcement of a support order for a period which is twelve (12) weeks in arrears, or a certified copy of the support order, or other evidence acceptable to the head of the governmental entity, establishing this fact, must be submitted.

§ 581.203 Information minimally required to accompany legal process.

(a) Sufficient identifying information must accompany the legal process in order to enable processing by the governmental entity named. Therefore, the following identifying information about the obligor, if known, is requested:
(1) Full name;
(2) Date of birth;
(3) Employment number, social security number, Veterans Administration claim number, or civil service retirement claim number;
(4) Component of the governmental entity for which the obligor works, and the official duty station or worksite; and
(5) Status of the obligor, e.g., employee, former employee, or annuitant.
(b) If the information submitted is not sufficient to identify the obligor, the legal process shall be returned directly to the court, or other authority, with an explanation of the deficiency. However, prior to returning the legal process, if there is sufficient time, and attempt should be made to inform the party who caused the legal process to be served, or the party's representative, that it will not be honored unless adequate identifying information is supplied.

Subpart C—Compliance With Process

§ 581.301 Suspension of payment.

Upon proper service of legal process, together with all supplementary documents and information as required by §§ 581.202 and 581.203, the head of the governmental entity, or his/her designee, shall identify the obligor to whom that governmental entity holds moneys due and payable as remuneration for employment and shall suspend, i.e., withhold payment of such moneys for the amount necessary to permit compliance with the legal process.

§ 581.302 Notification of obligor.

(a) As soon as possible, but not later than fifteen (15) calendar days after the date of valid service of legal process, the

agent designated to accept legal process shall send to the obligor, at his or her duty station or last known home address, written notice:

(1) That such process has been served, including a copy of the legal process, and, if submitted, such other documents as may be required by § 581.202;

(2) Of the maximum garnishment limitations set forth in § 581.402, with a request that the obligor submit supporting affidavits or other documentation necessary for determining the applicable percentage limitation;

(3) That by submitting supporting affidavits or other necessary documentation, the obligor consents to the disclosure of such information to the garnishor; and

(4) Of the percentage that will be deducted if he/she fails to submit the documentation necessary to enable the governmental entity to respond to the legal process within the time limits set forth in § 581.303.

(b) The governmental entity may provide the obligor with the following additional information:

(1) Copies of any other documents submitted in support of the legal process;

(2) That the United States does not represent the interests of the obligor in the pending legal proceedings;

(3) That the obligor may wish to consult legal counsel regarding defenses to the legal process that he or she may wish to assert; and

(4) That obligors in the uniformed services may avail themselves of the protections provided in sections 520, 521, and 523 of the Soldiers' and Sailors' Civil Relief Act of 1940 (50 U.S. Code App. 501 *et seq.*).

§ 581.303 Response to legal process or interrogatories.

(a) Whenever the designated agent is validly served with legal process, the agent shall respond within thirty (30) calendar days, or within such longer period as may be prescribed by applicable State or local law, after the date valid service is made. The agent shall also respond within this time period to interrogatories which accompany legal process.

(b) If State or local law authorizes the issuance of interrogatories prior to or after the issuance of legal process, the agent shall respond to the interrogatories within thirty (30) calendar days after receipt: *Provided,* That the document(s) required by § 581.202(c) have been presented.

§ 581.304 Nonliability for disclosure.

(a) No Federal employee whose duties include responding to interrogatories pursuant to § 581.303(b), shall be subject to any disciplinary action or civil or criminal liability or penalty for any disclosure of information made by him/her in connection with the carrying out of any duties pertaining directly or indirectly to answering the interrogatories.

(b) However, a governmental entity would not be precluded from taking disciplinary action against an employee who consistently or purposely failed to provide correct information requested by interrogatories.

§ 581.305 Honoring legal process.

(a) The governmental entity shall comply with legal process, except where the process cannot be complied with because:

(1) It does not, on its face, conform to the laws of the jurisdiction from which it was issued;

(2) The legal process would require the withholding of funds not deemed moneys due from, or payable by, the United States as remuneration for employment;

(3) The legal process is not brought to enforce legal obligation(s) for alimony and/or child support;

(4) It does not comply with the mandatory provisions of this part;

(5) An order of a court of competent jurisdiction enjoining or suspending the operation of the legal process has been served on the governmental entity; or

(6) Where notice is received that the obligor has appealed the underlying alimony and/or child support order, payment of moneys subject to the legal process shall be suspended until the governmental entity is ordered by a court, or other authority, to resume payments. However, no suspension action shall be taken where the applicable law of the jurisdiction wherein the appeal is filed requires compliance with the legal process while an appeal is pending.

(b) Under the circumstances set forth in § 581.305(a), or where the governmental entity is directed by the Justice Department not to comply with the legal process, the entity shall respond directly to the court, or other authority, setting forth its objections to compliance with the legal process. In addition, the governmental entity shall inform the garnishor, or the garnishor's representative, that the legal process will not be honored. Thereafter, if litigation is initiated or threatened, the entity shall immediately refer the matter to the United States Attorney for the district from which the legal process issued. To ensure uniformity in the executive branch, governmental entities which have statutory authority to represent themselves in court shall coordinate their representation with the United States Attorney.

(c) In the event that a governmental entity is served with more than one legal process for the same moneys due or payable to an individual, then the moneys shall be available to satisfy such processes on a first-come, first-served basis: *Provided,* That in no event will the total amount garnished for any pay or disbursement cycle exceed the applicable limitation set forth in § 581.402.

(d) Neither the United States, any disbursing officer, nor governmental entity shall be liable for any payment made from moneys due from, or payable by, the United States to any individual pursuant to legal process regular on its face, if such payment is made in accordance with this part. However, where a governmental entity negligently fails to comply with legal process, the United States shall be liable for the amount that the governmental entity would have paid, if the legal process had been properly honored.

(e) Governmental entities affected by legal process served under this part shall not be required to vary their normal pay or disbursement cycles to comply with the legal process. However, legal process, valid at the time of service, which is received too late to be honored during the disbursement cycle in which it is received, shall be honored to the extent that the legal process may be satisfied during the next disbursement cycle within the limits set forth in § 581.402. The fact that the legal process may have expired during this period would not relieve the governmental entity of its obligation to honor legal process which was valid at the time of service. If, in the next disbursement cycle, no further payment will be due from the entity to the obligor, the entity shall follow the procedures set forth in § 581.306.

§ 581.306 Lack of moneys due from, or payable by, a governmental entity served with legal process.

(a) When legal process is served on a governmental entity, and the individual identified in the legal process as the obligor is found not to be entitled to moneys (the entitlement to which is based upon remuneration for employment) due from, or payable by, the governmental entity the entity shall follow the procedures set forth in the legal process for that contingency or, if no procedures are set forth therein, shall return the legal process to the court, or

other authority from which it was issued, and advise the court, or other authority, that no moneys, the entitlement to which is based upon remuneration for employment are due from, or payable by, the governmental entity to the named individual.

(b) Where it appears that remuneration for employment is only temporarily exhausted or otherwise unavailable, the court, or other authority, shall be fully advised as to why, and for how long, the remuneration will be unavailable, if that information is known by the governmental entity.

(c) In instances where an obligor employee separates from his/her employment with a governmental entity which is presently honoring a continuing legal process, the entity shall inform the party who caused the legal process to be served, or the party's representative, and the court, or other authority, that the payments are being discontinued. In cases where the obligor has retired, or separated and requested a refund of retirement contributions, or transferred, or is receiving benefits under the Federal Employee's Compensation Act, and where this information is known by the entity, the entity shall provide the party with the designated agent for the new disbursing governmental entity.

Subpart D—Consumer Credit Protection Act Restrictions

§ 581.401 Aggregate disposable earnings.

The "aggregate disposable earnings", when used in reference to the amounts due from, or payable by, the United States or the District of Columbia which are garnishable under the Consumer Credit Protection Act for child support and/or alimony, are the obligor's remuneration for employment less those amounts deducted in accordance with § 581.105.

§ 581.402 Maximum garnishment limitations.

Pursuant to section 1673(b)(2) (A) and (B) of title 15 of the United States Code (the Consumer Credit Protection Act, as amended), unless a lower maximum garnishment limitation is provided by applicable State or local law, the maximum part of the aggregate disposable earnings subject to garnishment to enforce any support order(s) shall not exceed:

(a) Fifty (50) percent of the obligor's aggregate disposable earnings for any workweek, where he/she asserts by affidavit, or by other acceptable evidence, that he/she is supporting a spouse and/or dependent child, other than the former spouse and/or child for whose support such order is issued, except that an additional five (5) percent will apply if it appears on the face of the legal process, or from other evidence submitted in accordance with § 581.202(d), that such earnings are to enforce a support order for a period which is twelve (12) weeks prior to that workweek. An obligor shall be considered to be supporting a spouse and/or dependent child only if the obligor provides over half of the spouse's and/or dependent child's support.

(b) Sixty (60) percent of the obligor's aggregate disposable earnings for any workweek, where he/she fails to assert by affidavit or establishes by other acceptable evidence, that he/she is supporting a spouse and/or dependent child, other than a former spouse and/or child with respect to whose support such order is issued, except that an additional five (5) percent will apply if it appears on the face of the legal process, or from other evidence submitted in accordance with § 581.202(d), that such earnings are to enforce a support order for a period which is twelve (12) weeks prior to that workweek.

(c) Where, under § 581.302(a)(2), an obligor submits evidence that he/she is supporting a second spouse and/or child, copies of the evidence shall be sent by the governmental entity to the garnishor, or the garnishor's representative, as well as to the court, or other authority, together with notification that the obligor's support claim will be honored. If the garnishor disagrees with the obligor's support claim, the garnishor should immediately refer the matter to the court, or other authority, for resolution.

Subpart E—Implementation by Governmental Entities

§ 581.501 Rules, regulations, and directives by governmental entities.

Appropriate officials of all governmental entities shall, to the extent necessary, issue implementing rules, regulations, and/or directives that are consistent with this part.

Appendix A—List of Agents Designated to Accept Legal Process

(This appendix lists the agents designated to accept legal process for the executive branch of the United States, including the United States Postal Service, the Postal Rate Commission, the District of Columbia, American Samoa, Guam, the Virgin Islands, and the Smithsonian Institution.)

I. Departments

Department of Agriculture

General Counsel, Department of Agriculture, 14th & Independence Ave., SW., Washington, D.C. 20250, (202) 447–3351.

Department of Commerce

1. For employee obligors in the Office of the Secretary, Economic Development Administration, Domestic and International Business Administration, Bureau of Economic Analysis, Office of Minority Business Enterprise, National Fire Prevention and Control Administration, United States Travel Service, Office of Regional Economic Coordination, Appalachian Regional Commission, and Regional Action Planning Commissions: Director, Finance Operations Division, Department of Commerce, Room 6830–A, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, (202) 377–2227.

2. Census Bureau: Chief, Finance Division, Bureau of the Census, Suite 111, Iverson Mall, Washington, D.C. 20233, (301) 763–5654.

3. National Oceanic and Atmospheric Administration: Chief, Finance Division, National Oceanic and Atmospheric Administration, Building AD–5, Room 300, 6010 Executive Boulevard, Rockville, MD 20852, (301) 443–8795.

4. Patent and Trademark Office: Director, Office of Finance, Patent and Trademark Office, Room 2–6D–07, Crystal Plaza, Washington, D.C. 20231, (703) 557–3761.

5. National Bureau of Standards, National Technical Information Service, and Office of Telecommunications: Chief, Financial Management Division, National Bureau of Standards, Room A–931, Administration Building, Washington, D.C. 20234, (301) 921–2507.

6. Maritime Administration: Chief, Division of Accounts, Office of Financial Management, Maritime Administration, Room 3090, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, (202) 377–4764.

7. In cases where the name of the operating unit in the Department of Commerce cannot be ascertained: Chief, Accounting Standards Division, Office of the Secretary, Room 6800, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, (202) 377–4407.

Department of Defense

Army

Commander, Army Finance and Accounting Center, Attention: FINCL–G, Indianapolis, IN 46249, (317) 542–4284.

Navy and Marine Corps

1. Navy Active-duty, Reserve, Fleet Reserve or retired Navy: Director Navy Family Allowance Activity, A. J. Celebrezze Federal Building, Room 967, Cleveland, Ohio 44199.

2. Marine Corps Active-duty, Reserve, Fleet Marine Corps Reserve, or retired, and civilian personnel, except non-appropriated fund employees: Commanding Officer, Marine Corps Finance Center (AA) Kansas City, Missouri 64197.

3. Civilian personnel of the Navy or Marine Corps, Director of Civilian Personnel Law, Office of the General Counsel, Navy Department, Washington, D.C. 23090.

4. Non-civil service civilian personnel of Navy Exchange or related non-appropriated fund instrumentalities administered by the Navy Resale System Office: Commanding Officer, Navy Resale System Office, Attention: Industrial Relations Officer, 29th Street & Third Avenue, Brooklyn, New York 11232.

5. Non-civil service civilian personnel of Navy clubs, messes, or recreation facilities (non-appropriated funds): Chief of Naval Personnel Director, Recreation Services Division (Pers/NMPC-72) Washington, D.C. 20370.

Air Force

1. Active duty, reserve, Air National Guard (ANG), retired military members and civilian employees of appropriated fund activities: Commander, Air Force Accounting and Finance Center, Attention: JA, Denver, CO 80279, (303) 370-7524.

2. Non-appropriated fund civilian employees of base exchanges: Army and Air Force Exchange Service, Attention: GC-G, Dallas, TX 75222, (214) 330-2174.

3. Civilian employees of all other Air Force nonappropriated fund activities: AFMPC/JA, Attention: NAF Law Division, Randolph AFB, TX 78548, (512) 652-6691.

With respect to other civilian employees of Department of Defense agencies, or other employing activities within the Department of Defense or the Military Departments, the Director of the agency or activity shall assist by receiving and forwarding process to the designated agent in the appropriate disbursing office.

Defense Communications Agency

General Counsel and Deputy General Counsel, Office of the General Counsel (Code 105), Defense Communications Agency, Washington, D.C. 20305 (202) 692-2009.

Defense Contract Audit Agency

Director of Personnel, Defense Contract Audit Agency, Cameron Station, Alexandria, VA 22314 (202) 274-7325.

Defense Logistics Agency

Accounting & Finance Officer (DCSC-CA), Defense Construction Supply Center, Columbus, OH 43215, (614) 236-3161.

Accounting & Finance Officer (DESC-CA), Defense Electronics Supply Center, 1507 Wilmington Pike, Dayton, OH 45444 (513) 296-6415.

Command Security Officer, Defense General Supply Center, Richmond, VA 23297 (804) 275-4751.

Accounting & Finance Officer (DPSC-ZA), Defense Personnel Support Center, 2800 South 20th Street, Philadelphia, PA 19101 (215) 952-2741.

Accounting & Finance Officer (DDMP-BD), Defense Depot Mechanicsburg, Mechanicsburg, PA 17055, (717) 790-2992.

Accounting & Finance Officer (DDMT-FD), Defense Depot Memphis, 2163 Airways Boulevard, Memphis, TN 38114 (901) 744-5541.

Accounting & Finance Officer (DDOU-RF), Defense Depot Ogden, Ogden, UT 84407, (801) 399-7358.

Accounting & Finance Officer (DDT-GD), Defense Depot Tracy, S. Chrisman Road, Tracy, CA 95376 (209) 835-9316.

Accounting & Finance Officer (DASC-F), Cameron Station, Alexandria, VA 22314 (202) 274-6108.

Accounting & Finance Officer (DCRA-FA), Defense Contract Administration Services Region, Atlanta, 805 Walker Street, Marietta, GA 30060 (404) 424-9304.

Accounting & Finance Officer (DCRB-FA), Defense Contract Administration Services Region, Boston, 666 Summer Street, Boston, MA 02210 (617) 542-8893.

Accounting & Finance Officer (DCRI-FA), Defense Contract Administration Services Region, Chicago, O'Hare International Airport, 6400 North Mannheim Road, P.O. Box 66475, Chicago, IL 60666 (312) 694-2245.

Accounting & Finance Officer (DCRO-FA), Defense Contract Administration Services Region, Cleveland, Anthony J. Celebrezze Federal Building, 1240 East Ninth Street, Cleveland, OH 44199 (216) 522-5490.

Accounting & Finance Center Officer (DCRT-FA), Defense Contract Administration Services Region, Dallas, 500 South Ervay Street, Dallas, TX 75201 (214) 670-1350.

Accounting & Finance Officer (DCRL-FA), Defense Contract Administration Services Region, Los Angeles, 11099 South La Cienega Boulevard, Los Angeles, CA 90045 (213) 643-2210.

Accounting & Finance Center (DCRN-FA), Defense Contract Administration Services Region, New York, 60 Hudson Street, New York, NY 10013 (212) 374-9408.

Accounting & Finance Officer (DCRS-FA), Defense Contract Administration Services Region, St. Louis, 1136 Washington Avenue, St. Louis, MO 63101 (314) 263-6510.

Defense Mapping Agency

1. For employee obligors in the Headquarters and Components listed below:
   Headquarters, Defense Mapping Agency, Building 56, U.S. Naval Observatory, Washington, D.C. 20315.
   Defense Mapping School, Fort Belvoir, Virginia 22060.
   DMA Inter American Geodetic Survey, Fort Sam Houston, Texas 78234.
   General Counsel, Defense Mapping Agency, Building 56, U.S. Naval Observatory, Washington, D.C. 20305 (202) 254-4431.

2. For employee obligors in the DMA Aerospace Center: Counsel, DMA Aerospace Center, St. Louis Air Force Station, St. Louis, Missouri 63118 (314) 263-4501.

3. For employee obligors in the DMA Hydrographic/Topographic Center: Counsel, DMA Hydrographic/Topographic Center, Washington, D.C. 20315 (202) 227-2268.

Defense Nuclear Agency

General Counsel, Defense Nuclear Agency, Washington, D.C. 20305 (703) 325-7681.

Department of Energy

Power Administrations

1. Alaska Power Administration: Administrator, Alaska Power Administration, Department of Energy, P.O. Box 50, Juneau, AK 99802, (907) 586-7405.

2. Bonneville Power Administration: Head, Disbursement Audit Section (SNJ), Bonneville Power Administration, Department of Energy, 1002 N.E. Holladay, Portland, OR, (503) 234-3361.

3. Southeastern Power Administration: Director, Washington Financial Services Division (CR-46), Mail Station C-212, Department of Energy, Washington, D.C. 20545, (301) 353-5316.

4. Southwestern Power Administration: Chief Counsel, Southwestern Power Administration, Department of Energy, P.O. Drawer 1619, Tulsa, OK 74101, (918) 581-7426.

5. Western Area Power Administration: General Counsel, Western Area Power Administration, Department of Energy, P.O. Box 3402, Golden, CO 80401, (303) 231-1529.

Field Offices

1. Albuquerque Operations Office and Richland Operations Office (includes Fast Flux Test Facility Project Office): Chief Counsel, Albuquerque Operations Office, Department of Energy, P.O Box 5400, Albuquerque, NM 87115, (505) 264-7265.

2. Chicago Operations Office and Oak Ridge Operations Office (includes Clinch River Breeder Reactor Project Office, and the Technical Information Center): Chief Counsel, Oak Ridge Operations Office, Department of Energy, P.O. Box E, Oak Ridge, TN 37830, (615) 693-7153.

3. Grand Junction Office, Nevada Operations Office, San Francisco Operations Office: Chief, Collection, Disbursement and Funds Branch, Nevada Operations Office, Department of Energy, P.O. Box 14100, Las Vegas, NV 89114, (702) 734-3166.

4. Idaho Operations Office: Chief, General and Fund Accounting Branch, Idaho Operations Office, Department of Energy, 550 Second Street, Idaho Falls, ID 43201, (208) 526-1598.

5. Savannah River Operations Office: Director, Finance Division, Savannah River Operations Office, Department of Energy, P.O. Box A, Aiken, SC 29801, (803) 725-2681.

6. Pittsburgh Naval Reactors Office, Schenectady Naval Reactors Office, Washington Headquarters, and all other organizations: Director, Washington Financial Services Division (CR-46), Mail Station C-212, Department of Energy, Washington, D.C. 20545, (301) 353-5316.

Department of Health and Human Services

1. For the garnishment of the remuneration of employees of the Department of Health and Human Services: Garnishment Agent, Office of General Counsel, Room 5362—North Building, 330 Independence Ave., S.W., Washington, D.C. 20201, (202) 472-3109.

2. For the garnishment of benefits under Title II of the Social Security Act, legal process may be served on the office manager at any Social Security District or Branch Office. The addresses and telephone numers of the Social Security District or Branch Offices may be found in the local telephone directory.

Department of Housing and Urban Development

Chief, Operations Branch, Personnel Systems and Payroll Division, Department of Housing and Urban Development, 451

Seventh Street, S.W., Room 2132, Washington, D.C. 20410, (202) 755–8906.

Department of the Interior

Secretarial Offices; Office of Territorial Affairs; Office of Water Research and Technology; Commission of Fine Arts; Delaware River Basin Commission; and Susquehanna River Basin Commission; Chief, Division of Fiscal Services, Department of the Interior, 18th & C Streets, NW., Room 5261, Washington, D.C. 20240, (202) 343–5207.

Bureau of Mines: Chief, Branch of Finance, Bureau of Mines, Department of the Interior, Denver Federal Center, Bldg. 20, Rm. D–2038, Denver, CO 80225, (303) 234–2354.

Fish and Wildlife Service: Chief, Division of Financial and Management Systems, Fish and Wildlife Service, Department of the Interior, 18th & C Streets, NW, Washington, D.C. 20240, (202) 343–8991.

Geological Survey: Chief, Branch of Financial Management, MS 270, Geological Survey, Department of the Interior, 12201 Sunrise Valley Drive, Reston, VA 22092, (804) 860–6181.

Heritage Conservation and Recreation Service: Chief, Division of Personnel and Management, Heritage Conservation and Recreation Service, Department of the Interior, Pension Building, 440 G Street, NW, Washington, D.C. 20243, (202) 343–4275.

National Park Service: Chief, Division of Finance, National Park Service, Department of the Interior, 1100 L Street, NW, Washington, D.C. 20005, (202) 523–5150.

Water and Power Resources Service (formerly Bureau of Reclamation): Chief, Division of Personnel and Management, Water and Power Resources Service, Department of the Interior, 18th & C Streets, NW, Washington, D.C. 20240, (202) 343–4626.

Bureau of Indian Affairs: Chief, Branch of Employee Data and Compensation, Bureau of Indian Affairs, Department of the Interior, 500 Gold Avenue, SW., Albuquerque, NM 87103, (505) 766–2936.

Office of Surface Mining Reclamation and Enforcement: Chief, Budget and Financial Management Division, Office of Surface Mining Reclamation and Enforcement, Department of the Interior, 1951 Constitution Avenue, NW, Washington, D.C. 20245, (202) 343–4926.

Bureau of Land Management: Chief, Division of Finance, Bureau of Land Management, Department of the Interior, 18th & C Streets, NW, Room 3559, Washington, D.C. 20240, (202) 343–3607.

Department of Justice

1. For all employees, except employees of the Federal Bureau of Investigation: Assistant Director, Employee Data Service, Systems Operations Staff, Justice Management Division, Department of Justice, P.O. Box 2922, Washington, D.C. 20013, (202) 633–4442.
2. For employees of the Federal Bureau of Investigation: Personnel Officer, FBI Headquarters, Department of Justice, J. Edgar Hoover Building, Room 6052, Washington, D.C. 20535, (202) 324–4981.

Department of Labor

1. Payments to employees of the Department of Labor: Director, Office of Accounting, Room N1309, Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210, (202) 523–8314.
2. Process relating to moneys due and payable by the United States under the Longshoremen's Act should be directed to the: Associate Director for Longshore and Harbor Workers' Compensation, Room C–3520, 200 Constitution Avenue, NW., Washington, D.C. 20210, (202) 523–8721.
3. Process relating to benefits payable under the Federal Employees' Compensation Act should be directed to the appropriate district office of the Office of Workers' Compensation Programs.

District No. 1

Deputy Commissioner, Office of Workers' Compensation Programs, Room 1800, John F. Kennedy Building, Government Center, Boston, MA 12203, (617) 223–6755.

Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont

District No. 2

Deputy Commissioner, Office of Workers' Compensation Programs, 1515 Broadway (at West 44th), New York, NY 10036, (212) 399–5501.

New Jersey, New York, Puerto Rico, and the Virgin Islands

District No. 3

Deputy Commissioner, Office of Workers' Compensation Programs, Gateway Building, Room 2150, 3535 Market Street, Philadelphia, PA 19104, (215) 596–1180.

Delaware, Pennsylvania, and West Virginia

District No. 6

Assistant Deputy Commissioner, Office of Workers' Compensation Programs, 400 West Bay Street, Box 35049, Jacksonville, FL 32202, (904) 791–3426.

Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee

District No. 7

Assistant Deputy Commissioner, Office of Workers' Compensation Programs, Hale Boggs Federal Building, 500 Camp Street, New Orleans, LA 70130, (504) 589–6135.

Arkansas and Louisiana

District No. 9

Assistant Deputy Commissioner, Office of Workers' Compensation Programs, 1240 East 9th Street, Room 867, Cleveland, OH 44199, (216) 522–3803.

Indiana, Michigan, and Ohio

District No. 10

Deputy Commissioner, Office of Workers' Compensation Programs, 230 S. Dearborn Street, 8th Floor, Chicago, IL 60604, (312) 353–5650.

Illinois, Minnesota, and Wisconsin

District No. 11

Deputy Commissioner, Office of Workers' Compensation Programs, 1910 Federal Office Building, 911 Walnut Street, Kansas City, MO 64106, (816) 374–2723.

District No. 12

Deputy Commissioner, Office of Workers' Compensation Programs, Drawer 3558, Federal Building, 1961 Stout Street, Denver, CO 80202, (303) 837–5402.

Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming

District No. 13

Deputy Commissioner, Office of Workers' Compensation Programs, 450 Golden Gate Avenue, Box 36022, San Francisco, CA 94102, (415) 556–6183.

Arizona, California, and Nevada

District No. 14

Deputy Commissioner, Office of Workers' Compensation Programs, 4010 Federal Office Building, 909 First Avenue, Seattle, WA 98174, (206) 442–5521.

Alaska, Idaho, Oregon, and Washington

District No. 15

Assistant Deputy Commissioner, Office of Workers' Compensation Programs, 300 Ala Moana Boulevard, Room 5108, Box 50209, Honolulu, HI 96850, (808) 546–836.

All land and water areas west of the continents of North and South America to 60 degrees east longitude (excluding Iran)

District No. 16

Deputy Commissioner, Office of Workers' Compensation Programs, 555 Griffin Square Building, Room 100, Griffin and Young Streets, Dallas, TX 75201, (214) 767–4712.

Arkansas, Louisiana, New Mexico, Oklahoma, and Texas

District No. 17

Deputy Commissioner, Office of Workers' Compensation Programs, 1371 Peachtree Street, NE, Room 331, Atlanta, GA 30309, (404) 881–7566.

Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee

District No. 25

Assistant Deputy Commissioner, Office of Workers' Compensation Programs, 666 11th Street, NW., Room 405, Washington, D.C. 20211, (202) 724–0713.

District of Columbia, Maryland, and Virginia

4. Process relating to claims arising out of the places set forth below and process seeking to attach Federal Employees' Compensation Act benefits payable to employees of the Department of Labor should be directed to the: Associate Director for Federal Employees' Compensation, Room S3229, 200 Constitution Avenue, NW., Washington, D.C. 20210, (202) 523–7552.

Canada, Mexico, Central and South America, and all land and water areas east of the continents of North and South America to 60 degrees east longitude (including Iran but excluding Puerto Rico and the Virgin Islands)

Department of State

Secretary, Attention: Executive Director, Office of the Legal Adviser (L–EX), 2201 C Street, NW., Washington, D.C. 20502, (202) 632–0460.

Agency for International Development

Chief, Employee Relations & Services Division, Office of Personnel Management, Agency for International Development, Washington, D.C. 20523 (202) 632–2954.

Department of Transportation

Office of the Secretary, General Counsel, 400 7th Street, SW., Washington, D.C. 20590, (202) 426–4702.

United States Coast Guard, Chief Counsel, 2100 2nd Street, SW., Washington, D.C. 20593, (202) 426–1616.

Federal Aviation Administration

1. Headquarters (Washington, D.C.) and overseas employees: Chief Counsel, 800 Independence Ave., S.W., Washington, D.C. 20591 (202) 426–3773.
2. Central Region: Nebraska, Kansas, Iowa, and Missouri. Regional Counsel, ACE–7, 601 E. 12th Street, Kansas City, Missouri 64106 (816) 374–5446.
3. Alaskan Region: Regional Counsel, AAL–7, 701 C Street, Box 14, Anchorage, Alaska 99513 (907) 271–5269.
4. Pacific-Asia Region: Regional Counsel, APC–7, P.O. Box 50109, Honolulu, Hawaii 46850 (808) 546–5621.
5. Eastern Region: New York, Pennsylvania, New Jersey, West Virginia, Maryland, Delaware and Virginia. Regional Counsel, AEA–7, Federal Building, JFK International Airport, Jamaica, New York 11430 (212) 995–2814.
6. Great Lakes Region: Minnesota, Wisconsin, Michigan, Illinois, Indiana and Ohio. Regional Counsel, AGL–7, 2300 East Devon, Des Plaines, Illinois 60018 (312) 694–4500, ext. 311.
7. Northeast Region: Maine, New Hampshire, Vermont, Massachusetts, Connecticut and Rhode Island. Regional Counsel, ANE–7, 12 New England Executive Park, Burlington, Massachusetts 01803 (617) 273–7384.
8. Northwest Region: Washington, Oregon and Idaho. Regional Counsel, ANW–7, FAA Building, 9010 E. Marginal Way South, King County International Airport (Boeing Field), Seattle, Washington 98108 (206) 767–2670.
9. Rocky Mountain Region: Montana, North Dakota, South Dakota, Wyoming, Utah, Colorado. Regional Counsel, ARM–7, 10455 East 25th Avenue, Aurora, Colorado 80010 (303) 837–4846.
10. Southern Region: Kentucky, North Carolina, Tennessee, Mississippi, Alabama, Georgia, South Carolina, Florida, Puerto Rico, Republic of Panama and Virgin Islands, Regional Counsel, ASO–7, P.O. Box 20636, Atlanta, Georgia 30320 (404) 763–7204.
11. Southwest Region: Arkansas, Louisiana, Oklahoma, Texas, New Mexico. Regional Counsel, ASO–7, P.O. Box 1689, Forth Worth, Texas 76101 (213) 536–6270.
12. Mike Monroney Aeronautical Center: Center Counsel, AAC–7, P.O. Box 25082, Oklahoma City, Oklahoma 73103 (405) 686–2296.
13. FAA Technical Center: Central Region, ACT–7, Atlantic City, New Jersey 08405 (604) 641–8200, ext. 3605.

Federal Highway Administration, Chief Counsel, 400 7th Street, SW., Washington, D.C. 20590, (202) 426–0740.

Federal Railroad Administration

1. For all employees, except those of the Alaska Railroad; Chief Counsel, 400 7th Street, S.W., Washington, D.C. 20590 (202) 426–0767.
2. For employees of the Alaska Railroad; Personnel Officer, Chief, Employment Section, The Alaska Railroad, RAR–14, Pouch 7–2111, Anchorage, Alaska 99510 (907) 265–2436.

National Highway Traffic Safety Administration, Chief Counsel, 400 7th Street, SW., Washington, D.C. 20590, (202) 426–9511.

Urban Mass Transportation Administration, Chief Counsel, 400 7th Street, SW., Washington, D.C. 20590, (202) 426–4063.

St. Lawrence Seaway Development Corporation, General Counsel, P.O. Box 520, Massena, New York, 13662, (315) 764–0271.

Research and Special Programs Administration, Chief Counsel, 400 7th Street, SW., Washington, D.C. 20590, (202) 755–4972.

Department of the Treasury

1. Office of the Secretary—General Counsel, Department of the Treasury, Room 3000, Main Treasury Building, 1500 Pennsylvania Avenue, NW., Washington, D.C. 20220, (202) 566–2093.
2. Office of Revenue Sharing—Chief Counsel, Fifteenth Floor, 2401 E Street, NW., Washington, D.C. 20226, (202) 634–5182.
3. Office of Foreign Assets Control—Chief Counsel, Room 401, 1331 G Street, NW., Washington, D.C. 20220, (202) 376–0236.
4. U.S. Savings Bond Division—Assistant General Counsel (ALFO), Room 1410, Main Treasury Building, 1500 Pennsylvania Avenue, NW., Washington, D.C. 20220, (202) 566–8464.
5. Bureau of Government Financial Operations—Assistant General Counsel (ALFO), Room 1410, Main Treasury Building, 1500 Pennsylvania Avenue, NW., Washington, D.C. 20220, (202) 566–8464.
6. Internal Revenue Service—Director, General Legal Services Division, Office of Chief Counsel, 1111 Constitution Avenue, N.W., Washington, D.C. 20224, (202) 566–3488.
7. Bureau of Alcohol, Tobacco & Firearms—Chief Counsel, Room 5526, Federal Building, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20226, (202) 566–7772.
8. Bureau of Public Debt—Chief Counsel, Room 309, Washington Building, Washington, D.C. 20226, (202) 376–0244.
9. Secret Service—Legal Counsel, Room 842, 1800 G Street, N.W., Washington, D.C. 20223, (202) 535–5771.
10. Bureau of Engraving & Printing—Legal Counsel, Room 109M, 14th & C Streets, N.W., Washington, D.C. 20228, (202) 447–1425.
11. Office of the Comptroller of the Currency—Director, Litigation, Office of Chief Counsel, Fifth Floor, 490 L'Enfant Plaza East, S.W., Washington, D.C. 20219, (202) 447–1893.
12. Bureau of the Mint—Legal Counsel, Room 1033, 501 13th Street, N.W., Washington, D.C. 20220, (202) 376–0565.
13. Federal Law Enforcement Training Center—Legal Counsel, Building 94, Glynco, GA 31520, (912) 267–2441.
14. Customs Service

(a) Headquarters (Washington, D.C.) and Overseas employees: Assistant Chief Counsel of Customs (Hearings and Claims), 1301 Constitution Ave., N.W., Washington, D.C. 20229, (202) 566–2482.

(b) Employees not located at headquarters or overseas, service of process may be made upon the Regional Counsel of Customs in whose region the obligor is employed, as listed below:

Region I—Regional Counsel of Customs, Suite 1739, 100 Summer Street, Boston, MA 02110, (617) 223–0075.

Region II—Regional Counsel of Customs, Room 732, 6 World Trade Center, New York, NY 10048, (212) 466–4562.

Region III—Regional Counsel of Customs, 40 S. Gay Street, Baltimore, MD 21202, (301) 962–4119.

Region IV—Regional Counsel of Customs, 99 S.E. 5th Street, Miami, FL 33131, (305) 350–4321.

Region V—Regional Counsel of Customs, Suite 2422, 1440 Canal Street, New Orleans, LA 70112, (504) 589–6981.

Region VI—Regional Counsel of Customs, Suite 1220, 500 Dallas Avenue, Houston, TX 77002, (713) 226–4887.

Region VII—Regional Counsel of Customs, 300 N. Los Angeles Street, Los Angeles, CA 90053, (213) 688–5936.

Region VIII—Regional Counsel of Customs, Suite 1000, 211 Main Street, San Francisco, CA 94105, (415) 556–3873.

Region IX—Regional Counsel of Customs, Suite 1417, 55 E. Monroe Street, Chicago, IL 60603, (312) 353–7860.

II. Agencies

(Unless otherwise indicated below, all agencies of the executive branch shall be subject to service of legal process brought for the enforcement of an individual's obligation to provide child support and/or make alimony payments where such service is sent by certified or registered mail, return receipt requested, or by personal service, upon the head of the agency.)

Central Intelligence Agency

Director of Personnel Policy, Planning, and Management, Central Intelligence Agency, Washington, D.C. 20505, or

Chief, Special Activities Staff, Office of Personnel Policy, Planning, and Management, Central Intelligence Agency, Washington, D.C. 20505, (703) 351–3452.

Civil Aeronautics Board

General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, (202) 673–5233. or Director, Office of Human Resources, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, (202) 673–6140.

Commodity Futures Trading Commission

Director of Personnel, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, D.C. 20581, (202) 254–3275.

Consumer Product Safety Commission

Office of the General Counsel, Room 509, 1111 18th Street, NW., Washington, D.C. 20207, (202) 634–7770.

Farm Credit Administration

Director or Assistant Director, Administrative Division, 490 L'Enfant Plaza East, S.W., Washington, D.C. 20578, (202) 755–4394.

Federal Election Commission

Assistant Staff Director, Administrative Division, Federal Election Commission, 1325 K Street, NW., Washington, D.C. 20463, (202) 523–4112.

Federal Home Loan Bank Board

Director, Administration Division, Office of the General Counsel, Federal Home Loan Bank Board, 1700 G Street, NW., 3rd Floor, Washington, D.C. 20552, (202) 377–6462.

Federal Labor Relations Authority

Director of Personnel Federal Labor Relations Authority, 1900 E Street, NW., Room 7469, Washington, D.C. 20424, (202) 632–6880.

Federal Maritime Commission

Director of Personnel/Deputy Director of Personnel, Federal Maritime Commission, 1100 L Street, NW., Room 11213, Washington, D.C. 20573, (202) 523–5773.

Federal Mediation and Conciliation Service

General Counsel, Federal Mediation and Conciliation Service, 2100 K Street, NW., Washington, D.C. 20427, (202) 653–5209.

General Services Administration

1. Region 1: Maine, Vermont, New Hampshire, Massachusetts, Connecticut: Regional Counsel, John W. McCormack Post Office & Courthouse, Boston, MA 02109, (617) 223–2621.
2. Region 2: New York, New Jersey, Puerto Rico, Virgin Islands: Regional Counsel, 26 Federal Plaza, New York, NY 10007, (212) 264–8306.
3. Regional 3: Pennsylvania, West Virginia, Maryland, Virginia less the greater metropolitan area of Washington, D.C.: Regional Counsel, Ninth and Market Streets, Philadelphia, PA 19107, (215) 597–1319.
4. Region 4: Kentucky, Tennessee, North Carolina, Mississippi, Alabama, Georgia, South Carolina, Florida: Regional Counsel, R.B. Russell Federal Building and U.S. Courthouse, 75 Spring Street, S.W., Atlanta, GA 30303, (404) 881–3006.
5. Region 5: Minnesota, Wisconsin, Illinois, Indiana, Michigan, Ohio: Regional Counsel, 230 South Dearborn Street, Chicago, IL 60604, (312) 353–5392.
6. Region 6: Nebraska, Iowa, Kansas, Missouri: Regional Counsel: 1500 E. Bannister Road, Kansas City, MO 64131, (816) 926–7212.
7. Region 7: New Mexico, Texas, Oklahoma, Arkansas, Louisiana: Regional Counsel, 819 Taylor Street, Fort Worth, TX 76102, (817) 334–2325.
8. Region 8: Montana, North Dakota, South Dakota, Wyoming, Utah, Colorado: Regional Counsel, Building 41—Denver Federal Center, Denver, CO 80225, (303) 234–3813.
9. Region 9: California, Nevada, Arizona, Hawaii, Guam: Regional Counsel, 525 Market Street, San Francisco, CA 94105, (415) 556–3963.
10. Region 10. Washington, Oregon, Idaho, Alaska: Regional Counsel, GSA Center, Auburn, Washington 98002, (206) 883–6500, ext. 225.
11. Greater metropolitan area of Washington, D.C. (parts of Maryland and Virginia): Regional Counsel, 7th & D Streets, NW., Washington, D.C. 20407, (202) 472–1809.

Government Printing Office

General Counsel (Stop GC), Government Printing Office, Washington, D.C. 20401, (202) 275–2758.

International Communication Agency

General Counsel, International Communication Agency, 1750 Pennsylvania Avenue, NW., Washington, D.C. 20547, (202) 724–9563.

Interstate Commerce Commission

Chief, Budget and Fiscal Office, Interstate Commerce Commission, 12th and Constitution Avenue, NW., Washington, D.C. 20423.

Merit Systems Protection Board

Director, Office of Administration, Merit Systems Protection Board, 1717 H Street, NW., Room 362, Washington, D.C. 20419, (202) 632–4956.

National Aeronautics and Space Administration

NASA Headquarters—Assistant General Counsel for Litigation, 400 Maryland Avenue, SW, Washington, D.C. 20546, (202) 755–3920.

NASA Field Installations—

Chief Counsel, Ames Research Center, Moffett Field, CA 94035, (415) 965–5103.

Chief Counsel, Dryden Flight Research Center, Edwards, CA 93520, (805) 258–8787.

Chief Counsel, Goddard Space Flight Center, Greenbelt, MD 20771, (301) 344–8887.

Chief Counsel, Johnson Space Center, Houston, TX 77058, (713) 483–3021.

Chief Counsel, Kennedy Space Center, Kennedy Space Center, FL 32899, (305) 867–2550.

Chief Counsel, Langley Research Center and Wallops Flight Center, Hampton, VA 23665, (804) 827–3397.

Chief Counsel, Lewis Research Center, Cleveland, OH 44135, (216) 433–6411.

Chief Counsel, Marshall Space Flight Center, Marshall Space Flight Center, AL 35812, (205) 453–2440.

Chief Counsel, National Space Technology Laboratories, NSTL Station, MS 39529, (601) 688–2164.

National Capital Planning Commission

Administrative Officer, National Capital Planning Commission, 1325 G Street, NW., Washington, D.C. 20576, (202) 724–0170.

National Credit Union Administration

Director, Division of Personnel, National Credit Union Administration, 1776 G Street, NW., Washington, D.C. 20456, (202) 357–1156.

National Endowment for the Humanities

General Counsel, National Endownment for the Humanities, Washington, D.C. 20506, (202) 724–0367.

National Mediation Board

Administrative Officer, National Mediation Board, Washington, D.C. 20572, (202) 523–5950.

National Railroad Adjustment Board

Staff Director/Grievances, National Railroad Adjustment Board, 202 S. State Street, Chicago, IL 60604.

National Science Foundation

General Counsel, National Science Foundation, 1800 G Street, NW., Washington, D.C. 20550, (202) 634–4286.

Nuclear Regulatory Commission

Controller, Nuclear Regulatory Commission, Washington, D.C. 20555, (301) 492–7521.

National Transportation Safety Board

Chief, Personnel and Training Division, National Transportation Safety Board, 800 Independence Ave., SW., Washington, D.C. 20594. ATTN: AD–30, (202) 472–6166.

Office of Personnel Management

1. Payments to OPM employees: General Counsel, Office of the General Counsel, Room 5H30, Office of Personnel Managment, Washington, D.C. 20415, (202) 632–5524.
2. Payments of retirement benefits under the Civil Service Retirement System: Associate Director for Compensation, Office of Personnel Management, Allotment Section, P.O. Box 17, Washington, D.C. 20044, (202) 632–5437.

Panama Canal Commission

Director, Office of Executive Administration, Panama Canal Commission, APO Miami, Florida 34011 (52–3519).

Pension Benefit Guaranty Corporation

General Counsel or Deputy General Counsel, Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, D.C. 20006, (202) 254–4864).

Railroad Retirement Board

General Counsel, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611, (312) 751–4569.

Selective Service System

General Counsel, Selective Service System, 600 E Street, NW., Washington, D.C. 20435, (202) 724–0433.

Small Business Administration

(District Directors are designated to accept legal process for their respective districts as set forth in 13 CFR 101.3–1.)

District Director, Boston District Office, 150 Causeway Street, Boston, MA 02114, (617) 223–2100.

District Director, Augusta District Office, 40 Western Avenue, Augusta, ME 04330, (207) 622–6171.

District Director, Concord District Office, 55 Pleasant Street, Concord, NH 03301, (603) 224–4041.

District Director, Hartford District Office, One Financial Plaza, Hartford CT (203) 244–3600.

District Director, Montpelier District Office, 87 State Street, Montpelier, VT 05602 (802) 229–0538.

District Director, Providence District Office, 57 Eddy Street, Providence, RI 02903 (401) 528–4580.

District Director, New York District Office, 26 Federal Plaza, New York, NY 10007 (212) 264–4355.

District Director, Hato Rey District Office, Chardon & Bolivia Streets, Hato Rey, PR 00918 (809) 753–4572.

District Director, Newark District Office, 970 Broad Street, Newark, NJ 07102 (201) 645–2434.

District Director, Syracuse District Office, 100 South Clinton Street, Syracuse, NY 13260 (315) 423–5383.

District Director, Philadelphia District Office, 231 St. Asaphs Road, Bala Cynwyd, PA 19004 (215) 597–3311.

District Director, Baltimore District Office, 8600 LaSalle Road, Towson, MD 21204 (301) 962–4392.

District Director, Clarksburg District Office, 109 North 3rd Street, Clarksburg, WV 26301 (304) 623–5631.

District Director, Pittsburgh District Office, 1000 Liberty Avenue, Pittsburgh, PA 15222 (412) 644–2780.

District Director, Richmond District Office, 400 North 8th Street, Richmond, VA 23240 (804) 782–2617.

District Director, Washington District Office, 1030 15th Street, NW., Washington, D.C. 20417 (202) 655–4000.

District Director, Atlanta District Office, 1720 Peachtree Street, NW., Atlanta, GA 30309 (404) 881–4325.

District Director, Birmingham District Office, 908 South 20th Street, Birmingham, AL 35205 (205) 254–1344.

District Director, Charlotte District Office, 230 S. Tryon Street, Charlotte, NC 28202 (704) 371–6111.

District Director, Columbia District Office, 1835 Assembly Street, Columbia, SC 29201 (803) 765–5376.

District Director, Jackson District Office, 100 West Capitol Street, Jackson, MS 39201 (601) 969–4371.

District Director, Jacksonville District Office, 400 West Bay Street, Jacksonville, FL 32202 (904) 791–3782.

District Director, Louisville District Office, 600 Federal Place, Louisville, KY 40201 (502) 582–5971.

District Director, Miami District Office, 2222 Ponce De Leon Blvd., Coral Gables, FL 33134 (305) 350–5521.

District Director, Nashville District Office, 404 James Robertson Parkway, Nashville, TN 37219 (615) 251–5881.

District Director, Chicago District Office, 219 South Dearborn Street, Chicago, IL 60604 (312) 353–4528.

District Director, Cleveland District Office, 1240 East 9th Street, Cleveland, OH 44199 (216) 522–4180.

District Director, Columbus District Office, 85 Marconi Boulevard, Columbus, OH 43215 (614) 469–6860.

District Director, Detroit District, 477 Michigan Avenue, Detroit, MI 48226 (313) 226–6075.

District Director, Indianapolis District Office, 575 N. Pennsylvania Street, Indianapolis, IN 46204 (317) 269–7272.

District Director, Madison District Office, 212 E. Washington Avenue, Madison, WI 53703 (608) 264–5261.

District Director, Minneapolis District Office, 12 South 6th Street, Minneapolis, MN 55402 (612) 725–2362.

District Director, Dallas District Office, 1100 Commerce Street, Dallas, TX 75242 (214) 767–0605.

District Director, Albuquerque District Office, 5000 Marble Avenue, NE, Albuquerque, NM 87110 (505) 766–3430.

District Director, Houston District Office, 500 Dallas Street, Houston, TX 77002 (713) 226–4341.

District Director, Little Rock District Office, 611 Gaines Street, Little Rock, AR 72201 (501) 378–5871.

District Director, Lubbock District Office, 1205 Texas Avenue, Lubbock, TX 79401 (806) 762–7466.

District Director, Lower Rio Grande Valley District Office, 222 East Van Buren Street, Harlingen, TX 78550 (512) 423–4534.

District Director, New Orleans District Office, 1001 Howard Avenue, New Orleans, LA 70113 (504) 589–6685.

District Director, Oklahoma City District Office, 200 N.W. 5th Street, Oklahoma City, OK 73102 (405) 231–4301.

District Director, San Antonio District Office, 727 East Durango Street, San Antonio, TX 78206 (512) 229–6250.

District Director, Kansas City District Office, 1150 Grande Avenue, Kansas City, MO 64106 (816) 374–3416.

District Director, Des Moines District Office, 210 Walnut Street, Des Moines, IA 50309 (515) 284–4422.

District Director, Omaha District Office, 19th & Farnum Street, Omaha, NE 68102 (404) 221–4691.

District Director, St. Louis District Office, One Mercantile Center, St. Louis, MO 63101, (314) 425–4191.

District Director, Wichita District Office, 110 East Waterman Street, Wichita, KS 67202, (316) 267–6571.

District Director, Denver District Office, 721 19th Street, Denver, CO 80202, (303) 837–2607.

District Director, Casper District Office, 100 East B Street, Casper, WY 82602, (307) 265–5266.

District Director, Fargo District Office, 657 2nd Avenue, North, Fargo, ND 58108, (701) 237–5771.

District Director, Helena District Office, 301 South Park Avenue, Helena, MT 59601, (406) 449–5381.

District Director, Salt Lake City District Office, 125 South State Street, Salt Lake City, UT 84138, (314) 425–5800.

District Director, Sioux Falls District Office, 101 South Main Avenue, Sioux Falls, ND 57102, (605) 336–2980.

District Director, San Francisco District Office, 211 Main Street, San Francisco, CA 94105, (415) 556–7490.

District Director, Honolulu District Office, 300 Ala Moana, Honolulu, HI 96850, (808) 546–8950.

District Director, Los Angeles District Office, 350 S. Figueroa Street, Los Angeles, CA 90071, (213) 688–2956.

District Director, Phoenix District Office, 3030 North Central Avenue, Phoenix, AZ 85012, (602) 261–3611.

District Director, San Diego District Office, 880 Front Street, San Diego, CA 92188, (714) 293–5440.

District Director, Seattle District Office, 915 Second Avenue, Seattle, WA 98174, (206) 442–5534.

District Director, Las Vegas District Office, 301 E. Stewart, Las Vegas, NV 89101, (702) 385–6611.

District Director, Anchorage District Office, 1016 West 6th Avenue, Anchorage, AK 99501, (907) 271–4022.

District Director, Boise District Office, 1005 Main Street, Boise, ID 83701, (208) 384–1096.

District Director, Portland District Office, 1220 S.W. Third Avenue, Portland, OR 97204, (503) 221–2682.

District Director, Spokane District Office, West 920 Riverside Avenue, Spokane, WA 99210, (509) 456–5310.

Tennessee Valley Authority

1. Payments to TVA employees: Chairman, Board of Directors, Tennessee Valley Authority, 400 Commerce Avenue, Knoxville, TN 37902, (615) 632–2101.
2. Payments of retirement benefits under the TVA Retirement System: Chairman, Board of Directors, TVA Retirement System, 400 Commerce Avenue, Knoxville, TN 37702, (615) 632–2904.

Veterans Administration

The fiscal officer at each VA facility shall be the designated agent for VA employee obligors at that facility. When a facility at which an individual is employed does not have a fiscal officer, the address and telephone number listed is for the fiscal officer servicing such a facility.

In those limited cases where a portion of VA service-connected benefits may be subject to garnishment, service of process, unless otherwise indicated below, should be made at the regional office nearest the veteran obligor's permanent residence.

Alabama

Fiscal Officer, Birmingham Medical Center, 700 South 19th Street, Birmingham, AL 35233, (205) 933–8101.

Mobile Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 215 Perry Hill Road, Montgomery, AL 36109 (205) 272–4670 ext. 204.

National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Gulfport, MS 39501 (601) 863–1972 ext. 225.
Fiscal Officer, Montgomery Regional Office, 474 South Court Street, Montgomery, AL 36104 (205) 832–7172.
Fiscal Officer, Montgomery Medical Center, 215 Perry Hill Road, Montgomery, AL 36109 (205) 272–4670 ext. 204.
Fiscal Officer, Tuscaloosa Medical Center, Tuscaloosa, AL 35401 (205) 553–3760.
Fiscal Officer, Tuskegee Medical Center, Tuskegee, AL 36083 (205) 727–0550 ext. 0622.

Alaska

Fiscal Officer, Anchorage Regional Office—Outpatient Clinic, Old Federal Bldg. & Post Office, 605 West 4th Avenue, Anchorage, AK 99501 (907) 271–4562.
Juneau VA Office—Send to: Fiscal Officer, VA Regional Office, Old Federal Bldg. & Post Office, 605 West 4th Avenue, Anchorage, AK 99501 (907) 271–4562.
Sitka National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 4435 Beacon Avenue, South, Seattle, WA 98108 (206) 762–1016 ext. 286.

Arizona

Fiscal Officer, Phoenix Regional Office, 3225 North Central Avenue, Phoenix, AZ 85102 (602) 241–2735.
Fiscal Officer, Phoenix Medical Center, Seventh St. & Indian School Rd., Phoenix, AZ 85012 (602) 277–5551.
Fiscal Officer, Prescott Medical Center, Prescott, AZ 86313 (602) 445–4860 ext. 264.
Prescott National Cemetery Area Office—Send to: Fiscal Officer, VA Center, Prescott, AZ 86313 (602) 445–4860 ext. 264.
Fiscal Officer, Tucson Medical Center, Tucson, AZ 85723 (602) 792–1450 ext. 710.

Arkansas

Fayetteville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Fayetteville, AR 72701 (501) 443–4301.
Fiscal Officer, Fayetteville Medical Center, Fayetteville, AR 72701 (501) 443–4301.
Fort Smith National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Fayetteville, AR 72701 (501) 443–4301.
Fiscal Officer, Little Rock Regional Office, 1200 W. 3d Street, Little Rock, AR 72201 (501) 378–5142.
Fiscal Officer, Little Rock Medical Center, 300 Roosevelt Road, Little Rock, AR 72206 (501) 372–8361 ext. 781.

California

Bell Supply Depot—Send to: Fiscal Officer, VA Supply Depot, P.O. Box 27, Hines, IL 60141, (312) 681–6800.
Fiscal Officer, Fresno Medical Center, 2615 East Clinton Avenue, Fresno, CA 94703, (209) 225–6100.
Fiscal Officer, Livermore Medical Center, Livermore, CA 94550, (415) 447–2560 ext. 217.
Fiscal Officer, Loma Linda Medical Center, 11201 Benton Street, Loma Linda, CA 92357, (714) 825–7084 ext. 2550/2551.
Fiscal Officer, Long Beach Medical Center, 5901 East Seventh Street, Long Beach, CA 90822, (213) 498–1313 ext. 2101.
Fiscal Officer, Los Angeles Regional Office, Federal Bldg., 11000 Wilshire Blvd., Los Angeles, CA 90024, (213) 824–7565; Jurisdiction over the following counties in California: Inyo, Kern, Los Angeles, Orange, San Bernardino, San Luis Obispo, Santa Barbara and Ventura.
Los Angeles Data Processing Center—Send to: Fiscal Officer, VA Regional Office, Federal Bldg., 11000 Wilshire Blvd., Los Angeles, CA 90024, (213) 824–7565.
Fiscal Officer, Los Angeles Medical Center, Los Angeles (Brentwood), CA 90073, (213) 478–3478.
Fiscal Officer, Los Angeles Medical Center, Los Angeles (Wadsworth), CA 90073, (213) 478–3478.
Fiscal Officer, Los Angeles Outpatient Clinic, 425 South Hill Street, Los Angeles, CA 90013, (213) 688–3870.
Los Angeles Field Office of Audit—Send to: Fiscal Officer, VA Medical Center, Los Angeles (Wadsworth), CA 90073, (213) 478–3478.
Los Angeles National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Los Angeles (Brentwood), CA 90073, (213) 478–3478.
Fiscal Officer, Martinez Medical Center, 150 Muir Rd., Martinez, CA 94553, (415) 228–6800 ext. 235.
Fiscal Officer, Palo Alto Medical Center, 3801 Miranda Avenue, Palo Alto, CA 94304, (415) 493–5000 ext. 5643.
Riverside National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Los Angeles (Wadsworth), CA 90073, (213) 478–3478.
San Bruno National Cemetery Area Officer—Send to: Fiscal Officer, VA Medical Center, 4150 Clement Street, San Bruno, CA 94121, (415) 221–4810 ext. 315/316.
Fiscal Officer, San Diego Medical Center, 3350 La Jolla Village Drive, San Diego, CA 92161 (714) 453–7500 ext. 3351.
San Diego National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 3350 La Jolla Village Drive, San Diego, CA 92161, (714) 453–7500 Ext. 3351.
San Diego Outpatient Clinic—Send to: VA Medical Center, 3350 La Jolla Village Drive, San Diego, CA 92161, (714) 453–7500 ext. 3351.
Fiscal Officer, San Diego Regional Office, 2022 Camino Del Rio North, San Diego, CA 92108, (714) 293–5703; Jurisdiction over the following counties in California: Imperial, Riverside and San Diego.
San Francisco National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 4150 Clement Street, San Francisco, CA 94121 (415) 221–4810 ext. 315/316.
Fiscal Officer, San Francisco Regional Office, 211 Main Street, San Francisco, CA 94105 (415) 556–0483; Jurisdiction over all counties in California except Inyo, Kern, Los Angeles, Orange, San Bernardino, San Luis Obispo, Santa Barbara, Ventura, Imperial, Riverside, San Diego, Alpine, Lassen, Modoc and Mono.
Fiscal Officer, San Francisco Medical Center, 4150 Clement Street, San Francisco, CA 94121 (415) 221–4810 ext. 315/316.
Fiscal Officer, Sepulveda Medical Center, 16111 Plummer Street, Sepulveda, CA 91343 (213) 891–2377.

Colorado

Fiscal Officer, Denver Regional Office, Denver Federal Center, Bldg. 20, Denver CO 80225 (303) 234–3920.
Fiscal Officer, Denver Medical Center, 1055 Clermont Street, Denver, CO 80220 (303) 399–8020.
Denver National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1055 Clermont Street, Denver, CO 80220 (303) 399–8020.
Fort Logan National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1055 Clermont Street, Denver, CO 80220 (303) 399–8020.
Fort Lyon National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Fort Lyon, CO 81038 (303) 456–1260.
Fiscal Officer, Fort Lyon Medical Center, Fort Lyon, CO 81038 (303) 456–1260.
Fiscal Officer, Grand Junction Medical Center, Grand Junction, CO 81501 (303) 242–0731.

Connecticut

Fiscal Officer, Hartford Regional Office, 450 Main Street, Hartford, CT 06103 (203) 244–3217.
Fiscal Officer, Newington Medical Center, 555 Willard Avenue, Newington, CT 06111 (203) 666–6951 ext 370.
Fiscal Officer, West Haven Medical Center, West Spring Street, West Haven, CT 06516 (203) 932–5711 ext. 271.

Delaware

Fiscal Officer, Wilmington Medical and Regional Office Center, 1601 Kirkwood Highway, Wilmington, DE 19805 (302) 994–2511.

District of Columbia

Finance Division Chief (047B2), Washington Central Office, Room C–50, 810 Vermont Avenue, NW, Washington, D.C. 20420 (202) 389–3901.
Washington Data Processing Center—Send to: Finance Division Chief (047B2), VA Central Office, Room C–50, 810 Vermont Avenue, NW, Washington, D.C. 20420 (202) 389–3901.
Washington Veterans Canteen Service Field Office—Send to: Finance Division Chief (047B2), VA Central Office, Room C–50, 810 Vermont Avenue, NW, Washington, D.C. 20420 (202) 389–3901.
Fiscal Office, Washington Regional Officer, 941 North Capitol Street, NE, Washington, D.C. 20421 (202) 275–1349; Jurisdiction over all foreign countries or overseas areas except Mexico, American Samoa, Guam, Midway, Wake, Trust Territory of the Pacific Islands, Virgin Islands and Philippines. Also, jurisdiction over Prince Georges and Montgomery Counties in Maryland; Fairfax and Arlington Counties and the cities of Alexandria, Fairfax and Falls Church in Virginia.

Fiscal Officer, Washington Medical Center, 50 Irving Street, NW, Washington, D.C. 20422 (202) 389–7593.

Florida

Fiscal Officer, Bay Pines Medical Center, National Cemetery Area Office, Bay Pines, FL 33504 (813) 391–9644 ext. 584.

Fiscal Officer, Gainesville Medical Center, Archer Road, Gainesville, FL 32602 (904) 376–1611 ext. 6685.

Jacksonville Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, Archer Road, Gainesville, FL 32602 (904) 376–1611 ext. 6685.

Jacksonville VA Office—Send to: Fiscal Officer, VA Regional Office, 144 First Avenue, South, St. Petersburg, FL 33731 (813) 893–3227.

Fiscal Officer, Lake City Medical Center, Lake City, FL 32055 (904) 752–1400.

Miami VA Office—Send to: Fiscal Officer, VA Regional Office, 144 First Avenue, South, St. Petersburg, FL 33731 (813) 893–3227.

Fiscal Officer, Miami Medical Center, 1201 Northwest 16th St., Miami, FL 33125 (305) 324–4455.

Orlando Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 1300 North 30th Street, Tampa, FL 33612 (813) 971–4500.

Riviera Beach Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 1201 Northwest 16th St., Miami, FL 33125 (305) 324–4455.

Pensacola National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Gulfport, MS 39501 (601) 863–1972 ext. 225.

St. Augustine National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Archer Road, Gainesville, FL 32602 (904) 376–1611 ext. 6685.

Fiscal Officer, St. Petersburg Regional Office, 144 First Avenue, South, St. Petersburg, FL 33731 (813) 893–3227.

Fiscal Officer, Tampa Medical Center, 13000 North 30th Street, Tampa, FL 33612 (813) 971–4500.

Georgia

Fiscal Officer, Atlanta Regional Office, 730 Peachtree Street, NE, Atlanta, GA 30308 (404) 881–3381.

Atlanta Veterans Canteen Service Field Office—Send to: Fiscal Officer, VA Medical Center, 1670 Clairmont Road, Decatur, GA 30033 (404) 321–6111.

Atlanta National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1670 Clairmont Road, Decatur, GA 30033 (404) 321–6111.

Atlanta Field Office of Audit—Send to: Fiscal Officer, VA Regional Office, 730 Peachtree Street, NE, Atlanta, GA 30308 (404) 881–3381.

Fiscal Officer, Augusta Medical Center, Augusta, GA 30904 (404) 733–4471 ext. 675–676.

Fiscal Officer, Decatur Medical Center, 1670 Clairmont Road, Decatur, GA 30033 (404) 321–6111.

Fiscal Officer, Dublin Medical Center, Dublin, GA 31021 (912) 272–1210 ext. 373.

Marietta National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1670 Clairmont Road, Decatur, GA 30033 (404) 321–6111.

Hawaii

Fiscal Officer, Honolulu Regional Office, P.O. Box 50188, Honolulu, HI 96850 (808) 546–2109; Jurisdiction over Islands of American Samoa, Guam, Wake, Midway and Trust Territory of the Pacific Islands.

Honolulu National Cemetery Area Office—Send to: Fiscal Officer, VA Regional Office, P.O. Box 50188, Honolulu, HI 96850 (808) 546–2109.

Idaho

Fiscal Officer, Boise Medical Center, Fifth and Fort Street, Boise, ID 83702 (208) 336–5100 ext. 315.

Fiscal Officer, Boise Regional Office, Federal Bldg. & U.S. Courthouse, 550 West Fort St., Box 044, Boise ID 83724 (208) 334–1009.

Illinois

Alton National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, St. Louis, MO 63125 (314) 894–4631.

AMF O'Hare Field Office of Audit—Send to: Fiscal Officer, VA Medical Center, Hines, IL 60141 (312) 343–7200 ext. 2481.

Fiscal Officer, Chicago Regional Office, 536 South Clark Street, Chicago, IL 60680 (312) 353–4025.

Fiscal Officer, Chicago Medical Center, 333 East Huron St. (Lakeside), Chicago, IL 60611 (312) 943–6600.

Fiscal Officer, Chicago Medical Center, 820 South Damen Avenue (West Side), Chicago, IL 60680 (312) 666–6500 ext. 281.

Fiscal Officer, Danville Medical Center, Danville, IL 61832 (217) 442–8000.

Danville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Danville, IL 61832 (217) 442–8000.

Fiscal Officer, Hines Medical Center, Hines, IL 60141 (312) 343–7200 ext. 2481.

Hines Marketing Center—Send to: Fiscal Officer, VA Supply Depot, P.O. Box 27, Hines, IL 60141 (312) 681–6800.

Fiscal Officer, Hines Supply Depot, P.O. Box 27, Hines, IL 60141 (312) 681–6800.

Fiscal Officer, Hines Data Processing Center, P.O. Box 66303, AMF O'Hare, Hines, IL 60666 (312) 681–6650.

Fiscal Officer, Marion Medical Center, Marion, IL 62959 (618) 997–5311.

Mound City National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Marion, IL 62959 (618) 997–5311.

Fiscal Officer, North Chicago Medical Center, North Chicago, IL 60064 (312) 689–1900.

Quincy National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Iowa City, IA 52240 (319) 338–0581 ext. 304.

Rock Island National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Iowa City, IA 52240 (319) 338–0581 ext. 304.

Springfield National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Danville, IL 61832 (217) 442–8000.

Indiana

Evansville Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, Marion, IL 62959 (618) 997–5311.

Fiscal Officer, Fort Wayne Medical Center, 1600 Randalia Drive, Fort Wayne, IN 46805 (219) 743–5431.

Fiscal Officer, Indianapolis Regional Office, 575 North Pennsylvania St., Indianapolis, IN 46204 (317) 269–7840.

Fiscal Officer, Indianapolis Medical Center, 1481 West 10th Street, Indianapolis, IN 46202 (317) 635–7401 ext. 2293.

Indianapolis National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1481 West 10th Street, Indianapolis, IN 46202 (317) 635–7401 ext. 2293.

Fiscal Officer, Marion Medical Center, Marion, IN 46952 (317) 674–3321 ext. 211.

Marion National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Marion, IN 46952 (317) 674–3321 ext. 211.

New Albany National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 800 Zorn Avenue, Louisville, KY 40202 (502) 895–3401.

Iowa

Fiscal Officer, Des Moines Regional Office, 210 Walnut Street, Des Moines, IA 50309 (515) 284–4220.

Fiscal Officer, Des Moines Medical Center, 30th & Euclid Avenue, Des Moines, IA 50310 (515) 255–2173.

Fiscal Officer, Iowa City Medical Center, Iowa City, IA 52240 (319) 338–0581 ext. 304.

Keokuk National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Iowa City, IA 52240 (319) 338–0581 ext. 304.

Fiscal Officer, Knoxville Medical Center, Knoxville, KY 50138 (515) 842–3101 ext. 241.

Kansas

Ft. Leavenworth National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Leavenworth, KS 66048 (913) 682–2000 ext. 214.

Ft. Scott National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Leavenworth, KS 66048 (913) 682–2000 ext. 214.

Leavenworth National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Leavenworth, KS 66048 (913) 682–2000 ext. 214.

Fiscal Officer, Leavenworth Medical Center, Leavenworth, KS 66048 (913) 682–2000 ext. 214.

Fiscal Officer, Topeka Medical Center, 2200 Gage Blvd., Topeka, KS 66622 (913) 272–3111 ext. 521.

Fiscal Officer, Wichita Medical Center, 5500 East Kellogg, Wichita, KS 67218 (316) 685–2221 ext. 256.

Wichita Regional Office—Send to: VA Medical Center, 5500 East Kellogg, Wichita, KS 67211 (316) 685–2221 ext. 256; Process for VA service-connected benefits should also be sent to the Wichita Medical Center, rather than to the Wichita Regional Office.

Kentucky

Danville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Lexington, KY 40507 (606) 233–4511.

Lebanon National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Lexington, KY 40507 (606) 233–4511.

Lexington National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Lexington, KY 40507 (606) 233–4511.

Fiscal Officer, Lexington Medical Center, Lexington, KY 40507 (606) 233–4511.

Fiscal Officer, Louisville Regional Office, 600 Federal Place, Louisville, KY 40202 (502) 582–6482.

Fiscal Officer, Louisville Medical Center, 800 Zorn Avenue, Louisville, KY 40202 (502) 895–3401.

Louisville National Cemetery Area Office (Zachary Taylor)—Send to: Fiscal Officer, VA Medical Center, 800 Zorn Avenue, Louisville, KY 40202 (502) 895–3401.

Louisville National Cemetery Area Office (Cave Hill)—Send to: Fiscal Officer, VA Medial Center, 800 Zorn Avenue, Louisville, KY 40202 (502) 895–3401.

Nancy National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Lexington, KY 40507 (606) 233–4511.

Nicholasville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Lexington, KY 40507 (606) 233–4511.

Perryville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Lexington, KY 40507 (606) 233–4511.

Louisiana

Fiscal Officer, Alexandria Medical Center, Alexandria, LA 71301 (318) 442–0251.

Baton Rouge National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1601 Perdido Street, New Orleans, LA 70146 (504) 568–0811.

Fiscal Officer, New Orleans Regional Office, 701 Loyola Avenue, New Orleans, LA 70113 (504) 589–6604.

Fiscal Officer, New Orleans Medical Center, 1601 Perdido St., New Orleans, LA 70146 (504) 568–0811.

Pineville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Alexandria, LA 71301 (318) 442–0251.

Fiscal Officer, Shreveport Medical Center, 510 East Stoner Avenue, Shreveport, LA 71130 (318) 221–8411 ext. 722.

Shreveport VA Office—Send to: Fiscal Officer, VA Regional Office, 701 Loyola Avenue, New Orleans, LA 70113 (504) 589–6604.

Zachary National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1601 Perdido St., New Orleans, LA 70146 (504) 568–0811.

Maine

Portland VA Office—Send to: Fiscal Officer, VA Center, Togus, ME 04330 (207) 623–8411.

Fiscal Officer, Togus Medical & Regional Office Center, Togus, ME 04330 (207) 623–8411.

Togus National Cemetery Area Office—Send to: Fiscal Officer, VA Center, Togus, ME 04330 (207) 623–8411.

Maryland

Annapolis National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 3900 Loch Raven Blvd., Baltimore, MD 21218 (301) 467–9932 ext. 5281/5282.

Fiscal Officer, Baltimore Regional Office, Federal Bldg., 31 Hopkins Plaza, Baltimore, MD 21201 (301) 962–4410; Jurisdiction does not include Prince Georges and Montgomery Counties which are included under the Washington, D.C. Regional Office.

Baltimore Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, 3900 Loch Raven Blvd., Baltimore, MD 21218 (301) 467–9932 ext. 5281/5282.

Fiscal Officer, Baltimore Medical Center, 3900 Loch Raven Blvd., Baltimore, MD 21218 (301) 467–9932 ext. 5281/5282.

Baltimore National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 3900 Loch Raven Blvd., Baltimore, MD 21218 (301) 467–9932 ext. 5281/5282.

Baltimore National Cemetery Area Office (Loudon Park)—Send to: Fiscal Officer, VA Medical Center, 3900 Loch Raven Blvd., Baltimore, MD 21218 (301) 467–9932 ext. 5281/5282.

Fiscal Officer, Fort Howard Medical Center, Fort Howard, MD 21052 (301) 447–1800 ext. 328.

Hyattsville Field Office of Audit—Send to: Finance Division Chief (047B2), VA Central Office, Room C–50, 810 Vermont Avenue, NW, Washington, D.C. 20420 (202) 389–3901.

Fiscal Officer, Perry Point Medical Center, Perry Point, MD 21902 (301) 642–2411 ext. 313.

Massachusetts

Fiscal Officer, Bedford Medical Center, 200 Springs Road, Bedford, MA 01730 (617) 275–7500.

Fiscal Officer, Boston Regional Office, John Kennedy Bldg., Government Center, Boston, MA 02203 (617) 223–3034; Jurisdiction over certain towns in Bristol and Plymouth Counties and the counties of Barnstable, Dukes and Nantucket is allocated to the Providence, Rhode Island Regional Office.

Boston Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, 150 South Huntington Avenue, Boston, MA 02130 (617) 232–9500 ext. 427/420.

Fiscal Officer, Boston Medical Center, 150 South Huntington Avenue, Boston, MA 02130 (617) 232–9500 ext. 427/420.

Bourne National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Brockton, MA 02401 (617) 583–4500 ext. 266.

Fiscal Officer, Brockton Medical Center, Brockton, MA 02401 (617) 583–4500 ext. 266.

Lowell Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 150 South Huntington Avenue, Boston, MA 02130 (617) 232–9500 ext. 427/420.

New Bedford Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, Providence, RI 02908 (401) 273–7100.

Fiscal Officer, Northampton Medical Center, Northampton, MA 01060 (413) 584–4040.

Springfield Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, Northampton, MA 01060 (413) 584–4040.

Springfield VA Office—Send to: Fiscal Officer, VA Regional Office, John Kennedy Bldg., Government Center, Boston, MA 02203 (617) 223–3034.

Fiscal Officer, West Roxbury Medical Center, 1400 Veterans of Foreign Wars Parkway, West Roxbury, MA 02132 (617) 323–7700 ext. 5650.

Worcester Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 1400 Veterans of Foreign Wars Parkway, West Roxbury, MA 02132 (617) 323–7700 ext. 5650.

Michigan

Fiscal Officer, Allen Park Medical Center, Allen Park, MI 48101 (313) 562–6000 ext. 535.

Fiscal Officer, Ann Arbor Medical Center, 2215 Fuller Road, Ann Arbor, MI 48105 (313) 769–7100 ext. 288/289.

Fiscal Officer, Battle Creek Medical Center, Battle Creek, MI 49016 (616) 965–3281 ext. 566.

Grand Rapids Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 2215 Fuller Road, Ann Arbor, MI 48105 (313) 769–7100 ext. 288/289.

Fiscal Officer, Detroit Regional Office, 477 Michigan Avenue, Detroit, MI 48226 (313) 226–4190.

Fiscal Officer, Iron Mountain Medical Center, Iron Mountain, MI 49801, (906) 774–3300 ext. 301.

Fiscal Officer, Saginaw Medical Center, 1500 Weiss Street, Saginaw, MI 48602, (517) 793–2340 ext. 270.

Minnesota

Fiscal Officer, Minneapolis Medical Center, 54th & 48th Avenue, South, Minneapolis, MN 55417, (612) 725–6767 ext. 6311.

Fiscal Officer, St. Cloud Medical Center, St. Cloud, MN 56301, (612) 252–1600 ext. 411.

Fiscal Officer, St. Paul Center (Regional Office), Federal Bldg., Ft. Snelling, St. Paul, MN 55111, (612) 725–4075; Jurisdiction over the counties of Becker, Beltrami, Clay, Clearwater, Kittson, Lake of the Woods, Mahnomen, Marshall, Norman, Otter Trail, Pennington, Polk, Red Lake, Roseau and Wilkin is allocated to the Fargo, North Dakota Center.

St. Paul National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 54th & 48th Avenue, South, Minneapolis, MN 55417, (612) 725–6767 ext. 6311.

St. Paul Data Processing Center—Send to: Fiscal Officer, VA Center, Federal Bldg., Ft. Snelling, St. Paul, MN 55111, (612) 725–4075.

St. Paul Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, 54th & 48th

Avenue, South, Minneapolis, MN 55417, (612) 725–6767 ext. 6311.

Mississippi

Biloxi National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Biloxi, MS 39531, (601) 863–1972 ext. 225.

Fiscal Officer, Biloxi Medical Center, Biloxi, MS 39531, (601) 863–1972 ext. 225.

Corinth National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1030 Jefferson Avenue, Memphis, TN 38104, (901) 523–8990.

Fiscal Officer, Gulfport Medical Center, Gulfport, MS 39601, (601) 863–1972 ext. 225.

Fiscal Officer, Jackson Medical Center, 1500 East Woodrow Wilson Drive, Jackson, MS 39216, (601) 362–4471 ext. 1471.

Jackson Regional Office—Send to: VA Medical Center, 1500 East Woodrow Wilson Drive, Jackson, MS 39216, (601) 362–4471 ext. 1471.

Process for VA service-connected benefits should also be sent to the Jackson Medical Center, rather than to the Jackson Regional Office.

Natchez National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1500 East Woodrow Wilson Drive, Jackson, MS 39216, (601) 362–4471 ext. 1471.

Missouri

Fiscal Officer, Columbia Medical Center, 800 Stadium Road, Columbia, MO 65201, (314) 443–2511.

Jefferson City National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 800 Stadium Road, Columbia, MO 65201, (314) 443–2511.

Fiscal Officer, Kansas City Medical Center, 4801 Linwood Blvd., Kansas City, MO 64128, (816) 861–4700.

Fiscal Officer, Poplar Bluff Medical Center, Poplar Bluff, MO 63901, (314) 686–4151.

St. Louis National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, St. Louis, MO 63125 (314) 894–4631.

Fiscal Officer, St. Louis Regional Office, 1520 Market Street, St. Louis, MO 63103 (314) 435–5112.

St. Louis Veterans Canteen Service Field Office—Send to: Fiscal Officer, VA Medical Center, St. Louis, MO 63125 (314) 894–4631.

Fiscal Officer, St. Louis Medical Center, St. Louis, MO 63125 (314) 894–4631.

St. Louis Records Processing Center—Send to: Fiscal Officer, VA Regional Office, 1520 Market Street, St. Louis, MO 63103 (314) 425–5112.

Springfield National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Fayetteville, AR 72701 (501) 443–4301.

Montana

Fiscal Officer, Fort Harrison Medical & Regional Office Center, Fort Harrison, MT 59636 (406) 442–6410 ext. 329/326.

Fiscal Officer, Miles City Medical Center, Miles City, MT 59301 (406) 232–3060.

Nebraska

Fiscal Officer, Grand Island Medical Center, Grand Island, NE 68801 (308) 382–3660 ext 244.

Fiscal Officer, Lincoln Regional Office, 100 Centennial Mall North, Lincoln, NE 68508 (402) 471–5041.

Fiscal Officer, Lincoln Medical Center, 600 South 70th Street, Lincoln, NE 68510 (402) 489–3802 ext. 332.

Maxwell National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Grand Island, NE 68801 (308) 382–3660 ext. 244.

Fiscal Officer, Omaha Medical Center, 4101 Woolworth Avenue, Omaha, NE 68105 (402) 346–8800.

Nevada

Las Vegas Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, 1000 Locust Street, Reno, NV 89520 (702) 786–7200 ext. 244.

Fiscal Officer, Reno Regional Office, 1201 Terminal Way, Reno, NV 89520 (702) 784–5637; Jurisdiction over the following counties in California: Alpine, Lassen, Modoc and Mono.

Fiscal Officer, Reno Medical Center, 1000 Locust Street, Reno, Nevada 89520 (702) 786–7200 ext. 244.

Henderson Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, 1000 Locust Street, Reno, NV 89520 (702) 786–7200 ext. 244.

New Hampshire

Fiscal Officer, Manchester Regional Office, 275 Chestnut Street, Manchester, NH 03103 (603) 666–7638.

Fiscal Officer, Manchester Medical Center, 718 Smyth Road, Manchester, NH 03104 (603) 624–4366.

New Jersey

Beverly National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, University & Woodland Avenues, Philadelphia, PA 19104 (215) 382–2400 ext. 291/292.

Fiscal Officer, East Orange Medical Center, Tremont Avenue & So. Center St., East Orange, NJ 07019 (201) 676–1000 ext. 525.

Fiscal Officer, Lyons Medical Center, Lyons, NJ 07939 (201) 647–0180 ext. 372.

Newark Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, Tremont Avenue & So. Center St., East Orange, NJ 07019 (201) 676–1000 ext. 525.

Fiscal Officer, Newark Regional Office, 20 Washington Place, Newark, NJ 07102 (201) 645–3508.

Salem National Cemetery Area Office—Send to: Fiscal Officer, VA Center, 1601 Kirkwood Highway, Wilmington, DE 19805 (302) 994–2511.

Fiscal Officer, Somerville Supply Depot, Somerville, NJ 08876 (201) 725–2540.

New Mexico

Fiscal Officer, Albuquerque Regional Office, 500 Gold Avenue, SW, Albuquerque, NM 87102 (505) 766–2204.

Fiscal Officer, Albuquerque Medical Center, 2100 Ridgecrest Drive, SE, Albuquerque, NM 87108 (505) 265–1711.

Ft. Bayard National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 2100 Ridgecrest Drive, SE, Albuquerque, NM 87108 (505) 265–1711.

Santa Fe National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 2100 Ridgecrest Drive, SE, Albuquerque, NM 87108 (505) 265–1711.

New York

Fiscal Officer, Albany Medical Center, Albany, NY 12208 (518) 462–3311 ext. 355.

Albany VA Office—Send to: Fiscal Officer, VA Regional Office, 252 Seventh Avenue, New York, NY 10001 (212) 620–6293.

Fiscal Officer, Batavia Medical Center, Batavia, NY 14020 (716) 343–7500 ext. 215.

Fiscal Officer, Bath Medical Center, Bath, NY 14810 (607) 776–2111.

Bath National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Bath, NY 14810 (607) 776–2111.

Fiscal Officer, Bronx Medical Center, 130 West Kingsbridge Road, Bronx, NY 10468 (212) 584–9000.

Fiscal Officer, Brooklyn Medical Center, 800 Poly Place, Brooklyn, NY 11209 (212) 836–6600.

Brooklyn National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 800 Poly Place, Brooklyn, NY 11209 (212) 836–6600.

Brooklyn Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, 800 Poly Place, Brooklyn, NY 11209 (212) 836–6600.

Fiscal Officer, Buffalo Regional Office, 111 West Huron Street, Buffalo, NY 14202 (716) 846–5251; Jurisdiction over all counties in New York not listed under the New York Regional Office.

Fiscal Officer, Buffalo Medical Center, 3495 Bailey Avenue, Buffalo, NY 14215 (716) 834–9200.

Calverton National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Northport, NY 11768 (516) 261–4400 ext. 2462/2463.

Fiscal Officer, Canandaigua Medical Center, Canandaigua, NY 14424 (716) 394–2000 ext. 336.

Fiscal Officer, Castle Point Medical Center, Castle Point, NY 12511 (914) 831–2000 ext. 322.

Elmira National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Bath, NY 14810 (607) 776–2111.

Farmingdale National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Northport, NY 11768 (516) 261–4400 ext. 2462/2463.

Fiscal Officer, Montrose Medical Center, Montrose, NY 10548 (914) 737–4400 ext. 463.

Fiscal Officer, New York Regional Office, 252 Seventh Avenue at 24th Street, New York, NY 10001 (212) 620–6293; Jurisdiction over the following counties in New York: Albany, Bronx, Clinton, Columbia, Delaware, Dutchess, Essex, Franklin, Fulton, Greene, Hamilton, Kings, Montgomery, Nassau, New York, Orange, Otsego, Putnam, Queens, Rensselaer, Richmond, Rockland, Saratoga, Schenectady, Schoharie, Suffolk, Sullivan, Ulster, Warren, Washington and Westchester.

New York Prosthetics Center—Send to: Fiscal Officer, VA Regional Office, 252 Seventh Avenue, New York, NY 10001 (212) 620–6293.

New York Veterans Canteen Service Field Office—Send to: Fiscal Officer, VA Medical Center, First Avenue at East 24th Street, New York, NY 10010 (212) 686–7500.

Fiscal Officer, New York Medical Center, First Avenue at East 24th Street, New York, NY 10010 (212) 686–7500.

New York Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, First Avenue at East 24th Street, New York, NY 10010 (212) 686–7500.

Fiscal Officer, Northport Medical Center, Northport, NY 11768 (516) 261–4400 ext. 2462/2463.

Rochester VA Office—Send to: Fiscal Officer, VA Regional Office, 111 West Huron Street, Buffalo, NY 14202 (716) 846–5251.

Rochester Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, Batavia, NY 14020 (716) 343–7500 ext. 215.

Fiscal Officer, Syracuse Medical Center, Irving Avenue & University Place, Syracuse, NY 13210 (315) 476–7461.

Syracuse VA Office—Send to: Fiscal Officer, VA Regional Office, 111 West Huron Street, Buffalo, NY 14202 (716) 846–5251.

North Carolina

Fiscal Officer, Asheville Medical Center, Asheville, NC 28805, (704) 298–7911 ext. 374.

Fiscal Officer, Durham Medical Center, 508 Fulton Street, Durham, NC 27705, (919) 286–0411 ext. 6469.

Fiscal Officer, Fayetteville Medical Center, 2300 Ramsey Street, Fayetteville, NC 28301, (919) 488–2120.

New Bern National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 2300 Ramsey Street, Fayetteville, NC 28301, (919) 488–2120.

Raleigh National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 508 Fulton Street, Durham, NC 27705, (919) 286–0411 ext. 6469.

Fiscal Officer, Salisbury Medical Center, Salisbury, NC 28144, (704) 636–2351.

Salisbury National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Salisbury, NC 28144, (704) 636–2351.

Wilmington National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 2300 Ramsey Street, Wilmington, NC 28301, (919) 488–2120.

Fiscal Officer, Winston-Salem Regional Office, 251 North Main Street, Winston-Salem, NC 27102, (919) 761–3513.

Winston-Salem Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, Salisbury, NC 28144, (704) 636–2351.

North Dakota

Fiscal Officer, Fargo Medical and Regional Office Center, 21st & Elm, Fargo, ND 58102, (701) 232–3241 ext. 249; See the listing under the St. Paul, Minnesota Center for the names of the counties in Minnesota which come under the jurisdiction of the Fargo, North Dakota Center.

Ohio

Fiscal Officer, Chillicothe Medical Center, 17273 State Route 104, Chillicothe, OH 45601, (614) 773–1141 ext. 203.

Fiscal Officer, Cincinnati Medical Center, 3200 Vine Street, Cincinnati, OH 45220, (513) 559–5040 ext. 4113.

Cincinnati VA Office—Send to: Fiscal Officer, VA Regional Office, 1240 East Ninth Street, Cleveland, OH 44199, (216) 522–3540.

Fiscal Officer, Cleveland Regional Office, 1240 East Ninth Street, Cleveland, OH 44199, (216) 522–3540.

Fiscal Officer, Cleveland Medical Center, 10701 East Boulevard, Cleveland, OH 44106, (216) 526–3030 ext. 531.

Fiscal Officer, Columbus Outpatient Clinic, 456 Clinic Drive, Columbus, OH 43210, (614) 469–6712.

Columbus VA Office—Send to: Fiscal Officer, VA Regional Office, 1240 East Ninth Street, Cleveland, OH 44199, (216) 522–3540.

Fiscal Officer, Dayton Medical Center, Dayton, OH 45428, (513) 268–6511 ext. 356.

Dayton National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Dayton, OH 45428, (513) 268–6511 ext. 356.

Oklahoma

Fort Gibson National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Memorial Station, Honor Heights Drive, Muskogee, OK 74401 (918) 683–3261 ext. 392.

Fiscal Officer, Muskogee Regional Office, 125 South Main Street, Muskogee, OK 74401 (918) 687–2520.

Fiscal Officer, Muskogee Medical Center, Memorial Station, Honor Heights Drive, Muskogee, OK 74401 (918) 683–3261 ext. 392.

Fiscal Officer, Oklahoma City Medical Center, 921 Northeast 13th Street, Oklahoma City, OK 73104 (405) 272–9876 ext. 500.

Oklahoma City VA Office—Send to: Fiscal Officer, VA Regional Office, 125 South Main Street, Muskogee, OK 74401 (918) 687–2520.

Oregon

Portland National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 3710 SW U.S. Veterans Hospital Road, Portland, OR 97201 (503) 222–9221 ext. 377.

Fiscal Officer, Portland Regional Office, 1220 SW 3rd Avenue, Portland, OR 97204 (503) 221–3040.

Fiscal Officer, Portland Medical Center, 3710 SW U.S. Veterans Hospital Road, Portland, OR 97201 (503) 222–9221 ext. 377.

Portland Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, 3710 SW U.S. Veterans Hospital Road, Portland, OR 97201 (503) 222–9221 ext. 377.

Fiscal Officer, Roseburg Medical Center, Roseburg, OR 97470 (503) 672–4411.

Roseburg National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Roseburg, OR 97470 (503) 672–4411.

Fiscal Officer, White City Domiciliary, White City, OR 97501 (503) 826–2111 ext. 241.

White City National Cemetery Area Office—Send to: Fiscal Officer, VA Domiciliary, White City, OR 97501 (503) 826–2111 ext. 241.

Pennsylvania

Fiscal Officer, Altoona Medical Center, Altoona, PA 16603 (814) 943–8164.

Annville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Lebanon, PA 17042 (717) 272–6621 ext. 229.

Fiscal Officer, Butler Medical Center, Butler, PA 16001 (412) 287–4781.

Fiscal Officer, Coatesville Medical Center, Coatesville, PA 19320 (215) 384–7711 ext. 342.

Fiscal Officer, Erie Medical Center, 135 East 38th Street, Erie, PA 16501 (814) 868–8661.

Harrisburg Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, Lebanon, PA 17042 (717) 272–6621 ext. 229.

Fiscal Officer, Lebanon Medical Center, Lebanon, PA 17042 (717) 272–6621 ext. 229.

Fiscal Officer, Philadelphia Center (Regional Office), P.O. Box 8079, Philadelphia, PA 19101 (215) 951–5321; Jurisdiction over the following counties in Pennsylvania: Adams, Berks, Bradford, Bucks, Cameron, Carbon, Centre, Chester, Clinton, Columbia, Cumberland, Dauphin, Delaware, Franklin, Juniata, Lackawanna, Lancaster, Lebanon, Lehigh, Luzerne, Lycoming, Mifflin, Monroe, Montgomery, Montour, Northampton, Northumberland, Perry, Philadelphia, Pike, Potter, Schuylkill, Snyder, Sullivan, Susqehanna, Tioga, Union, Wayne, Wyoming, and York.

Philadelphia Data Processing Center—Send to: Fiscal Officer, VA Center, P.O. Box 8079, Philadelphia, PA 19101 (215) 951–5321.

Philadelphia National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, University & Woodland Avenues, Philadelphia, PA 19104 (215) 382–2400 ext. 291/292.

Philadelphia Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, University & Woodland Avenues, Philadelphia, PA 19104 (215) 382–2400 ext. 291/292.

Fiscal Officer, Philadelphia Medical Center, University & Woodland Avenues, Philadelphia, PA 19104 (215) 382–2400 ext. 291/292.

Fiscal Officer, Pittsburgh Regional Office, 1000 Liberty Avenue, Pittsburgh, PA 15222 (412) 644–6640; Jurisdiction over all of the countries in Pennsylvania that are not listed under the Philadelphia Center (Regional Office) and jurisdiction over the following counties in West Virginia: Brooke, Hancock, Marshall and Ohio.

Fiscal Officer, Pittsburgh Medical Center, Highland Drive, Pittsburgh, PA 15206 (412) 363–4900 ext. 235.

Fiscal Officer, Pittsburgh Medical Center, University Drive C, Pittsburgh, PA 15240 (412) 683–3000 ext. 652/675.

Pittsburgh Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, University

Drive C, Pittsburgh, PA 15240 (412) 683–3000 ext. 652/675.
Fiscal Officer, Wilkes-Barre Medical Center, 1111 East End Blvd., Wilkes-Barre, PA 18711 (717) 824–3521 ext. 247.

Philippines

1. Manila Regional Office—Outpatient Clinic.
2. Manila Medical and Regional Office Center.

For either of the above, send to: Director, U.S. Veterans Administration, APO, San Francisco 96528, 59–80–11 Local 2574.

Puerto Rico

Bayamon National Cemetery Area Office—Send to: Fiscal Officer, VA Center, GPO, Box 4867, San Juan, PR 00936 (809) 763–0275.
Hato Rey Medical and Regional Office Center—Send to: Fiscal Officer, VA Center, GPO, Box 4867, San Juan, PR 00936 (809) 763–0275.
Mayaguez Outpatient Clinic Substation—Send to: Fiscal Officer, VA Center, GPO, Box 4867, San Juan, PR 00936 (809) 763–0275.
Ponce Outpatient Clinic Substation—Send to: Fiscal Officer, VA Center, GPO, Box 4867, San Juan, PR 00936 (809) 763–0275.
Rio Piedras Medical and Regional Office Center—Send to: Fiscal Officer, VA Center, GPO, Box 4867, San Juan, PR 00936 (809) 763–0275.

Rhode Island

Fiscal Officer, Providence Regional Office, 321 South Main Street, Providence, RI 02903 (401) 528–4480; Jurisdiction over the following towns and counties in Massachusetts: All towns in Bristol County except Mansfield and Easton, the towns of Lakeville, Middleboro, Carver, Rochester, Mattapoisett, Marion, and Wareham in Plymouth County; and the counties of Dukes, Nantucket and Barnstable.
Fiscal Officer, Providence Medical Center, Davis Park, Providence, RI 02908 (401) 273–7100.

South Carolina

Beaufort National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 109 Bee Street, Charleston, SC 29403 (803) 577–5011 ext. 222.
Fiscal Officer, Charleston Medical Center, 109 Bee Street, Charleston, SC 29403 (803) 577–5011 ext. 222.
Fiscal Officer, Columbia Regional Office, 1801 Assembly Street, Columbia, SC 29201 (803) 765–5210.
Fiscal Officer, Columbia Medical Center, Columbia, SC 29201 (803) 776–4000 ext. 149.
Florence National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Columbia, SC 29201 (803) 776–4000 ext. 149.
Greenville Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, Columbia SC 29201 (803) 776–4000 ext. 149.

South Dakota

Fort Meade National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Fort Meade, SD 57741 (605) 347–2511 ext. 272.
Fort Meade Medical Center—Send to: Fiscal Officer, VA Medical Center, Fort Meade, SD 57741 (605) 347–2511 ext. 272.
Hot Springs National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Hot Springs, SD 57747 (605) 745–4101 ext. 246.
Fiscal Officer, Hot Springs Medical Center, Hot Springs, SD 57747 (605) 745–4101 ext. 246.
Fiscal Officer, Sioux Falls Medical Center, 2501 West 22nd St., Sioux Falls, SD 57101 (605) 336–3230 ext. 201.
Sioux Falls Regional Office—Send to: VA Medical Center, 2501 West 22nd St., Sioux Falls, SD 57101 (605) 336–3230 ext. 201; Process for VA service-connected benefits should also be sent to the Sioux Falls Medical Center, rather than to the Sioux Falls Regional Office.
Sturgis National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Fort Meade, SD 57741 (605) 347–2511 ext. 272.

Tennessee

Chattanooga Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 1310 24th Avenue, South, Nashville, TN 37203 (615) 327–4651 ext. 553.
Chattanooga National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Murfreesboro, TN 37130 (615) 893–1360 ext. 346.
Knoxville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Mountain Home, TN 37684 (615) 926–1171.
Knoxville Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 1310 24th Avenue, South, Knoxville, TN 37203 (615) 327–4651 ext. 553.
Madison National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1320 24th Avenue, South, Nashville, TN 37203 (615) 327–4751 ext. 553.
Fiscal Officer, Memphis Medical Center, 1030 Jefferson Avenue, Memphis, TN 38104 (901) 523–8990.
Memphis National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1030 Jefferson Avenue, Memphis, TN 38104 (901) 523–8990.
Fiscal Officer, Mountain Home Medical Center, Mountain Home, TN 37684 (615) 926–1171.
Mountain Home National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Mountain Home, TN 37684 (615) 926–1171.
Fiscal Officer, Murfreesboro Medical Center, Murfreesboro, TN 37130 (615) 893–1360 ext. 346.
Fiscal Officer, Nashville Regional Office, 110 Ninth Avenue, South, Nashville, TN 37203 (615) 251–5352.
Fiscal Officer, Medical Center, 1310 24th Avenue, South, Nashville, TN 37203 (615) 327–4751 ext. 553.

Texas

Fiscal Officer, Amarillo Medical Center, 6010 Amarillo Blvd., W., Amarillo, TX 79106 (806) 355–9703 ext. 216.
Fiscal Officer, Austin Data Processing Center, 1615 East Woodward Street, Austin, TX 78772 (512) 397–7366.
Beaumont Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 2002 Holcombe Blvd., Houston, TX 77211 (713) 795–4411.
Fiscal Officer, Big Spring Medical Center, Big Spring, TX 79720 (915) 263–7361 ext. 327.
Fiscal Officer, Bonham Medical Center, Bonham, TX 75418 (214) 583–2111.
Corpus Christi Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 7400 Merton Minter Blvd., San Antonio, TX 78284 (512) 696–9660 ext. 6301.
Fiscal Officer, Dallas Medical Center, 4500 South Lancaster Rd., Dallas, TX 75216 (214) 376–5451.
Dallas VA Office—Send to: Fiscal Officer, VA Regional Office, 1400 North Valley Mills Drive, Waco, TX 76710 (817) 756–6511 ext. 635.
Fiscal Officer, El Paso Outpatient Clinic, 5919 Brook Hollow Drive, El Paso, TX 79925 (915) 543–7960/7961.
Fort Bliss National Cemetery Area Office—Send to: Fiscal Officer, VA Outpatient Clinic, 5919 Brook Hollow Drive, El Paso, TX 79925 (915) 543–7960/7961.
Fiscal Officer, Houston Regional Office, 2515 Murworth Drive, Houston, TX 77054 (713) 226–4185; Jurisdiction over the country of Mexico and the following counties in Texas: Angelina, Aransas, Atascosa, Austin, Bandera, Bee, Bexar, Blanco, Brazoria, Brewster, Brooks, Caldwell, Calhoun, Cameron, Chambers, Colorado, Comal, Crockett, DeWitt, Dimmitt, Duval, Edwards, Fort Bend, Frio, Galveston, Gillespie, Goliad, Gonzales, Grimes, Guadalupe, Hardin, Harris, Hays, Hidalgo, Houston, Jackson, Jasper, Jefferson, Jim Hogg, Jim Wells, Karnes, Kendall, Kenedy, Kerr, Kimble, Kinney, Kleberg, LaSalle, Lavaca, Liberty, Live Oak, McCulloch, McMullen, Mason, Matagorda, Marverick, Medina, Menard, Montgomery, Necogdoches, Newton, Nueces, Orange, Pecos, Polk, Real, Refugio, Sabine, San Augustine, San Jacinto, San Patricio, Schleicher, Shelby, Starr, Sutton, Terrell, Trinity, Tyler, Ulvalde, Val Verde, Victoria, Walker, Waller, Washington, Webb, Wharton, Willacy, Wilson, Zapata and Zavala.
Fiscal Officer, Houston Medical Center, 2002 Holcombe Blvd., Houston, TX 77211 (713) 795–4411.
Houston National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 2002 Holcombe Blvd., Houston, TX 77211 (713) 795–4411.
Fiscal Officer, Kerrville Medical Center, Kerrville, TX 78028 (512) 896–2020 ext. 215.
Kerrville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Kerrville, TX 78028 (512) 896–2020 ext. 215.
Lubbock VA Office—Send to: Fiscal Officer, VA Regional Office, 1400 North Valley

Mills Drive, Waco, TX 76710 (817) 756–6511 ext. 635.
Fiscal Officer, Lubbock Outpatient Clinic, 1205 Texas Avenue, Lubbock, Tx 79401 (806) 762–7209.
Fiscal Officer, Marlin Medical Center, Marlin, TX 76661 (817) 883–3511 ext. 224.
McAllen Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, 7400 Merton Minter Blvd., San Antonio, TX 78284 (512) 696–9660 ext. 6301.
Fiscal Officer, San Antonio Medical Center, 7400 Merton Minter Blvd., San Antonio, TX 78284 (512) 696–9660 ext. 6301.
San Antonio VA Office—Send to: Fiscal Officer, VA Regional Office, 2515 Murworth Drive, Houston, TX 77054 (713) 226–4185.
San Antonio National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 7400 Merton Minter Blvd., San Antonio, TX 78284 (512) 696–9660 ext. 6301.
San Antonio National Cemetery Area Office (Fort Sam Houston)—Send to: Fiscal Officer, VA Medical Center, 7400 Merton Minter Blvd., San Antonio, TX 78284 (512) 696–9660 ext. 6301.
Fiscal Officer, Temple Medical Center, Temple, TX 76501 (817) 778–4811.
Fiscal Officer, Waco Regional Office, 1400 North Valley Mills Drive, Waco, TX 76710 (817) 756–6511 ext. 635; Jurisdiction over all counties in Texas not listed under the Houston Regional Office.
Fiscal Officer, Waco Medical Center, Memorial Drive, Waco, TX 76703, (817) 752–6581.
Waco Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, Memorial Drive, Waco, TX 76703, (817) 752–6581.

Utah

Fiscal Officer, Salt Lake City Regional Office, 125 South State Street, Salt Lake City, Utah 84138, (801) 525–5945.
Fiscal Officer, Salt Lake City Medical Center, 500 Foothill Blvd., Salt Lake City, Utah 84148, (801) 582–1565/1520.

Vermont

Fiscal Officer, White River Junction Medical and Regional Office Center, White River Junction, Vermont 05001, (802) 295–9363.

Virginia

Alexandria National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 50 Irving Street, NW, Washington, D.C. 20422, (202) 389–7593.
Culpepper National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Martinsburg, WV 25401, (304) 263–0811 ext. 280.
Danville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Salem, VA 24153, (703) 982–2463.
Hopewell National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1201 Broad Rock Road, Richmond, VA 23249, (804) 231–9011 ext. 205.
Leesburg National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 50 Irving Street, NW, Washington, D.C. 20422, (202) 389–7593.
Mechanicsville National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1201 Broad Rock Road, Richmond, VA 23249, (804) 231–9011 ext. 205.
Fiscal Officer, Hampton Medical Center, Hampton, VA 23667, (804) 722–9961.
Hampton National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Hampton, VA 23667, (804) 722–9961.
Quantico National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 50 Irving Street, NW, Washington, D.C. 20422, (202) 389–7593.
Fiscal Officer, Richmond Medical Center, 1201 Broad Rock Road, Richmond, VA 23249, (804) 231–9011 ext. 205.
Richmond National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1201 Broad Rock Road, Richmond, VA 23249, (804) 231–9011 ext. 205.
Fiscal Officer, Roanoke Regional Office, 210 Franklin Rd. SW, Roanoke, VA 24011, (703) 982–6116; Jurisdiction over Fairfax and Arlington Counties and the cities of Alexandria, Fairfax, and Falls Church is allocated to the Washington, D.C. Regional Office.
Fiscal Officer, Salem Medical Center, Salem, VA 24153 (703) 982–2463.
Sandston National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 1201 Broad Rock Road, Richmond, VA 23249 (804) 231–9011 ext. 205.
Staunton National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Salem, VA 24135 (703) 982–2463.
Winchester National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Martinsburg, WV 25401 (304) 263–0811 ext. 280.

Washington

Fiscal Officer, American Lake Medical Center, Tacoma, WA 98493 (206) 582–8440 ext. 303.
Fiscal Officer, Seattle Regional Office, 915 Second Avenue, Seattle, WA 98174 (206) 442–5025.
Fiscal Officer, Seattle Medical Center, 4435 Beacon Avenue, South, Seattle, WA 98108 (206) 762–1016 ext. 286.
Seattle Outpatient Clinic—Send to: Fiscal Officer, VA Medical Center, 4435 Beacon Avenue, South, Seattle, WA 98108 (206) 762–1016 ext. 286.
Fiscal Officer, Spokane Medical Center, North 4815 Assembly Street, Spokane, WA 99208 (509) 328–4521.
Fiscal Officer, Vancouver Medical Center, Vancouver, WA 98661 (206) 696–4061 ext. 331.
Fiscal Officer, Walla Walla Medical Center, 77 Wainwright Drive, Walla Walla, WA 99362 (509) 525–5200.

West Virginia

Fiscal Officer, Beckley Medical Center, 200 Veterans Avenue, Beckley, WV 25801 (304) 255–2121.
Fiscal Officer, Clarksburg Medical Center, Clarksburg, WV 26301 (304) 623–3461 ext. 335.
Grafton National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, Clarksburg, WV 26301 (304) 623–3461 ext. 335.
Fiscal Officer, Huntington Regional Office, 502 Eighth Street, Huntington, WV 25701 (304) 529–5477; Jurisdiction over the counties of Brooke, Hancock, Marshall and Ohio is allocated to the Pittsburgh, Pennsylvania Regional Office.
Fiscal Officer, Huntington Medical Center, 1540 Spring Valley Drive, Huntington, WV 25704 (304) 429–6741 ext. 327.
Fiscal Officer, Martinsburg Medical Center, Martinsburg, WV 25401 (304) 263–0811 ext. 280.
Wheeling Outpatient Clinic Substation—Send to: Fiscal Officer, VA Medical Center, University Drive C, Pittsburgh, PA 15240 (412) 363–4900 ext. 235.

Wisconsin

Fiscal Officer, Madison Medical Center, 2500 Overlook Terrace, Madison, WI 53705 (608) 256–1901 ext. 381.
Fiscal Officer, Milwaukee Regional Office, 342 North Water Street, Milwaukee, WI 53202 (414) 291–1201.
Fiscal Officer, Tomah Medical Center, Tomah, WI 54660 (608) 372–3971 ext. 204.
Fiscal Officer, Wood Medical Center, 5000 West National Avenue, Wood, WI 53193 (414) 384–2000 ext. 2591.
Wood National Cemetery Area Office—Send to: Fiscal Officer, VA Medical Center, 5000 West National Avenue, Wood, WI 53193 (414) 384–2000 ext. 2591.

Wyoming

Fiscal Officer, Cheyenne Medical & Regional Office Center, 2360 East Pershing Blvd., Cheyenne, WY 82001 (307) 778–7550 ext. 351.
Fiscal Officer, Sheridan Medical Center, Sheridan, WY 82801 (307) 672–3473.

III. The United States Postal Service and the Postal Rate Commission

United States Postal Service

Service of process may be made on the postmaster or head of the installation where the employee works. However, if the installation where the employee works cannot be determined, service of process may be made on the appropriate Regional Counsel. The geographic areas served by the Regional Counsels and their addresses are as follows:

Regional Counsel, Northeast Region, U.S. Postal Service, 1633 Broadway, New York, NY 10098 (212) 974–8531; Serving: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, northern New Jersey (ZIP codes beginning with 070–079 and 088–089), New York (ZIP codes beginning with 090–098 and 100–129), and the Caribbean Islands.
Regional Counsel, Eastern Region, U.S. Postal Service, 1845 Walnut Street, P.O. Box 8601, Philadelphia, PA 19101 (215) 597–9715; Serving: The District of Columbia, Delaware, Maryland, Pennsylvania, Virginia, West Virginia, southern New Jersey (ZIP codes beginning with 080–087) and New York (ZIP codes beginning with 130–149).

Regional Counsel, Southern Region, U.S. Postal Service, 1407 Union Avenue, Memphis, TN 38166 (901) 534–4411; Serving: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee and Texas.

Regional Counsel, Central Region, U.S. Postal Service, 433 Van Buren Street, Chicago, IL 60699 (212) 886–3175; Serving: Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin.

Regional Counsel, Western Region, U.S. Postal Service, 850 Cherry Avenue, San Bruno, CA 94099 (415) 876–9225; Serving: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming, and the Pacific Islands including the Trust Territory.

Processing of garnishments will be substantially expedited by serving the postmaster or installation head rather than the Regional Counsel.

Postal Rate Commission

Chief Administrative Officer, Postal Rate Commission, 2000 L Street, NW., Washington, D.C. 20268 (202) 254–3880.

IV. The District of Columbia, American Samoa, Guam, and the Virgin Islands

The District of Columbia

Assistant City Administrator for Financial Management, The District Building, Room 412, 14th and Pennsylvania Avenue, NW., Washington, D.C. 20004 (202) 727–6979.

American Samoa

Director of Administrative Service, American Samoa Government, Pago Pago, American Samoa 96799 (684) 633–4155.

Guam

Attorney General, P.O. Box DA, Agana, Guam 96910, 472–6841 (Country Code 671).

The Virgin Islands

Attorney General, P.O. Box 280, St. Thomas, VI 00801 (809) 774–1163.

V. Instrumentality

SMITHSONIAN INSTITUTION

For service of process in garnishment proceedings for child support and/or alimony of present Smithsonian Institution employees:

General Counsel, The Smithsonian Institution, Room 408, 1000 Jefferson Drive, SW, Washington, D.C. 20560 (202) 381–5866.

For service of process in garnishment proceedings for child support and/or alimony involving retirement annuities of former trust fund employees of the Smithsonian Institution:

General Counsel, Teachers Insurance and Annuity Association of America, College Retirement Equity Fund (TIAA/CREF), 730 Third Avenue, New York, NY 10017 (212) 490–9000.

[FR Doc. 80-40501 Filed 12-29-80; 8:45 am]

BILLING CODE 6325-01-M

5 CFR Part 831

Retirement; Survivor Benefit Provisions

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is revising its regulations to reflect current survivor benefit provisions of the Civil Service Retirement law and to establish spouse notification requirements pursuant to recent amendment.

EFFECTIVE DATE: January 5, 1981.

FOR FURTHER INFORMATION CONTACT: Doris Reeves, 202–632–4634.

SUPPLEMENTARY INFORMATION: On November 14, 1980, OPM published (45 FR 75217) proposed rules to incorporate statutory provisions that permit elimination of the survivorship reduction in a retiree's annuity under certain circumstances, permit retirees who were married at retirement to elect a reduced annuity with survivor benefits to a spouse acquired after retirement, provide for substituting a spouse acquired after retirement for the survivor benefit elected at retirement, and afford the retiree an opportunity of electing not to provide survivor protection for the spouse acquired after retirement even though such survivor benefit was elected at retirement.

The rules also established OPM's requirements under Pub. L. 96–391 which must be followed in order for a married employee's or Member's election of other than maximum survivorship protection to be valid in annuities commencing on and after January 5, 1981. In the latter case, OPM will accept a signed and witnessed declaration from the spouse to be submitted with the retirement application, in which the spouse acknowledges his/her understanding of the employee's or Member's election of other than a fully reduced annuity for survivor annuity purposes. Where an employee/Member elects other than a fully reduced annuity but cannot obtain the spouse's signature acknowledging the loss of or reduction in benefits, the proposed regulations will require the employee/Member to submit the spouse's last known mailing address to OPM. OPM will then send the spouse an explanatory letter by certified mail with return receipt requested. The spouse will be asked to sign the letter acknowledging his/her understanding of the employee's or Member's election and return to OPM. If the letter is not signed by the spouse or returned to OPM, notification will be considered properly made upon return of the certified mail receipt to OPM; and the employee's or Member's election to exclude the spouse from benefits, either fully or partially, will become effective by final adjudication of the retirement application. On the other hand, where the employee/Member fails to cooperate in furnishing either (1) the spouse's witnessed acknowledgment of less than maximum survivor annuity protection or (2) the spouse's last known mailing address, OPM is required to complete final adjudication of the retirement application with the full reduction for survivor annuity benefits provided by statute (5 U.S.C. 8339(j)).

Comments: During the 30 day comment period which ended December 15, 1980, one agency submitted a suggestion that we require the spouse's acknowledgment to be notarized rather than merely witnessed. They rationalized that this would provide maximum protection against the possibility of fraud. We believe that requiring notarization would impose a hardship on the employee, and on the spouse, which was not intended by Congress. Further, the unavailability of notaries in many suburban and rural locations, as well as the fees involved, would probably result in some spouses refusing to acknowledge the employee's election. Since we are not convinced that requiring notarization would be effective when the employee is determined to violate the regulations, we are issuing the final regulations without change from those which were proposed.

The Director of OPM finds that good cause exists for making this amendment effective in less than 30 days, in order to give timely effect to the provisions of Pub. L. 96–391 which requires that spouses of married employees whose annuities commence on and after January 5, 1981 be notified when such employees elect less than maximum survivor annuity protection.

Office of Personnel Management.

JoAnn B. Platter,

Assistant Issuance System Manager.

Accordingly, the Office of Personnel Management amends 5 CFR Part 831 as follows:

(1) Section 831.601 (c) and (e) are revised to read as follows:

§ 831.601 Survivor benefits.

* * * * *

(c) The employee or Member shall communicate his/her choice of option over his/her signature on Standard Form 2801, Application for Retirement, for use in filing claim for annuity. Receipt of the communication in OPM constitutes prima facie evidence of the existence of all the elements of an election, except that an election by a married employee or Member of a life annuity, or an election to base the benefit payable to the surviving spouse on less than the full amount of annuity, is not valid unless:

(1) The employee of Member provides OPM with the spouse's signed and witnessed declaration (the employee or Member may not witness the declaration) acknowledging the loss of or reduction in survivor benefits; or

(2) The employee or Member provides OPM with the spouse's mailing address (or last known mailing address) in order for OPM to attempt to notify the spouse about the loss of or reduction in survivor benefits. The election is considered made when the prima facie evidence becomes conclusive by final adjudication of the claim by OPM.

* * * * *

(e) When an election has been conclusively made under this section, the employee or Member may not revoke or change the election or name another survivor, except as provided under 5 U.S.C. 8339 (j) and (k).

§ 831.601 [Amended]

(2) Paragraph (f) of §831.601 is deleted and paragraphs (g) and (h) are redesignated as (f) and (g), respectively.

(5 U.S.C. 8347(g))

[FR Doc. 80-40494 Filed 12-29-80; 8:45 am]

BILLING CODE 6325-01-M

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5 CFR Parts 870, 871, 872, and 873

Basic Life Insurance, Standard Optional Life Insurance, Additional Optional Life Insurance, and Family Optional Life Insurance

Note.—This document originally appeared in the **Federal Register** for Wednesday, December 24, 1980. It is reprinted in this issue to meet requirements for publication on the Tuesday–Friday schedule assigned to the Office of Personnel Management.

AGENCY: Office of Personnel Management.

ACTION: Interim regulations, with comments invited for consideration in final rulemaking.

SUMMARY: The Office of Personnel Management is issuing interim regulations governing the second phase of implementation of the Federal Employees' Group Life Insurance Act of 1980 (FEGLI), approved October 10, 1980, which has changed the FEGLI program from a two-part to a four-part package consisting of basic insurance and three optional plans.

DATES:

Effective date: The interim regulations are effective on December 24, 1980, unless otherwise specified.

Comment date: Comments must be received by February 23, 1981.

ADDRESS: Send written comments to Mr. Craig B. Pettibone, Director, Office of Pay and Benefits Policy, Compensation Group, Office of Personnel Management, P.O. Box 57, Washington, D.C. 20044.

FOR FURTHER INFORMATION CONTACT: John Landers (202) 632–4634.

SUPPLEMENTARY INFORMATION: Pursuant to section 553(d)(3) of title 5, United States Code, the Director finds that good cause exists for making this amendment effective in less than 30 days, in order to give immediate and timely effect to provisions of Pub. L. 96–427 which require timely implementation of new group life insurance plans. The immediate effective date makes possible OPM's preparation and distribution of forms and materials necessary to make the new insurance available within the statutory time limit.

Introduction

The FEGLI program has been amended by Pub. L. 96–427, the Federal Employees' Group Life Insurance Act of 1980, approved October 10, 1980. The Act makes four major changes in the FEGLI program by (1) increasing basic FEGLI protection (beginning in October 1981) for employees under age 45 with no corresponding increase in withholdings, (2) requiring employees who retire or become entitled to receive workers' compensation after 1989 to continue paying premiums for unreduced basic insurance coverage to age 65, (3) permitting retiring employees to choose either the current post-retirement basic life insurance protection, which ultimately declines to 25 percent of the face value, or post-retirement coverage that, for an additional contribution, reduces at a lesser rate or not at all, and (4) adding to the existing $10,000 optional insurance two new optional insurance plans affording additional life insurance on employees in multiples of one to five times annual pay, as well as life insurance on family members.

The Act allows OPM from 60 to 180 days in which to implement the increased post-retirement basic insurance coverage and to make available the two new optional plans. OPM implemented the offering of increased post-age 65 basic life insurance at the earliest date permitted under the law, December 9, 1980 (see 45 FR 80472, December 5, 1980). The present interim regulations govern the two new optional plans, establish premium rates for coverage under them, and reduce the rates under the existing basic insurance and standard optional insurance effective on the first day of the first pay period beginning on or after April 1, 1981.

All employees will be given the opportunity to enroll for basic and optional coverages during an open enrollment period from March 1 through 31, 1981. Elections will be effective on or after April 1, 1981.

New Rates for Basic Insurance and Standard Optional Insurance

The Office of Personnel Management has re-evaluated the premium rates for basic insurance and standard optional insurance on the basis of experience. The new rates will be effective on the first day of the first pay period beginning on or after April 1, 1981. The biweekly rate for basic insurance for employees is reduced from 25.5 cents to 24 cents per $1,000 of the employee's basic insurance amount. The biweekly rates for the $10,000 of standard optional insurance will be:

Age	Current rate	New rate
Under 35	$0.60	$0.60
35–39	1.00	0.80
40–44	1.70	1.40
45–49	2.40	2.20
50–54	3.50	3.20
55–59	7.50	7.50
60 or over	9.00	9.00

Additional Optional Insurance

Pub. L. 96–427 authorizes OPM to purchase a group life insurance policy, without competitive bidding, which will make available to each employee who is insured for basic insurance additional optional life insurance. This coverage is referred to in the regulations as "additional optional insurance." Employees pay the full cost of coverage. There is no Government contribution.

The biweekly cost per $1,000 of the additional optional insurance is:

Age	Rate
Under 35	$.05
35–39	.07
40–44	.12
45–49	.20
50–54	.30
55–59	.60
60 or over	.95

Employees must affirmatively elect the additional optional insurance in order to obtain the coverage. All employees who are serving in positions which are not excluded from FEGLI coverage must either elect or decline the additional optional insurance during an open enrollment period to be held Government-wide from March 1 through 31, 1981. Only those employees who enroll for basic insurance are allowed to elect additional optional insurance. An employee who fails to elect this coverage during that period will not be allowed to enroll at a later date unless he/she meets the requirements discussed below, or the employing agency determines within 6 months that the employee was not able to elect the coverage due to reasons beyond his/her control.

The additional optional insurance is offered in multiples of 1, 2, 3, 4, or 5 times the annual rate of basic pay payable to the employee. Before multiplying, the pay is rounded to the next higher multiple of $1,000. (When the annual pay is an exact multiple of $1,000, the exact rate is used.) Additional optional insurance coverage may not exceed 5 times the annual rate of basic pay payable for positions at level II of the Executive Schedule under 5 U.S.C. 5313, rounded to the next higher $1,000. Covered persons may elect to reduce or stop additional optional insurance coverage at any time, though the opportunity to re-elect or increase multiples is strictly limited by the regulations.

After March 31, 1981, an employee who does not have additional optional insurance will be allowed to elect it if he/she is enrolled (or enrolls) for basic insurance and (1) he/she is under age 50, (2) at least 1 year has elapsed since the date of the declination, and (3) he/she submits satisfactory medical evidence of insurability. An employee who satisfies all three requirements will be allowed to elect the additional optional insurance or to increase the number of multiples of this coverage. Also, an employee under age 36 may elect additional optional insurance without showing medical insurability if he/she has basic insurance and elects the coverage in timely fashion (usually within 60 days after the event permitting the election) following the birth, adoption or other acquisition of a child, as defined by the regulations. These interim regulations will also permit an employee under age 50 who has in force at least 1 multiple of pay under the additional optional insurance plan to increase the number of multiples without showing medical insurability upon the employee's marriage or acquisition of a child. The employee must elect the increase in timely fashion (usually within 60 days after the event permitting the increase). The regulations limit the number of multiples acquired on the basis of the occurrence of an event to the number of family members (spouse and/or children) acquired with the event, e.g., 1 new multiple for a single birth, 2 new multiples upon birth of twins.

Family Optional Insurance

Pub. L. 96–427 authorizes OPM to purchase a group life insurance policy, without competitive bidding, which shall make available to each employee covered for basic insurance an amount of optional insurance on his/her family members. This coverage is referred to in the regulations as "family optional insurance." Employees pay the full cost of coverage. There is no Government contribution. The amount of family optional insurance is $5,000 upon the death of a spouse and $2,500 upon the death of a child. The benefit is paid to the employee, unless the employee dies before the payment can be made, in which case the benefit is paid to the employee's beneficiary for basic insurance.

The biweekly cost of the family insurance is:

Age	Rate
Under 35	$0.50
35–39	0.60
40–44	0.70
45–49	0.90
50–54	1.30
55–59	2.00
60 or over	3.00

Employees must affirmatively elect the family optional insurance in order to obtain coverage. All employees who are serving in positions which are not excluded from FEGLI coverage must either elect or decline the family optional insurance during the March 1981 open enrollment period. Only those employees who enroll for basic insurance are allowed to elect the family optional insurance. An employee who fails to elect this coverage during March 1981 will be allowed to enroll at a later date only in the event that he/she marries, or upon the birth or adoption of a child, or other acquisition of a child, as defined in the regulations, or if the employing agency determines within 6 months that the employee was not able to elect the coverage due to reasons beyond his/her control.

Under the definition of a family member for the purposes of the FEGLI law "child" means an unmarried dependent child who is under the age of 22, or who is 22 years of age or older and incapable of self-support because of a mental or physical disability which existed before the child became 22 years of age. These interim regulations provide the criteria to be used in determining the question of dependency, and in determining whether a child is to be considered incapable of self-support within the meaning of the FEGLI law. These regulations are similar to those in effect under Civil Service Retirement and Federal Employees Health Benefits regulations (see 45 FR 76087, November 18, 1980).

Open Enrollment Period

Because of the significant changes in the FEGLI program brought about by Pub. L. 96–427, OPM will hold an open enrollment period during the month of March 1981. Employees will be allowed to elect insurance irrespective of age, health or past participation in the program. The regulations provide that all waivers and declinations of existing basic and optional insurance filed before March 1981 are automatically canceled.

All non-excluded employees will be required to complete a Life Insurance Election form during March 1981, whether or not they are already participating in the FEGLI program. Employees who are already covered for basic insurance will continue that coverage unless they waive it. Employees who are already covered for standard optional insurance ($10,000) will lose that portion of their coverage unless they affirmatively re-elect it during March 1981. In the event that an employee does not complete the Life Insurance Election form during March 1981, employing agencies will file an election of basic insurance and a declination of all optional coverages on his/her behalf on March 31, 1981. However, if within 6 months an agency determines that an employee was unable to complete the form during March for reasons beyond his/her control, the employee will be allowed 31 days from the date of the agency's determination in which to complete the form.

Effective Dates

Open enrollment period elections will generally become effective on the first day on or after April 1, 1981, on which an employee actually enters on duty in a pay status. An employee who is on leave and an employee who does not actually return to duty at his/her workplace on or after April 1, 1981, does not satisfy this requirement.

New hires during the month of March 1981 who are eligible for life insurance will be immediately covered for basic insurance from the time they actually enter on duty in pay status, unless they file a waiver of coverage before the end of the first pay period. These new hires will have the standard optional insurance on the first day they actually enter on duty in a pay status on or after the date on which they file an election of that coverage. However, additional optional insurance and family optional insurance coverage, if elected during March, become effective on the first day on or after April 1, on which the employee actually enters on duty in a pay status.

An employee who is already covered for standard optional insurance during March 1981 and who declines that coverage while retaining basic insurance will continue to be insured for both basic insurance and the standard optional insurance through the end of the pay period which includes March 31, 1981. A waiver of all coverage is effective at the end of the pay period in which it is received in the employing office.

Continuation of Insurance During Retirement or Receipt Workers' Compensation

An employee who retires on an immediate annuity, or who becomes entitled to receive workers' compensation under the Federal Employees Compensation Act because of disease or injury to himself/herself is entitled to continue as many multiples of additional optional insurance as have been in force for not less than: (1) the 5 years of service immediately preceding the date of retirement or entitlement to compensation or (2) the full period(s) of service during which the insurance was available to him/her. The same participation requirement for continuation of insurance exists under the law for standard optional insurance and family optional insurance. The optional coverages may continue for as long as the individual continues to be enrolled for basic insurance while the individual continues to receive annuity or workers' compensation and is held by the Department of Labor to be unable to return to duty. Withholdings for the full cost of the optional insurance continue to be taken from the annuity or compensation payments until the month following the month in which the individual becomes 65 years of age and is retired or receiving compensation.

Beginning with the second calendar month after a retiree or compensationer become 65 years of age the optional coverages begin to reduce by 2 percent a month. The maximum reduction for the standard optional insurance is 75 percent of the face value. For additional optional insurance and family optional insurance this reduction continues until the insurance stops completely after 50 months. Once the reductions have begun, there are no withholdings from annuity or compensation for the optional coverages.

Reemployed Annuitants

There shall be no change in the current treatment of reemployed annuitants with respect to standard optional insurance coverage during reemployment. Retirees who are continuing standard optional insurance during retirement and who are reemployed in non-excluded positions will have the standard optional insurance coverage as employees unless the coverage is declined or waived, and the standard optional insurance as a retiree is suspended during reemployment. Withholdings for the full cost of the coverage are taken from salary. Following reemployment which is qualifying for a supplemental annuity, the individual may continue the reemployment-acquired insurance. If the reemployment period does not continue long enough for a supplemental annuity benefit to attach, the suspended insurance may be reinstated following separation from the reemployment.

These interim regulations provide for the same treatment with regard to family optional insurance of reemployed annuitants. However, the additional optional insurance of reemployed annuitants who have this coverage as retirees will not be automatically suspended upon reemployment. A reemployed annuitant in a non-excluded position will have the opportunity to elect either to continue additional optional insurance as a retiree or to have that coverage suspended and have additional optional insurance as an employee during reemployment. Following reemployment which is qualifying for a supplemental annuity, the individual may then continue the additional optional insurance acquired as a reemployed annuitant or the suspended additional optional insurance may be reinstated (if any remains after the post-age 65 reductions). If reemployment does not qualify the person for a supplemental annuity, any suspended additional optional insurance which remains in effect may be reinstated following separation from reemployment.

Waiver of Collection of Overpayment

Pub. L. 96-427 amends the FEGLI law to allow an agency which has failed to withhold the proper FEGLI deductions from an individual's salary, annuity or compensation to waive the collection of the corresponding overpayments of salary, annuity or compensation if, in the judgment of the agency, the individual is without fault and recovery would be against equity and good conscience. However, if the agency waives the collection of any unpaid amount, it must still submit to OPM the uncollected FEGLI withholdings and contributions for deposit to the Employees' Life Insurance Fund.

Current Civil Service Retirement regulations, 5 CFR Part 831, provide standards for waiver of overpayments from the Civil Service Retirement Fund. These interim regulations provide that waivers of collections of life insurance deductions will be governed by the same standards, in cases where OPM fails to withhold proper FEGLI deductions from annuity. Agency standards for waivers of overpayments from salary will be those which the agency must follow under 4 CFR Subchapter G, Chapter I, which implements the provisions of 5 U.S.C. 5584 allowing agencies to waive collections of over-paid salary or allowances.

These interim regulations also make a technical amendment to 5 CFR 870.601(b) (see 45 FR 80472, December 5, 1980) needed to correct a reference in that paragraph to a non-existent paragraph (h). The reference is changed to paragraph (g) of the same section.

At the time OPM publishes final regulations, uniform nomenclature changes and editorial revisions will be added throughout Parts 870 and 871.

OPM has determined that this is a significant regulation for the purposes of E.O. 12044.

Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

Accordingly, the Office of Personnel Management is amending Parts 870 and 871 of Title 5, Code of Federal Regulations, and adding new Parts 872 and 873, as follows:

PART 870—BASIC LIFE INSURANCE

(1) In Part 870, paragraphs (a), (b), and (f)(1) of § 870.401 are revised, effective on the first day of the first pay period beginning on or after April 1, 1981, to read as follows:

Subpart D—Withholdings and Contributions

§ 870.401 Withholdings and contributions.

(a) During any period in any part of which an insured employee is in pay

status, $0.24 for each $1,000 of the employee's BIA shall be withheld from the biweekly pay of the employee. The amount withheld from the pay of an employee who is paid on other than a biweekly basis is determined at a proportionate rate, adjusted to the nearest cent.

(b) The amount withheld from the pay of an insured employee whose annual pay is paid during a period shorter than 52 workweeks is the sum obtained by converting the biweekly rate of $0.24 for each $1,000 of the employee's BIA to an annual rate and prorating the annual rate over the number of installments of pay regularly paid during the year.

* * * * *

(f)(1) Except as provided under paragraph (g) of this section, an insured person who elects continued basic life insurance coverage during receipt of annuity or compensation payments as provided under §§ 870.601(c)(2) or 870.701(c)(2) (maximum reduction of 75 percent after age 65) shall have withheld from his/her payments basic life insurance withholdings at the monthly rate (for annuitants) of $0.52 for each $1,000 of the BIA or at the weekly rate (for compensationers) of $0.120 for each $1,000 of the BIA.

* * * * *

(2) In Part 870, § 870.601(b) is revised to read as follows:

Subpart F—Retired Employees

§ 870.601 Eligibility for life insurance.

* * * * *

(b) An employee who meets the requirements under paragraphs (a) or (g) of this section for continuation or reinstatement of life insurance shall execute a written election on a form furnished by OPM at the time entitlement to continuation or reinstatement of the insurance arises. To be considered valid, the election form must be received in OPM before final adjudication of the employee's application for annuity or supplemental annuity. In the absence of a valid election, the insured shall be deemed to have filed a valid election under paragraph (c)(2) of this section.

* * * * *

(3) The heading of Part 871 is revised, effective April 1, 1981, to read as follows:

PART 871—STANDARD OPTIONAL LIFE INSURANCE

(4) In Part 871, § 871.101 is revised, effective April 1, 1981, to read as follows:

Subpart A—Administration and General Provisions

§ 871.101 Actions on the policy.

Optional life and accidental death and dismemberment benefits (referred to in this part as "standard optional insurance") shall be payable in accordance with an amendment to the policy purchased by OPM from the Metropolitan Life Insurance Co., 1 Madison Avenue, New York, NY 10010, under section 8709 of title 5, United States Code, to provide group insurance coverage (referred to in this part as "basic insurance"). Actions at law or in equity to recover on the policy, in which there is not alleged any breach of any obligations undertaken by the United States should be brought against the insurance company.

(5) In Part 871, § 871.202 and § 871.204(b) are revised, and §§ 871.204(d) and 871.205(e) are added, effective March 1, 1981, to read as follows:

Subpart B—Coverage

§ 871.202 Election or declination.

(a) Except as otherwise provided in paragraph (b) of this section, each employee shall, on the form entitled Life Insurance Election, elect or decline standard optional insurance within 31 days after becoming eligible, unless during earlier employment he/she filed an election or declination which remains in effect.

(b) On a determination by an employing office, within 6 months after a person becomes eligible, that he/she was unable, for cause beyond his/her control to elect or decline the standard optional insurance within the prescribed time limit, the employee shall elect or decline the standard optional insurance within 31 days after he/she is advised of that determination. Standard optional insurance in that case is retroactive to the first day of the first pay period beginning after the date the person became eligible, or after April 1, 1981, whichever is later, and the person shall pay the full cost of the insurance from that date for the time that he/she is in a pay status or retired and under age 65.

(c) A person who does not file a Life Insurance Election form with his/her employing office does not have standard optional insurance.

§ 871.204 Declination.

* * * * *

(b) A cancellation of standard optional insurance becomes effective and standard optional insurance stops at the end of the pay period in which the declination or waiver is received in the employing office, except that a declination of standard optional insurance (which is not also a waiver of basic insurance) which is filed during the period from March 1, 1981 through March 31, 1981, becomes effective and standard optional insurance stops at the end of the pay period which includes March 31, 1981.

* * * * *

(d) For the purpose of having standard optional insurance as an employee, an election of insurance under this part filed on or before February 28, 1981, is deemed to have been canceled effective at the end of the pay period which includes March 31, 1981, unless the employee does not actually enter on duty in pay status during the first pay period which begins on or after April 1, 1981, in which case the election is deemed to have been canceled on the first day after the end of such pay period that the employee actually enters on duty in pay status. In order to retain or obtain standard optional insurance as an employee after the date of such declination an employee must affirmatively elect the coverage by filing the Life Insurance Election form with his/her employing office, subject to the provisions of § 871.205.

§ 871.205 Cancellation of declination.

* * * * *

(e) Declinations of standard optional insurance filed on or before February 28, 1981, are automatically canceled effective on the first day an employee whose declination is so canceled actually enters on duty in pay status on or after April 1, 1981, and the standard optional insurance is effective on the date of cancellation of the declination, provided that the employee has filed an affirmative election of standard optional insurance on the form entitled Life Insurance Election during the period from March 1, 1981 through March 31, 1981. An employee whose pre-March 1981 declination is so canceled and who does not file the form with his/her employing office during the period from March 1, 1981 through March 31, 1981, shall be deemed to have declined standard optional insurance on March 31, 1981, except that an employee who fails to file the form during that period due to cause beyond his/her control shall be allowed to enroll belatedly under the conditions prescribed under § 871.202(b).

(6) In Part 871, § 871.401(c) is revised, and § 871.401(g) is added, effective on the first day of the first pay period beginning on or after April 1, 1981, to read as follows:

Subpart D—Withholdings

§ 871.401 Withholdings.

* * * * *

(c) The biweekly full cost of the $10,000 of standard optional insurance (and for a person in receipt of annuity or compensation for work injury, of standard optional life insurance), until determined by OPM on the basis of experience to be otherwise, is:

For persons under age 35	$0.60
For persons ages 35 through 39	$0.80
For persons ages 40 through 44	$1.40
For persons ages 45 through 49	$2.20
For persons ages 50 through 54	$3.20
For persons ages 55 through 59	$7.50
For persons age 60 or over	$9.00

The amount withheld from the pay of a person paid on other than a biweekly period or insured for more than $10,000 shall be determined at a proportionate rate, adjusted to the nearest cent.

* * * * *

(g)(1) If OPM fails to withhold proper amounts of standard optional life insurance deductions from the annuity of a retired employee, OPM may waive the collection of the unpaid insurance deductions in accordance with section 8707(d) of title 5, United States Code. OPM shall use the standards for waiver of overpayments found under Subpart N of Part 831 of this chapter when determining whether a waiver of collection of the unpaid deductions may be granted, and shall follow the procedures under Subpart M of Part 831 of this chapter when applying the standards.

(2) If, under section 8707(d) of title 5, United States Code, an agency waives the collection of unpaid insurance deductions from an individual's pay, annuity or compensation, the agency shall submit an amount equal to the sum of the uncollected deductions and any applicable agency contributions required under section 8708 of title 5, United States Code, to OPM for deposit to the Employees' Life Insurance Fund. An agency will make its determination on the waiver of collection of an overpayment of pay in accorcdance with 5 U.S.C. 5584 as implemented by 4 CFR Chapter I, Subchapter G.

(7) In Part 871, paragraph (b) of § 871.501 is revised, paragraphs (c) and (d) are redesignated (d) and (e), and paragraph (c) is added, to read as follows:

Subpart E—Termination and Conversion

§ 871.501 Termination and conversion of insurance.

* * * * *

(b) If, because of a declination or waiver, an insured employee has not had the standard optional insurance during the full period(s) of service during which it was available to him/her, or for the 5 years of service immediately preceding the date on which that coverage stops, whichever is less, the optional insurance stops, subject to a 31-day extension standard optional life insurance coverage, on the date that his/her basic life insurance is continued or reinstated under the provisions of § 870.601 (during retirement) or § 870.701 (during receipt of compensation) of this chapter.

(c) If, at the time of an individual's election under §§ 870.601(b) or 870.701(b) of this chapter, he/she elects no basic life insurance during receipt of annuity or compensation (as provided under §§ 870.601(c)(1) and 870.701(c)(1) of this chapter), the standard optional insurance stops at the end of the month in which the election is received in OPM, subject to a 31-day extension of coverage.

* * * * *

(8) In Part 871, § 871.601 and § 871.604(b) are revised to read as follows:

Subpart F—Retired Employees and Employees Compensation

§ 871.601 Amount of insurance.

The amount of standard optional life insurance which is continued during receipt of annuity or compensation reduces by 2 percent a month effective at the beginning of the second calendar month after (a) the date the insurance would otherwise have stopped, or (b) the retiree's or compensationer's 65th birthday, whichever is later, with a maximum reduction of 75 percent.

§ 871.604 Reemployed retired employees.

* * * * *

(b) Standard optional insurance acquired during reemployment may be continued after termination of the reemployment of the retired employee:

(1) Qualifies for a supplemental annuity or acquires a new retirement right,

(2) Continues his/her basic insurance under paragraphs (c)(2), (c)(3) or (c)(4) of § 870.601 of this chapter, and

(3) Has had standard optional insurance in force for the 5 years of service immediately preceding separation from reemployment or for the full period(s) of service during which it was available to him/her, whichever is less.

If the standard optional life insurance acquired during reemployment is so continued, any suspended standard optional life insurance stops with no 31-day extension of coverage or right of conversion.

(9) Part 872 is added to read as follows:

PART 872—ADDITIONAL OPTIONAL LIFE INSURANCE

Subpart A—Administration and General Provisions

Sec.

Subpart B—Coverage

Subpart C—Amount of Insurance

Sec.

Subpart D—Withholdings

Subpart E—Termination and Conversion

Subpart F—Retired Employees and Employees Compensation

Authority: 5 U.S.C. 8716. Interprets and applies 5 U.S.C. 8714b.

Subpart A—Administration and General Provisions

§ 872.101 Actions on the policy.

Optional life insurance (referred to in this part as "additional optional insurance") shall be payable in accordance with an amendment to the policy purchased by OPM from the Metropolitan Life Insurance Co., 1 Madison Avenue, New York, N.Y. 10010, pursuant to section 8709 of title 5, United States Code, to provide group insurance coverage (referred to in this part as "basic insurance"). Actions at law or in equity to recover on the policy, in which there is not alleged any breach of any obligations undertaken by the United States, should be brought against the insurance company.

§ 872.102 Payment of benefits; designations of beneficiary.

Additional optional insurance in force on a person at the date of his/her death

shall be paid, on receipt of a valid claim, in the same order of precedence and under the same conditions as are applicable to basic insurance. A designation of beneficiary for basic insurance is also a designation of beneficiary for additional optional insurance unless the insured person specifies otherwise in his/her designation.

§ 871.103 Correction of an error, mistake, or omission.

The Associate Director for Compensation may order correction of an error, mistake, or omission upon a showing satisfactory to the Associate Director that it would be against equity and good conscience not to do so.

Subpart B—Coverage

§ 872.201 Eligibility.

Each employee, as defined in section 8701 of title 5, United States Code, who is insured for basic insurance and for whom an uncanceled declination of additional optional insurance is not in effect is eligible to elect the additional optional insurance, if his/her periodic pay, after all other deductions, is sufficient to cover its full cost

§ 872.202 Election or declination.

(a) Except as otherwise provided in paragraph (b) of this section, each employee shall, on the form entitled Life Insurance Election, elect or decline the additional optional insurance within 31 days after becoming eligible, unless during earlier employment he/she filed an election or declination which remains in effect. The 31-day time limit begins to run on the first day after February 28, 1981, on which an individual meets the definition of an employee under 5 U.S.C. 8701.

(b) On a determination by an employing office, within 6 months after a person becomes eligible, that he/she was unable, for cause beyond his/her control to elect the additional optional insurance within the prescribed time limit regulation, the employee shall elect or decline the optional insurance within 31 days after he/she is advised of that determination. Additional optional insurance in that case is retroactive to the first day of the first pay period beginning after the date the person became eligible, or after April 1, 1981, whichever is later, and the person shall pay the full cost of the insurance from that date for the time that he/she is in a pay status or retired and under age 65.

(c) A person who does not file a Life Insurance Election form with his/her employing office does not have the additional optional insurance.

§ 872.203 Effective date of insurance.

(a) The effective date of an election of additional optional insurance is the first day on or after April 1, 1981, that an employee actually enters on duty in a pay status on or after the day the election is received in his/her employing office.

(b) An election of additional optional insurance remains in effect until canceled as provided in § 872.204. For an employee whose additional optional insurance has stopped for a reason other than a declination or waiver, additional optional insurance is reinstated on the first day he/she actually enters on duty in a pay status in a position in which he/she again becomes eligible.

§ 872.204 Declination.

(a) An insured person may at any time cancel his/her additional optional insurance by filing with his/her employing office (which for a retired employee is the office that administers his/her retirement sytem, and, for an employee or former employee in receipt of compensation for work injury under subchapter I of chapter 81 of title 5, United States Code, is the Department of Labor) a declination of additional optional insurance or a waiver of basic insurance coverage. An insured person may at any time reduce the number of his/her multiples of additional optional insurance by filing a Life Insurance Election form with his/her employing office.

(b) A cancellation of additional optional insurance becomes effective and additional optional insurance stops at the end of the pay period in which the declination or waiver is received in the employing office. A reduction in the number of additional optional insurance multiples is effective at the end of the pay period in which the Life Insurance Election form is received in the employing office.

(c) A declination or reduction in multiples of additional optional insurance remains in effect until it is canceled as provided in § 872.205.

§ 872.205 Cancellation of declination.

(a)(1) An employee who has declined the additional optional insurance may elect it if (A) he/she is under age 50, (B) at least 1 year has elapsed since the effective date of his/her last declination or waiver, and (C) he/she furnishes satisfactory evidence of insurability.

(2) An employee who has declined additional optional insurance may elect it upon his/her marriage or the acquisition of an unmarried dependent child within the meaning of section 8701(d) of title 5, United States Code, and Subpart G of Part 873 of this chapter, except that the election must be received in the employing office before the employee's 36th birthday. In order to be valid, the election must be filed with the employing office on the Life Insurance Election form during the 60-day period following the date of the event which permits the election. This 60-day time limit may be extended if the individual is not serving in a covered position on the date of the event, or if the individual separates from covered service prior to completion of the 60-day time limit. This extension of the time limit is limited to coincide with the 31-day time limit for electing insurance following employment in a covered position. The number of multiples which an employee may obtain upon acquisition of a spouse or child is limited to the number of family members (spouse and/or children) acquired with the event which permits the employee to elect additional optional insurance under this paragraph.

(3) An employee who has in force additional optional insurance of at least 1 multiple of annual pay but less than 5 multiples of annual pay may increase the number of multiples if he/she meets the requirements of paragraph (a)(1) of this section.

(4) An employee who has in force additional optional insurance of at least 1 multiple of annual pay but less than 5 multiples of annual pay may elect to increase the number of multiples upon his/her marriage or the aquisition of an unmarried dependent child within the meaning of section 8701(d) of title 5, United States Code, and Subpart G of Part 873 of this chapter, except that the election must be received in the employing office before the employee's 50th birthday. In order to be valid, the election to increase multiples must be filed with the employing office on the Life Insurance Election form during the 60-day period following the date of the event which permits the increase. This 60-day time limit may be extended if the individual is not serving in a covered position on the date of the event, or if the individual separates from covered service prior to completion of the 60-day time limit. This extension of the time limit is limited to coincide with the 31-day limit for electing insurance following employment in a covered position. The number of multiples which an employee may add upon acquisition of a spouse or child is limited to the number of family members (spouse and/or children) acquired with the event which permits the employee to increase multiples.

(b)(1) The effective date of the additional optional insurance for an

employee who has complied with paragraphs (a)(1) or (a)(3) of this section is the first day he/she actually enters on duty in a pay status, on or after the day his/her election is received in his/her employing office following the approval of his/her Request for Insurance by the Office of Federal Employees' Group Life Insurance.

This approval is revoked automatically and the additional optional insurance does not become effective if the employee fails to submit his/her election or meet the pay and duty status requirement within 31 days following the date of the approval.

(2) The effective date of an election under paragraphs (a)(2) or (a)(4) of this section is the first day the employee actually enters on duty in a pay status, on or after the day his/her election is received in the employing office.

(c) A former employee and an employee who is continuing basic life insurance during receipt of compensation is not eligible to cancel a declination under this section, nor to increase multiples of additional optional insurance.

§ 872.206 Reconsideration.

(a) *Who may file.* An individual or annuitant may request the OPM to reconsider an agency decision or an initial decision of OPM denying additional optional insurance coverage.

(b) *Agency decision.* A request for reconsideration of an agency decision must be filed within 30 calendar days from the date of the written decision stating the right to reconsideration by OPM. The time limit may be extended as provided in paragraph (e) of this section.

(c) *Initial OPM decision.* An OPM decision shall be considered an initial decision when rendered by OPM in writing and stating the right to reconsideration. However, a decision initially rendered at the highest level of review available within OPM will not be subject to reconsideration.

(d) *Reconsideration.* A request for reconsideration must be made in writing, must include the claimant's name, address, date of birth, claim number, if applicable, and reasons for the request.

(e) *Time limit.* A request for reconsideration of an initial decision must be filed within 30 calendar days from the date of the initial decision. OPM may extend the time limit for filing when the individual shows that he/she was not notified of the time limit and was not otherwise aware of it, or that he/she was prevented by circumstances beyond his/her control from making the request within the time limit.

(f) *Final decision.* After consideration, OPM shall issue a final decision which shall be in writing and shall fully set forth the findings and conclusions of OPM.

Subpart C—Amount of Insurance

§ 872.301 Amount of employee's insurance.

An eligible employee may elect additional optional insurance of 1, 2, 3, 4, or 5 multiples of his/her annual pay. For this purpose, each multiple is equal to the lowest multiple of $1,000 which is not less than the current rate of the employee's annual pay as determined under § 870.302 of this chapter. A multiple shall not exceed the annual rate of basic pay payable for positions at level II of the Executive Schedule under section 5313 of title 5, United States Code, rounded to the next higher multiple at $1,000.

Subpart D—Withholdings

§ 872.401 Withholdings.

(a) During any period in any part of which an insured employee is in a pay status there shall be withheld from his/her pay the full cost of his/her additional optional insurance as specified in paragraph (c) of this section.

(b) Subject to the provisions of § 872.604, for any period before the first of the month following his/her 65th birthday during which an insured retired employee (or employee or former employee in receipt of compensation for work injury) receives annuity (or compensation), there shall be withheld from his annuity (or compensation) the full cost of his/her additional optional insurance as specified in paragraph (c) of this section.

(c) The biweekly full cost per $1,000 of additional optional insurance in force, until determined by OPM on the basis of experience to be otherwise, is:

For persons under age 35—$0.05
For persons ages 35 through 39—$0.07
For persons ages 40 through 44—$0.12
For persons ages 45 through 49—$0.20
For persons ages 50 through 54—$0.30
For persons ages 55 through 59—$0.60
For persons age 60 or over—$0.95

The amount withheld from the pay of a person paid on other than a biweekly period shall be determined at a proportionate rate, adjusted to the nearest one-tenth of one cent.

(d) For the purposes of this section, a person is deemed to attain 35, 40, 45, 50, 55, or 60 years of age on the first day of his/her pay period beginning on or after January 1 of the year following the one in which his/her corresponding birthday occurs.

(e) The amount withheld from the pay of an insured person whose annual pay is paid during a period shorter than 52 workweeks is the sum obtained by converting the biweekly rate for his/her age group to an annual rate and prorating the annual rate over the number of installments of pay regularly paid during the year.

(f) The amount withheld from the pay of an insured employee whose amount of insurance changes during a pay period is based on the last amount of insurance in force during the pay period.

(g)(1) If OPM fails to withhold proper amounts of insurance deductions from the annuity of a retired employee, OPM may waive the collection of the unpaid insurance deductions in accordance with section 8707(d) of title 5, United States Code. OPM shall use the standards for waiver of overpayments found under Subpart N of Part 831 of this chapter when determining whether a waiver of collection of the unpaid deductions may be granted, and shall follow the procedures under Subpart M of Part 831 of this chapter when applying the standards.

(2) If, under section 8707(d) of title 5, United States Code, an agency waives the collection of unpaid insurance deductions from an individual's pay, annuity or compensation, the agency shall submit an amount equal to the sum of the uncollected deductions and any applicable agency contributions required under section 8708 of title 5, United States Code, to OPM for deposit to the Employees' Life Insurance Fund. An agency will make its determination on the waiver of collection of an overpayment of pay in accordance with 5 U.S.C. 5584 as implemented by 4 CFR Chapter I, Subchapter G.

Subpart E—Termination and Conversion

§ 872.501 Termination and conversion of insurance.

(a) The additional optional insurance of an insured employee stops when his/her basic insurance stops as provided in § 870.501 of this chapter subject to a 31-day extension of additional optional insurance coverage.

(b) If, because of a declination or waiver, an insured employee has not had the additional optional insurance during the full period(s) of service during which it was available to him/her, or for the 5 years of service immediately preceding the date on which the insurance stops, whichever is less, the additional optional insurance stops, subject to a 31-day extension of additional optional insurance coverage, on the date that his/her basic life

insurance is continued or reinstated under the provisions of § 870.601 (for retirement) or § 870.701 (during receipt of compensation) of this chapter.

(c) If, at the time of an individual's election under §§ 870.601(b) or 870.701(b) of this chapter (for basic life insurance during receipt of annuity or compensation), he/she elects no basic life insurance (as provided under §§ 870.601(c)(1) or 870.701(c)(1) of this chapter), the additional optional insurance stops at the end of the month in which the election is received in OPM, subject to a 31-day extension of coverage.

(d) The additional optional insurance of an insured person who remains in a pay status stops, subject to a 31-day extension of coverage, at the end of the pay period in which it is determined that his/her periodic pay, compensation for work injury, or annuity, after all other deductions, is insufficient to cover the full cost of the additional optional insurance.

(e) During the 31-day extension of additional optional insurance coverage under this section, a person may, upon application and without medical examination convert all or any part of his/her additional optional insurance to an individual policy of life insurance at rates applicable to his/her attained age and class of risk unless, within 3 calendar days after the date his/her additional optional insurance stopped, he/she returns to a position in which he/she is not excluded from coverage.

Subpart F—Retired Employees and Employees Compensation

§ 872.601 Amount of insurance.

(a) Each multiple of additional optional insurance continued during receipt of annuity or compensation reduces by 2 percent a month effective at the beginning of the second calendar month after (1) the date the insurance would otherwise have stopped, or (2) the insured's 65th birthday, whichever is later. At 12:00 PM on the day preceding the 50th reduction the insurance stops, with no extension of coverage or right of conversion.

(b) The number of multiples of additional optional insurance which may be continued during receipt of annuity or compensation is the smallest number of multiples in force during (1) the 5 years of service immediately preceding separation from employment or entitlement to compensation, or (2) the full period(s) of service during which the additional optional insurance was available to the employee.

§ 872.602 Termination of annuity or compensation.

If the annuity or compensation for work injury paid to an insured person is terminated, or if the Department of Labor finds that an insured person receiving compensation for work injury is able to return to duty, additional optional insurance held as a retired employee or person receiving compensation stops, with no 31-day extension of coverage or right of conversion, on the date of that termination or finding.

§ 872.603 Waiver of suspension of annuity or compensation.

(a) Except as provided in paragraph (b) of this section, when annuity or compensation for work injury is waived or suspended, additional optional insurance continues. When payment of the annuity or compensation is resumed, the employing office shall withhold the full cost of the insurance for the period of waiver or suspension during which the person is under age 65.

(b) If suspension of annuity or compensation is because of reemployment, the reemployment office shall withhold the full cost of the insurance during each pay period of reemployment.

§ 872.604 Reemployed retired employees.

(a)(1) A retired employee appointed to a position in which he/she is not excluded from basic insurance by law or regulation is eligible for additional optional insurance as an employee, unless he/she has on file an uncanceled waiver of basic insurance or declination of additional optional insurance. If he/she has additional optional insurance as a retired employee, that insurance (and any applicable annuity withholdings) continues as if the individual were not reemployed, unless (i) the person files with his/her employing office within 31 days following the date of reemployment an election of additional optional insurance on the Life Insurance Election form, in which case the additional optional insurance (and corresponding annuity withholdings) as a retiree is suspended effective on the date that the additional optional insurance as an employee becomes effective, or (ii) the person files a waiver of basic insurance.

(2) Except as provided in paragraph (b) of this section, the additional optional insurance acquired as an employee stops, with no 31-day extension or right of conversion, on the date reemployment terminates and any suspended additional optional insurance which remains in force after applicable monthly reductions after age 65 (and corresponding annuity withholdings, if any) is reinstated on the day following termination of the reemployment.

(b) Additional optional insurance acquired during reemployment may be continued after termination of the reemployment if the retired employee:

(1) Qualifies for a supplemental annuity or acquires a new retirement right,

(2) Continues his/her basic insurance under paragraphs (c)(2), (c)(3), or (c)(4) of § 870.601 of this chapter, and

(3) Has had additional optional insurance in force for the 5 years of service immediately preceding separation from reemployment or for the full period(s) of service during which it was available to him/her, whichever is less. If the additional optional insurance acquired during reemployment is so continued, any suspended additional optional insurance stops with no 31-day extension of coverage or right of conversion.

(10) Part 873 is added to read as follows:

PART 873—FAMILY OPTIONAL LIFE INSURANCE

Subpart A—Administration and General Provisions

Sec.

Subpart B—Coverage

Subpart C—Amount of Insurance

Subpart D—Withholdings

Subpart E—Termination and Conversion

Subpart F—Retired Employees and Employees Compensation

Subpart G—Definition of Family Member

Authority: 5 U.S.C. 8716. Interprets and applies 5 U.S.C. 8714c.

Subpart A—Administration and General Provisions

§ 873.101 Actions on the policy.

Optional life insurance on family members (referred to in this part as "family optional insurance") shall be payable in accordance with an amendment to the policy purchased by OPM from the Metropolitan Life Insurance Co., 1 Madison Avenue, New York, N.Y. 10010, pursuant to section 8709 of title 5, United States Code, to provide group insurance coverage (referred to in this part as "basic insurance"). Actions at law or in equity to recover on the policy, in which there is not alleged any breach of any obligations undertaken by the United States, should be brought against the insurance company.

§ 873.102 Payment of benefits.

Family optional insurance in force on a spouse or child at the date of his/her death shall be paid to the employee or former employee whose pay, annuity or compensation is subject to withholding under § 873.401, except that in the event that payment is not made prior to the death of the employee, the insurance shall be paid to the person(s) eligible for the basic insurance on the employee or former employee.

§ 873.103 Correction of an error, mistake, or omission.

The Associate Director for Compensation may order correction of an error, mistake, or omission upon a showing satisfactory to the Associate Director that it would be against equity and good conscience not to do so.

Subpart B—Coverage

§ 873.201 Eligibility.

Each employee, as defined by section 8701 of title 5, United States Code, who is insured for basic insurance and for whom an uncanceled declination of family optional insurance is not in effect is eligible to elect the family optional insurance, if his/her periodic pay, after all other deductions, is sufficient to cover its full cost.

§ 873.202 Election or declination.

(a) Except as otherwise provided in paragraph (b) of this section, each employee shall, on the form entitled Life Insurance Election, elect or decline the family optional insurance within 31 days after becoming eligible, unless during earlier employment he/she filed an election or declination which remains in effect. The 31-day time limit begins to run on the first day after February 28, 1981, on which an individual meets the definition of an employee under 5 U.S.C. 8701.

(b) On a determination by an employing office, within 6 months after a person becomes eligible, that he/she was unable, for cause beyond his/her control to elect or decline the family optional insurance within the prescribed time limit, the employee shall elect or decline the family optional insurance within 31 days after he/she is advised of that determination. Family optional insurance in that case is retroactive to the first day of the first pay period beginning after the date the person became eligible, or after April 1, 1981, whichever is later, and the person shall pay the full cost of the insurance from that date for the time that he/she is in a pay status or retired and under age 65.

(c) A person who does not file a Life Insurance Election form with his/her employing office does not have the family optional insurance.

§ 873.203 Effective date of insurance.

(a) The effective date of an election of family optional insurance is the first day on or after April 1, 1981, that an employee actually enters on duty in a pay status on or after the day the election is received in his/her employing office.

(b) An election of family optional insurance remains in effect until canceled as provided in § 873.204. For an employee whose family optional insurance has stopped for a reason other than a declination or waiver, family optional insurance is reinstated on the first day he/she actually enters on duty in a pay status in a position in which he/she again becomes eligible.

§ 873.204 Declination.

(a) An employee may at any time cancel his/her family optional insurance by filing with his/her employing office (which for a retired employee is the office that administers his/her retirement system, and, for an employee or former employee in receipt of compensation for work injury under subchapter I of chapter 81 of title 5, United States Code, is the Department of Labor) a declination of family optional insurance or a waiver of basic insurance coverage.

(b) A cancellation of family optional insurance becomes effective and family optional insurance stops at the end of the pay period in which the declination or waiver is received in the employing office.

(c) A declination of family optional insurance remains in effect until it is canceled as provided in § 873.205.

§ 873.205 Cancellation of declination.

(a) An employee who has declined the family optional insurance may elect it upon his/her marriage or the acquisition of a child. In order to be valid, the election must be filed with the employing office on the Life Insurance Election form during the 60-day period following the date of the event which permits the election. This 60-day time limit may be extended if the individual is not serving in a covered position on the date of the event, if the individual separates from covered service prior to completion of the 60-day time limit, or if the event occurs during the period following a waiver of basic insurance when he/she is not eligible to cancel the waiver. This extension of the time limit is limited to coincide with the 31-day time limit for electing insurance following employment in a covered position, or with the 31-day period following the first day on which the individual becomes eligible to cancel a waiver of basic insurance.

(b) The effective date of the family optional insurance for an employee who has complied with paragraph (a) of this section is the first day he/she actually enters on duty in a pay status, on or after the day his/her election is received in his/her employing office and basic insurance is in force.

(c) A former employee and an employee who is continuing basic insurance as a compensationer is not eligible to make the election provided in paragraph (a) of this section.

§ 873.206 Reconsideration.

(a) *Who may file.* An individual or annuitant may request the OPM to reconsider an agency decision or an initial decision of OPM denying family optional insurance coverage.

(b) *Agency decision.* A request for reconsideration of an agency decision must be filed within 30 calendar days from the date of the written decision stating the right to reconsideration by OPM. The time limit may be extended as provided in paragraph (e) of this section.

(c) *Initial OPM decision.* An OPM decision shall be considered an initial decision when rendered by OPM in writing and stating the right to reconsideration. However, a decision initially rendered at the highest level of review available within OPM will not be subject to reconsideration.

(d) *Reconsideration.* A request for reconsideration must be made in writing, must include the claimant's name, address, date of birth, claim number, if applicable, and reasons for the request.

(e) *Time limit.* A request for reconsideration of an initial decision

must be filed within 30 calendar days from the date of the initial decision. OPM may extend the time limit for filing when the individual shows that he/she was not notified of the time limit and was not otherwise aware of it, or that he/she was prevented by circumstances beyond his/her control from making the request within the time limit.

(f) *Final decision.* After reconsideration, OPM shall issue a final decision which shall be in writing and shall fully set forth the findings and conclusions of OPM.

Subpart C—Amount of Insurance

§ 873.301 Amount of employee's insurance.

The amount of family optional insurance is $5,000 payable upon the death of a spouse and $2,500 payable upon the death of a child.

Subpart D—Withholdings

§ 873.401 Withholdings.

(a) During any period in any part of which an insured employee is in a pay status there shall be withheld from his/her pay the full cost of his/her family optional insurance as specified in paragraph (c) of this section.

(b) Subject to the provisions of § 873.604, for any period before the first of the month following his/her 65th birthday during which an insured retired employee (or employee or former employee in receipt of compensation for work injury) receives annuity (or compensation), there shall be withheld from his annuity (or compensation) the full cost of his/her family optional insurance as specified in paragraph (c) of this section.

(c) The biweekly full cost of family optional insurance in force, until determined by OPM on the basis of experience to be otherwise, is:

For persons under age 35—$0.50
For persons ages 35 through 39—$0.60
For persons ages 40 through 44—$0.70
For persons ages 45 through 49—$0.90
For persons ages 50 through 54—$1.30
For persons ages 55 through 59—$2.00
For persons age 60 or over—$3.00

The amount withheld from the pay of a person paid on other than a biweekly period shall be determined at a proportionate rate, adjusted to the nearest cent.

(d) For the purposes of this section, a person is deemed to attain 35, 40, 45, 50, 55, or 60 years of age on the first day of his/her pay period beginning on or after January 1 of the year following the one in which his/her corresponding birthday occurs.

(e)(1) If OPM fails to withhold proper amounts of insurance deductions from the annuity of a retired employee, OPM may waive the collection of the unpaid insurance deductions in accordance with section 8707(d) of title 5, United States Code. OPM shall use the standards for waiver of overpayments found under Subpart N of Part 831 of this chapter when determining whether a waiver of collection of the unpaid deductions may be granted, and shall follow the procedures under Subpart M of Part 831 of this chapter when applying the standards.

(2) If, under section 8707(d) of title 5, United States Code, an agency waives the collection of unpaid insurance deductions from an individual's pay, annuity or compensation, the agency shall submit an amount equal to the sum of the uncollected deductions and any applicable agency contributions required under section 8708 of title 5, United States Code, to OPM for deposit to the Employees' Life Insurance Fund. An agency will make its determination on the waiver of collection of an overpayment of pay in accordance with 5 U.S.C. 5584 as implemented by 4 CFR Chapter I, Subchapter G.

Subpart E—Termination and Conversion

§ 873.501 Termination and conversion of insurance.

(a) The family optional insurance of an insured employee stops when his/her basic insurance stops as provided in § 870.501 of this chapter subject to a 31-day extension of family optional insurance coverage.

(b) If, because of a declination or waiver, an insured employee has not had the family optional insurance during the full period(s) of service during which he/she was serving in a position subject to this part, or for the 5 years of service immediately preceding the date on which the insurance stops, whichever is less, the family optional insurance stops, subject to a 31-day extension of family optional insurance coverage, on the date that his/her basic life insurance is continued or reinstated under the provisions of § 870.601 (for retirement) or under the provisions of § 870.701 (during receipt of compensation) of this chapter.

(c) If, at the time of an individual's election under §§ 870.601(b) or 870.701(b) of this chapter (for basic life insurance during receipt of annuity or compensation), he/she elects no basic life insurance (as provided under §§ 870.601(c)(1) or 870.701(c)(1) of this chapter), the family optional insurance stops at the end of the month in which the election is received in OPM, subject to a 31-day extension of coverage.

(d) The family optional insurance of an insured person who remains in a pay status stops, subject to a 31-day extension of coverage, at the end of the pay period in which it is determined that his/her periodic pay, compensation for work injury, or annuity, after all other deductions, is insufficient to cover the cost of the family optional insurance.

(e) During the 31-day extension of family optional insurance coverage under this section, a person may, upon application and without medical examination, convert his/her family optional insurance to an individual policy of life insurance at rates applicable to his/her attained age and class of risk unless, within 3 calendar days after the date his/her family optional insurance stopped, he/she returns to a position in which he/she is not excluded from coverage.

(f) During the 31-day period following the death of an insured employee, or during the 31-day extension of family optional insurance under this section, each one of the employee's or former employee's family members as defined by 5 U.S.C. 8701(d) may, upon application and without medical examination, convert the amount of family optional insurance coverage in force (maximums of $5,000 for a spouse and $2,500 for a child) to an individual policy of life insurance at rates applicable to his/her attained age and class of risk unless, within 31 days after the date the employee's or former employee's family optional insurance stopped, he/she returns to a position in which he/she is not excluded from coverage. The family member's right of conversion does not attach if the employee or former employee exercises his/her right of conversion under paragraph (e) of this section.

(g) The amount of an individual policy as provided under paragraphs (e) or (f) of this section shall not be less than $1,000.

Subpart F—Retired Employees and Employees Compensation

§ 873.601 Amount of insurance.

The amount of family optional insurance (on each family member) continued during receipt of annuity or compensation reduces by 2 percent a month effective at the beginning of the second calendar month after (1) the date the insurance would otherwise have stopped, or (2) the retiree's or compensationer's 65th birthday, whichever is later. At 12:00 PM on the day preceding the 50th reduction the

insurance stops, with no extension of coverage or right of conversion.

§ 873.602 Termination of annuity or compensation.

If the annuity or compensation for work injury paid to an insured person is terminated, or if the Department of Labor finds that an insured person receiving compensation for work injury is able to return to duty, family optional insurance held as a retired employee or person receiving compensation stops, with no 31-day extension of coverage or right of conversion, on the date of that termination or finding.

§ 873.603 Waiver or suspension of annuity or compensation.

(a) Except as provided in paragraph (b) of this section, when annuity or compensation for work injury is waived or suspended, family optional insurance continues. When payment of annuity or compensation is resumed, the employing office shall withhold the full cost of the insurance for the period of waiver or suspension during which the person is under age 65.

(b) If suspension of annuity or compensation is because of reemployment, the reemploying office shall withhold the full cost of the insurance during each pay period of reemployment.

§ 873.604 Reemployed retired employees.

(a)(1) A retired employee appointed to a position in which he/she is not excluded from basic insurance coverage by law or regulation is eligible for family optional insurance as an employee. If he/she has family optional insurance as a retired employee, that insurance (and any corresponding withholdings) is suspended on the day preceding his/her first day in a pay status under the appointment and, unless he/she files with his/her employing office a declination of family optional insurance (or a waiver of basic insurance), he/she acquires family optional insurance as an employee.

(2) Except as provided in paragraph (b) of this section, the family optional insurance acquired as an employee stops, with no 31-day extension or right of conversion, on the date reemployment terminates and any suspended family optional insurance which may remain in force following reductions is reinstated on the day following termination of the reemployment.

(b) Family optional insurance acquired during reemployment may be continued after termination of the reemployment if the retired employee:

(1) Qualifies for a supplemental annuity or acquires a new retirement right,

(2) Continues his/her basic insurance under paragraphs (c)(2), (c)(3), or (c)(4) of § 870.601 of this chapter, and

(3) Has had family optional insurance in force for the 5 years of service immediately preceding separation from reemployment or for the full period(s) of service during which it was available to him/her, whichever is less.

If the family optional insurance acquired during reemployment is so continued, any suspended family optional insurance stops with no 31-day extension of coverage or right of conversion.

Subpart G—Definition of Family Member

§ 873.701 Definition of family member.

For the purposes of this part, the terms "spouse" and "child" shall mean a spouse and unmarried dependent child within the meaning of these terms under the definition of "family member" under 5 U.S.C. 8701(d).

§ 873.702 Proof of dependency.

(a) A child is considered to have been dependent on an employee or former employee if he/she is:

(1) A legitimate child,

(2) An adopted child,

(3) A stepchild or recognized natural child who lived with the employee or former employee in a regular parent-child relationship,

(4) A recognized natural child for whom a judicial determination of support had been obtained, or

(5) A recognized natural child to whose support the employee or former employee made regular and substantial contribution.

(b) The following are examples of proof of regular and substantial support. More than one of the following proofs may be required to show support.

(1) Evidence of eligibility as a dependent child for benefits under State or Federal programs,

(2) Proof of inclusion of the child as a dependent on the employee's or former employee's income tax returns,

(3) Canceled checks, money orders, or receipts, for periodic payments from the employee or former employee for or on behalf of the child,

(4) Evidence of goods or services which show regular and substantial contributions,

(5) Any other evidence which the Office of Federal Employees' Group Life Insurance shall find to be sufficient proof of support or of paternity or maternity.

(c) The Office of Federal Employees' Group Life Insurance may deny an individual coverage as a dependent child, if:

(1) Evidence shows that the employee or former employee did not recognize the child as his/her own despite a willingness to support the child, or

(2) Evidence calls the child's paternity or maternity into doubt, despite the employee's or former employee's recognition and support of the child.

(d) For the purposes of an employee's election of family optional insurance upon the acquisition of a child, as provided in § 873.205, the employing agency shall base any requisite determination of dependency on the criteria expressed in paragraphs (a), (b), and (c) of this section.

§ 873.703 Child incapable of self-support.

(a) Upon receipt of a claim for family optional insurance in the event of death of a child over the age of 21 years, the Office of Federal Employees' Group Life Insurance shall determine, on the basis of such evidence as it deems necessary, whether the deceased child was incapable of self-support because of a mental or physical disability which existed before becoming 22 years of age.

(b) In the event of an employee's election of family optional insurance under § 873.205, where the opportunity to elect is based solely on the acquisition of a child over age 21, the employee shall submit to the employing office at the time of filing the election, a certificate of the physician that the child is incapable of self-support because of a physical or mental disability which existed before the child became 22 years of age, and can be expected to continue for more than 1 year. The certificate shall include a statement of the name of the child, the nature of his/her disability, the period of time it has existed, and its probable future course and duration. The certificate shall be signed by the physician and show his/her office address.

(5 U.S.C. 8716)

[FR Doc. 80-40201 Filed 12-23-80; 8:45 am]

BILLING CODE 6325-01-M

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5 CFR Part 890

Federal Employees Health Benefits Program; Enrollee Deductibles

AGENCY: Office of Personnel Management.

ACTION: Interim Regulations with comments invited for consideration in final rulemaking.

SUMMARY: The Office of Personnel Management (OPM) is amending its

Federal Employees Health Benefits (FEHB) regulations to add a new paragraph pertaining to enrollee deductibles. This action is necessary to correct an inequity which can occur after an employee changes health benefits plans during the FEHB open season.

DATES: Effective date: January 1, 1981, and until final regulations are issued. Comment Date: March 2, 1981.

ADDRESS: Send or deliver written comments to Craig B. Pettibone, Director, Office of Pay and Benefits Policy, Compensation Group, Office of Personnel Management, P.O. Box 57, Washington, D.C. 20044.

FOR FURTHER INFORMATION CONTACT: Lauretta Hall, Issuances and Instructions Staff, (202) 632–4684.

SUPPLEMENTARY INFORMATION: Pursuant to section 553(d)(3) of title 5, U.S.C., the Director finds that good cause exists for making this amendment effective in less than 30 days, in order to give immediate and timely effect to a provision which corrects an inequity which can occur after an employee changes health benefits plans during an open season.

Under certain circumstances, an employee may be required to meet two deductibles during a calendar year before covered expenses may be reimbursed by the health benefits plan in which he/she is enrolled. This occurs mainly when an employee changes plans during the open season and incurs covered expenses subject to a deductible during the first few days of January, before his/her open season enrollment change becomes effective. Less than one percent of enrollees who change plans during the open season encounter this problem. However, it does give rise to complaints from those affected by it, who claim that the requirement to meet two deductibles in a calendar year is unfair.

Section 8902 of title 5, U.S.C., provides that each contract under the FEHB Program shall be for a uniform term of at least one year. Currently, health benefits contracts are negotiated to cover the period from January 1 through December 31 of a given year and the benefits are made available to cover an enrollee and eligible family members, if any, from Janaury 1. For calendar year 1981, there will be 121 plans under the FEHB Program offering various benefit packages. The two Government-wide plans, a number of the employee organization plans, and a few of the comprehensive plans currently offer benefit packages with certain annual deductibles which are directly related to the contract year. The maximum deductible for these plans is $150 for certain high options and $200 for certain low options.

If an individual is enrolled in a plan which has a deductible on January 1 (the beginning of a contract year), he/she must meet that plan's deductible, before receiving member benefits. If an individual's enrollment is transferred during the contract year from one plan to another plan with a deductible, he/she must also meet the new plan's deductible before receiving member benefits. To correct this inequity, OPM is amending its regulations to require that when an enrollee changes plans during an open season and his/her open season change becomes effective after January 1, any covered expenses incurred from January 1 to the effective date of the open season change shall count toward the deductible of the losing carrier for the prior year, or, if the covered expenses are in excess of the carrier's deductible or family limit for deductibles, the enrollee (or eligible family member) shall be eligible for reimbursement at the losing carrier's prescribed rate. The change made by this amendment shall apply only in *timely* filed open season changes. It shall *not* apply in cases of belated open season changes or any other permissible changes made during a contract year.

OPM has determined that this is a significant regulation for the purposes of E.O. 12044.

Office of Personnel Management.

JoAnn B. Platter,

Assistant Issuance System Manager.

Accordingly, OPM is adding a new § 890.201(a)(10), Title 5, Code of Federal Regulations, as set out below:

Subpart B—Health Benefits Plans

§ 890.201 Minimum standards for health benefits plans.

(a) * * *

(10) Provide that when an employee or annuitant changes enrollment from one health benefits plan which has an annual deductible to another plan with a deductible during an open season and his/her open season change becomes effective after January 1, any covered expenses incurred from January 1 to the effective date of the open season change shall count toward the deductible of the losing carrier for the prior year. If covered expenses for the prior year exceeded the losing carrier's deductible or family limit on deductibles, the enrolled employee or annuitant (and his/her eligible family members) shall be eligible for reimbursement of covered expenses, incurred during the current year, by the losing carrier based on contractual obligations for the current contract year. Reimbursement of covered expenses shall apply only to covered expenses incurred from January 1 to the effective date of the enrolled employee's or annuitant's open season change. This amendment shall apply only in *timely* filed open season changes. It shall *not* apply in belated open season changes or any other permissible changes made during a contract year.

* * * * *

(5 U.S.C. 8913)

[FR Doc. 80-40491 Filed 12-29-80; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 2

Revision of Delegations of Authority

AGENCY: Department of Agriculture.

ACTION: Final rule.

SUMMARY: This document revises the delegations of authority from the Secretary and General Officers of the Department to assign functional responsibilities under the Swine Health Protection Act.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: John C. Frey, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Washington, D.C. 20250 (202–447–5335 or 301–436–6466).

SUPPLEMENTARY INFORMATION: The delegations of authority by the Secretary and General Officers are being amended to provide that the Assistant Secretary for Marketing and Transportation Services and the Administrator, Animal and Plant Health Inspection Service, are responsible for administering the provisions of the Swine Health Protection Act. The Act, which will regulate the feeding of garbage to swine, is considered necessary to prevent outbreaks of Hog Cholera and African Swine Fever. The Department believes this delegation conforms to the mission of APHIS, and that this specific delegation will enable the Agency to serve the public more efficiently. This rule relates to internal agency management and, therefore, pursuant to 5 U.S.C. 553 it is found upon good cause that notice and other public procedures with respect thereto are impractical and contrary to the public interest, and good cause is found for making this rule effective less than 30 days after its publication in the **Federal Register.** Further, since this rule relates to internal agency management, it is exempt from

the provisions of E.O. 12044, Improving Government Regulations, and, thus, does not require the preparation of a regulatory impact analysis. Accordingly, 7 CFR Part 2 is amended as follows:

Subpart C—Delegations of Authority to the Deputy Secretary, the Under Secretary for International Affairs and Commodity Programs, Assistant Secretaries, and the Director of Economics, Policy Analysis and Budget

1. Section 2.17 is amended by adding a new paragraph (b)(34) to read as follows:

§ 2.17 Delegation of authority to the assistant secretary for marketing and transportation services.

* * * * *

(b) * * *

(34) The Swine Health Protection Act (Pub. L. 96–468, 94 Stat. 2229 (7 U.S.C. 3801–3812)).

* * * * *

Subpart F—Delegations of Authority by the Assistant Secretary for Marketing and Transportation Services

2. Section 2.51 is amended by adding a new paragraph (a)(35) to read as follows:

§ 2.51 Administrator, Animal and Plant Health Inspection Service.

(a) * * *

(35) The Swine Health Protection Act (Pub. L. 96–468, 94 Stat. 2229 (7 U.S.C. 3801–3812)).

(5 U.S.C. 301 and Reorganization Plan No. 2 of 1953)

For Subpart C:

Dated: December 22, 1980.

Bob Bergland,

Secretary of Agriculture.

For Subpart F:

Dated: December 22, 1980.

Jerry C. Hill,

Deputy Assistant Secretary for Marketing and Transportation Services.

[FR Doc. 80-40462 Filed 12-29-80; 8:45 am]

BILLING CODE 3410-01-M

Food and Nutrition Service

7 CFR Parts 271 and 272

[Amendment Number 187]

Food Stamp Act of 1977: Complaint Procedures

AGENCY: Food and Nutrition Service, USDA.

ACTION: final rule.

SUMMARY: This final rulemaking sets forth State agency procedures for handling complaints about the operation of the Food Stamp Program. These procedures were developed to assure that mechanisms to accept and resolve complaints exist, while not imposing burdensome Federal regulatory requirements on State agencies.

EFFECTIVE DATE: These rules are effective December 30, 1980, and must be implemented by State agencies no later than June 29, 1981.

FOR FURTHER INFORMATION CONTACT: Larry R. Carnes, Policy and Regulations Section, Program Standards Branch, Program Development Division, Family Nutrition Programs, Food and Nutrition Service, USDA, Washington, D.C., 20250. (202) 447–9075.

The final Impact Statement describing the options considered in developing this final rule and the impact of implementing each option is available on request from the above named individual.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been classified "not significant."

On April 10, 1979, the Department published a comprehensive proposal concerning the implementation of a State Complaint Procedure. The Department invited public scrutiny of that proposal and encouraged detailed written criticism and comment.

This preamble discusses both the basis and reasons for the significant changes made from the April 10 proposal. A total of 94 comment letters were received concerning the proposed complaint procedure. The Department gave careful consideration to all the comments made.

General Scope

Regulations currently provide for specific procedures to handle discrimination complaints and fair hearings to handle complaints concerning eligibility and level of benefits for specific households.

The proposed regulations were designed to assure that some system also existed to handle other complaints, such as complaints on delays in processing or on general service to participants.

Sixty-four commenters, including 3 regional offices and 5 State agencies, favored the concept of a formalized complaint system. Eighteen commenters opposed the concept of a formalized complaint system for reasons of increased burden on State agencies and project areas, increase in staff, and increases in administrative funding. Those opposed include 1 regional office, 11 State agencies and 5 local agencies. Four State agencies suggested that the entire section on the complaint regulations be deleted.

After analyzing the comments, the Department concurs with those commenters who believed that many of the specific requirements of the proposed rules represented an unnecessary degree of Federal regulation and unnecessarily limited State flexibility. The type of Federal requirements that are necessary in connection with fair hearings, in order to assure basic due process rights in determinations affecting a household's eligibility or benefit levels, are not really appropriate in this area. As a result, the final rules remove nearly all such requirements. The final rules require that States have a system for accepting complaints, resolving them in an appropriate manner, and responding to complainants on the outcome. How States choose to do this, and how States inform recipients and potential recipients of the complaint system, will be up to them.

The only other requirement in the final rules is that States analyze records of complaints at least annually and provide information on any patterns of deficiencies, as indicated by what the State found in looking into the complaints, to the Performance Reporting System coordinator.

Virtually all other requirements in the proposed rules have been deleted. The following discussion addresses some of these matters in more detail.

Staffing

The proposed rules required that the State agency designate a person to act as the coordinator of activities relating to complaints. Several of the State agencies opposed or questioned why the Department felt it necessary to designate a person to coordinate activities related to program complaints. These State agencies feel that additional staff is not necessary and that States should be allowed flexibility to coordinate program complaint activities with existing staff especially since funds are not always available to hire additional staff.

Twelve interest groups, one government organization and one participant recommended that a full-time State complaint coordinator be required for all States. The requirement could be waived after the situation is evaluated and it is determined by the State that a full-time coordinator is not warranted.

The Department agrees that States should have flexibility in managing complaints, and that a Federal requirement for a complaint coordinator is not necessary. Therefore, this requirement is not contained in the final rules.

Complaint System

The proposed regulations provided States with two options for administering the complaint system: (1) have all complaints handled at State level; or (2) use a two-tiered system to allow complainants to file a complaint at either the State or the local project area.

As a result of comments received on this section, the section has been deleted and the final regulations provide States with flexibility on this matter. Thirty-two comments were received on the complaint system section. One regional office and 22 interest groups indicated that they prefer the State-agency-level-only system. Two State agencies and one local agency favor the two-tiered system. Three State agencies, two local agencies, three government organizations and 10 interest groups, stated that if the two-tiered system is optional, it should be made clear that the complainant has the option to file at either the State or local level. The majority of the interest groups feel that the two-tiered system would be confusing to complainants and that many complainants would be reluctant to file complaints at the project area level. There was also concern among interest groups that local project areas may not provide satisfactory resolution of complaints.

The Department believes this is an area where Federal requirements may prove cumbersome, and where the proposed rules contained too much regulatory detail. The Department has decided to allow State agencies to determine how to structure their own complaint systems.

Filing Complaints

Thirty-five comments were received on this section. The most significant comments on this section concern the proposed time standards for filing complaints. Twenty-seven commenters recommended that the time standard be lengthened to 90 days—consistent with the time allowed for filing for fair hearings, or 180 days—consistent with the time allowed for discrimination complaints or for incidents occurring within a certification period. One regional office, two State agencies and one local agency recommended that the time standard be shortened to 30 days or less. One regional office supports the 60-day time standard. Here again the Department believes that specific federally prescribed time standards are not necessary, and that States should be afforded flexibility to handle individual complaints in an appropriate and timely manner.

Some of the public interest groups indicated that it should be made clear that complaints can be filed by groups and organizations acting on behalf of a complainant or on their own behalf, as one interest group suggested. This was the intent of the Department, and is clarified in the final rule.

Publicizing the complaint procedures

Twenty-eight comments were received on proposed requirements for publicizing addresses and phone numbers for filing complaints. Most comments were from public interest groups, a number of whom recommended that States be required to include the address and phone number of the complaint system on all applications and program notices.

The Department believes that such a requirement is not necessary, and could increase Federal and State printing costs. Moreover, the Department believes that the complaint procedures are not appropriate for Federal requirements of this sort.

As noted, some commenters questioned the need for the detailed Federal requirements contained in the proposed rules. While the final rules do require that State agencies have some method for making information on the complaint system available, the rules do not contain specific Federal requirements regarding how this must be done. The Department believes that State agencies should be provided flexibility to determine how best to publicize the particular complaint systems which they choose to establish.

Receipt of Complaints

The section on Receipt of Complaints received 34 comments, with the majority of commenters indicating a desire for the complainant to have the option of having the complaint processed by the fair hearing and/or the complaint procedures. Several of the interest groups indicated that complainants may be reluctant to use the fair hearing procedures for fear of retaliation. Also, it is believed that some complaints, considering the nature of the complaint, could be more adequately resolved if they were handled by both systems concurrently.

One State agency indicated that State agencies should have the authority to resolve complaints concerning level of benefits, eligibility, a denial or termination through the complaint system and that the complainants should be advised of their rights to a fair hearing. One government organization stated that only complaints which cannot be resolved to the complainant's satisfaction by a phone call to the local office should be processed through the fair hearing system.

One regional office and three interest groups recommended that the complaint officer accept hearing requests and that the day the complaint is filed be considered day one for the purpose of the fair hearing timeliness standard.

It is not the Department's intent that complaint procedures replace or be consolidated with fair hearing procedures, which are mandated by law. The final rules make clear that States need not handle under their complaint system any matter that can be addressed through a fair hearing. Beyond this, the final rules contain no further requirements in this area. Existing program regulations already require that households be notified of their right to a fair hearing in the event of disagreements over eligibility or benefit determinations.

Documentation of Complaints

The section on Documentation of Complaints prompted 15 comments, the majority of which were from interest groups. It was recommended by 3 interest groups and 2 government organizations that all complaints received be acknowledged by the complaint official sending a copy of the complaint record to the complainant. This acknowledgement should let the complainant know that the complaint was actually filed, that the complaint was described correctly in the record and when to expect corrective action. It was also recommended by 9 interest groups that reference to the State's manual which corresponds with a particular complaint be part of the complaint documentation. These recommendations were not adopted. The final rules require the State agency to respond to the complainant on the resolution of the complaint. The Department believes that additional Federal requirements are not appropriate. Those provisions of the proposed regulations regarding specific information States must take down regarding each complaint are removed as unnecessary. This is in keeping with the Department's decision to allow States flexibility to determine how to set up their complaint systems.

Minimum State Agency Requirements for Handling Program Complaints

One regional office, one State and 18 interest groups felt that the proposed 60-day time standard for notifying the complainant of actions taken or planned was too long. One regional office supported the 60-day time standard and two interest groups felt that the response time and implementation of corrective action on complaints from farmworkers/migrants should be shortened. The Department has removed this standard from the final rules, in accordance with its general determination that State Complaint Systems is not an area where so many specific Federal standards should be imposed. The Department encourages States to act expeditiously in resolving complaints.

Analysis of Complaints

There were 10 comments on the proposed requirement for a semi-annual analysis of complaint findings and records. Nine of the commenters, all interest groups supported this concept and one State agency opposed it. The Department does believe that States should use all available sources of information to identify deficiencies in State operations and has retained a requirement for an analysis of complaint records. However, the final rules require that the analysis only be done annually, and remove some of the detail in the proposed rules regarding the analysis.

Implementation

These final rules are effective upon publication. State agencies must implement these rules no later than 180 days after publication. This will assure State agencies adequate time to implement the new procedures during a period when other changes in the food stamp program are also being made.

Accordingly, Parts 271 and 272 of 7 CFR are amended as set forth below.

PART 271—GENERAL INFORMATION AND DEFINITIONS

1. Section 271.6 is amended by adding paragraph (a), (previously reserved), to include the following provisions:

§ 271.6 Complaint procedure.

(a) *State Agency Responsibility.* (1) *General Scope.* The State agency shall maintain a system of its choosing for handling program complaints filed by participants, potential participants, or other concerned individuals or groups. This shall not include complaints alleging discrimination on the basis of race, sex, age, religious creed, national origin, political beliefs or handicap; such complaints shall be handled in accordance with § 272.7. This procedure also need not include complaints that can be pursued through a fair hearing. Complaints regarding such areas as processing standards and service to participants and potential participants would generally be handled under this complaint procedure.

(2) *Minimum requirements.* The State agency shall follow up on complaints, resolve complaints and take corrective action where warranted, and respond to the complainant on the State agency's disposition of the complaint. The State agency shall make information on the complaint system and how to file a complaint available to participants, potential participants and other interested persons. The State agency may make the information available through written materials or posters at certification offices or other appropriate means.

(3) *Complaint analysis.* The State agency shall maintain records of complaints received and their disposition, and shall review records at least annually to assess whether patterns of problems may be present in local offices, project areas, or throughout the State. The results of this review shall be provided to the Performance Reporting System coordinator for appropriate action, and for inclusion, if appropriate, in the State Corrective Action Plan in accordance with § 275.16 of this Chapter. The information provided to the Performance Reporting System Coordinator shall include the identification, if any, of potential or actual patterns of deficiencies in local offices, project areas, or throughout the State, and any identification of causes of these problems.

(4) *Monitoring.* FNS shall monitor State compliance with these requirements through the Performance Reporting System.

PART 272—REQUIREMENTS FOR PARTICIPATING STATE AGENCIES

1. In subsection 272.1, a new subparagraph (25) is added to paragraph (g) of that subsection to read as follows:

§ 272.1 General terms and conditions.

* * * * *

(g) *Implementation.* * * *

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(25) Amendment 187. State agencies shall implement the complaint procedures required by § 271.6(a) no later than 180 days following publication of final regulations.

(91 Stat. 958 (7 U.S.C. 2011–2027))

(Catalog of Federal Domestic Assistance Programs No. 10551, Food Stamps)

Dated: December 19, 1980.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services.

[FR Doc. 80-40257 Filed 12-29-80; 8:45 am]

BILLING CODE 3410-30-M

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7 CFR Part 277

[Amdt. No. 188]

Payment of Certain Administrative Costs of State Agencies

AGENCY: Food and Nutrition Service.

ACTION: Final rulemaking.

SUMMARY: This final rulemaking sets forth requirements for payment of certain administrative costs of State agencies which operate the Food Stamp Program, and the Food Distribution Program and the Food Stamp Program on Indian Reservations, under the authority of the Food Stamp Act of 1977, as amended.

EFFECTIVE DATE: December 29, 1980.

FOR FURTHER INFORMATION CONTACT: Raymond A. Pugh, Sr., Deputy Administrator for Financial Management, Food and Nutrition Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447–3545. The Final Impact Statement describing the options considered in developing this final rule and the impact of implementing the rule is available from William E. Mothorpe, Director, State Financial Control Division, Food and Nutrition Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447–8275.

SUPPLEMENTARY INFORMATION: This final action has been reviewed under U.S. Department of Agriculture (USDA) procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044 and has been classified as not significant.

Introduction:

In order to decrease fraud and abuse in the Food Stamp Program and to encourage participation in the Program by Indians residing on reservations, Congress made a number of changes in the administrative funding formulas formerly used to reimburse State agencies for operation of the program under the Food Stamp Act of 1964. The Food Stamp Act of 1977, Sections 16(a) and 16(c), provides for increasing the Federal reimbursement rate for State administrative costs associated with investigations, prosecutions, and fraud hearings; increasing the reimbursement rate for State agency administrative costs from

50 percent to 60 percent when the States' cumulative allotment error rates with respect to eligibility, overissuance, and underissuance, as calculated in the Quality Control Program, are less than five percent; and allowing for an increase in the Federal share of administrative costs for Program operations on Indian reservations to a level determined by the Secretary to be necessary for effective operation of the program.

The Food Stamp Act Amendments of 1980 (Pub. L. 96–249: May 26, 1980) subsequently increased the number of enhanced funding levels available for low error rates. These changes will allow 65, 60, or 55 percent funding levels based on error rates for participating households, negative error rates for improperly denied households, and the reduction of the State's error rate. Since negative error rates must be included prior to any consideration of payment of enhanced funding, data on this aspect of program operations must be developed and analysis performed to establish the basis for such funding. Because of anticipated public interest, provisions implementing these portions of the Food Stamp Act Amendments of 1980 were published as proposed rules on October 3, 1980 (45 FR 65932) to allow for public comments.

The Food Stamp Act Amendments of 1980 also provided for a higher rate of Federal Financial Participation (FFP) for the acquisition and development of automatic data processing and information retrieval systems. The Amendments provide for 75 percent FFP for these costs, effective October 1, 1980. The Department will issue proposed regulations on this provision to encourage public comment and participation in the development of standards to be used by FNS in determining which costs or systems projects will be covered by the higher federal funding.

On November 9, 1979 (44 FR 65318), the Department published proposed State Plan of Operation rules which included provisions concerning the necessary revisions to the Regulations which define the area and content of administrative funding, formerly 7 CFR Part 275, subsequently changed to Part 277. In addition, in emergency final rulemaking the Department issued Regulations on August 10, 1979 (44 FR 47037) which implemented the provisions for increasing the share of Federal reimbursement for investigation and prosecution of fraud cases from 50 percent to 75 percent. Comments were solicited on this rulemaking as well as on the remainder of Part 277.

The majority of the language in Part 277 was formerly in place as Part 275 and, in turn, was derived from two major Federal Management Circulars (FMCs), FMC 74–4, issued originally by the General Services Administration, but now under the Office of Management and Budget (OMB), and OMB Circular A–102. During the comment period, the Department received 65 letters in response to both the emergency final rulemaking on § 277.15, published August 10, 1979, and the proposed rulemaking for Part 277, published November 9, 1979. Some of the respondents submitted separate comments on each of the two proposals, which resulted in receipt of 65 comment letters from 55 organizations. Twenty-two State welfare agencies, 14 local welfare agencies, 1 public interest group, 5 other government agencies, and 13 letters from our Regional Offices were received. In light of the comments received, the Department made various changes, primarily clarifying details of funding procedures. However, no comments were received on a majority of the proposal. Therefore, significant portions are unchanged from the proposed rulemaking.

In addition, § 277.14, Procurement Standards, has been rewritten since the November 9, 1979 proposal to conform to the requirements of the revised Attachment O to OMB Circular A–102. Also, a new § 277.17 has been added since the November 9 publication, incorporating Attachment P of OMB Circular A–102, Audit Requirements. Since Attachments O and P were both the subject of notice and comment rulemaking and both were adopted without substantial change by FNS, it was not deemed necessary for these parts to be proposed again prior to final publication.

Funding (Part 277.4)

The Food Stamp Act of 1977 required major changes from regulations which previously provided for Federal reimbursement for 50 percent payment of all allowable administrative cost incurred by State agencies. Section 16 of the Act provided for reimbursing specific areas of administrative costs incurred by State agencies at a rate higher than 50 percent. Under this section of the Act, the Department was directed to increase the Federally funded share of a State agency's administrative costs to 60 percent if the State agency's cumulative allotment error rate was less than five percent with respect to basic Program eligibility, overissuance and underissuance as determined by quality control and FNS validation reviews conducted in accordance with § 275.23. The proposed rules issued on November 9, 1979, included a provision to implement this Section of the Act. However, the 1980 Amendments to the Food Stamp Act, Pub. L. 96–249, changed the enhanced funding provisions. This law, signed on May 26, 1980, raised the possible reimbursement rate to 65 percent but also directed that the reimbursement at this higher level be based on cumulative allotment error rates *and* error rates in negative case actions.

As pointed out above, the Department proposed rules regarding these issues in the October 3, 1980 **Federal Register.** The comment period on these proposed rules has just recently closed. Because the comments have not been fully analyzed yet, it is unclear what the final rule on these issues will be. Therefore, the paragraph in § 277.4 of this final rulemaking pertaining to enhanced funding has been reserved. It will be added when final rules on the Quality Control Sanction and Incentive Systems are issued in the near future.

Section 16(a) of the Food Stamp Act of 1977, as amended, authorized the Secretary to pay 75 percent of the costs of State Food Stamp Program investigations and prosecutions. Section 277.4 allows for this increased funding level. The increased funding for this function is discussed in greater detail in § 277.15 of the final Regulations. Section 277.4 also makes changes in the reimbursement of administrative costs of State agencies administering the Program on Indian reservations. The details of this increased rate are discussed in Parts 281 and 282.

A total of sixteen comments were received which specifically addressed this Section. These comments were directed at the revised reimbursement rate. Additional comments were received which dealt with the specifics of the 75 percent funding for investigations and prosecutions. These comments are discussed further under § 277.15. Comments on § 277.4 included four which expressed the view that since State quality control reviews and recipient claim sections both contributed to the successful completion of fraud cases, both of these functions should be made eligible for the higher rate of Federal reimbursement.

The Department believes that quality control reviews are normal, ongoing program activities required of the State agency. The primary purpose or objective of such reviews is not the detection of fraud, although that may be disclosed, but rather to determine the quality of the certification activity conducted by the State. While the reviews may consequently provide

information needed for investigations and prosecutions, the reviews themselves cannot be said to be directly related to the investigation and prosecutive activities discussed in the legislative history. In regard to the comments relating to the eligibility of personnel engaged in recipient claims activities, we felt that a distinction must be made between claims which are established and maintained by eligibility workers (EWs) in the normal completion of their job duties and those which are handled by a unit expressly established for that function. Again returning to Congressional intent, we believe that establishing and maintaining claims is part of the normal duties of the EW and should not be eligible at the higher rate. A separate claims section which is an adjunct to an investigative and/or prosecutive unit would qualify at the higher rate.

However, we have added a provision that allows for an exception in the case of certain EWs whose principal function during some portion of their workweek is as an investigator. Section 277.15 has been revised to specifically require that only employees whose State or local job title is "investigator" are to be claimed at the higher rate. The exception to this requirement was added to allow for the higher payment in those counties or local jurisdictions whose caseload is not large enough to warrant a separate full-time investigator, but, nevertheless must routinely employ some member of their staff in an investigative capacity. Exceptions shall be granted by the FNS Regional Financial Management Officer based on an application for the exception by the county or local jurisdiction. Time sheets or time records must be used to substantiate any such exception.

Administrative Costs Principles (Section 277.9)

Five comments were received specifically addressing the present situation in which the Department cannot be charged for costs associated with the certification for Food Stamps for those households participating in the Aid to Families with Dependent Children (AFDC) Program. Two States were under the mistaken impression that this was a change and that such costs are currently being charged to the Department. This is not the case. Such charges have been allocated to the AFDC Program since the inception of the Food Stamp Program. This ongoing practice of allocating such charges to DHEW (now the Department of Health and Human Services) is contained in § 277.9. Since the cost of determining the eligibility of AFDC cases is not a charge to FNS, the enhanced funding for low error rates is also clearly not applicable to such costs.

Discussions are currently underway between the Department and the Department of Health and Human Services to more clearly define this area. These discussions may result in a need for some modification of this aspect of these regulations at a subsequent date. Pending any such modifications, the existing practice (as reflected in § 277.9) shall remain in effect.

Food Stamp Investigations and Prosecutions (Section 277.15)

Fifty-four comments were received on this section, 46 of which were received in response to the interim final publication of this section on August 10, 1979. The comments were most positive and supportive of the concept of enhanced funding for Food Stamp fraud investigations, prosecutions, and fraud hearings. However, most of the comments received indicated a desire for further clarification of the funding process. Commenters from both State and Federal agencies requested that additional information be provided to identify what constitutes allowable activities for enhanced funding. A primary concern was handling anti-fraud activities which cross program lines and which are part-time functions of eligibility workers. Various comments also indicated that further clarification was needed on procedures to provide enhanced funding to agencies other than State welfare agencies that are involved in fraud investigations. Two State agencies and two Regional Offices recommended that there be a requirement for the establishment of a contractual relationship between all providers of services and State agencies.

The reference in the preamble, as published August 10, 1979, regarding establishing minimum professional standards, produced varied comments. Three local agencies and one Regional Office recommended that the regulations establish qualification standards for investigative employees. Two State agencies recommended that the establishment of qualification standards be left to the State agencies. One State agency questioned the authority of the Secretary to impose qualification standards. Another State agency recommended that the regulations define minimum functions to be performed by investigators rather than minimum standards. In light of the many questions and comments relating to the areas of coverage of the enhanced funding, we have revised the langauge of that part of the section which relates to allowable costs. This revision now deals with those cost item in a manner similar to other allowable charges; that is, as direct and indirect charges for activities relating specifically to the function. The requirements in Appendix A of this Part 277 are now specifically referenced to this section, rather than making references in the section to certain indirect and support costs which are eligible for the enhanced funding.

In addition, we have specified that only those investigative activities related to workers whose State or local job title is "investigator" or similar, would be eligible for the enhanced funding. Accepting the fact that certain jurisdictions would not have a full-time investigator, allowances are made for part-time activity. In addition, an exception to the use of the State and local job title/description is included so that if the majority of the duties include investigations, the cost of this activity may be allowable at the 75 percent rate when approved by FNS. This action places the decision of allowable activities on the State or local civil service requirements for the investigation/prosecution function, rather than attempting to define the duties or mandatory qualifications on a national level for the enhanced funding. We believe that the State agency is in a better position to define its own needs in this area and we believe that current wording will allow for this.

Four comments were received which suggested that there be a requirement for a formal purchase of service agreement or contract between all providers of prosection services and the State or local agency. We have agreed that such a requirement would be beneifical in spelling out the requirement on each party's part and specifically detailing the method to be used for this function. Therefore, the final regulations require that a formal agreement be signed between the State agency and the third party provider of prosecution or investigation services before funding is approved by FNS. Further, the regulations make clear that FNS does not fund such third party providers directly. All funding at the 75 percent level will go from FNS to the State agency and from the State agency to the service provider under the conditions specified in their formal agreement or contract.

For the reasons set out in the preamble, Part 227 of 7 CFR is amended as set forth below.

Part 277—Payments of Certain Administrative Costs of State Agencies

Part 277 was reserved for administrative cost regulations, formerly designed as Part 275. Sections 277.1—277.9, 277.11—277.15, and 277.17,

formerly reserved, are now added. Sections 277.10 and 277.16, previously issued, are now revised. The new Part 275 supersedes and deletes material formerly designated as § 271.1(h), § 271.2 and Part 275 (including Appendix A). The new Part 277 as added and amended, read as follows:

PART 277—PAYMENTS OF CERTAIN ADMINISTRATIVE COSTS OF STATE AGENCIES

Sec.

Authority: 91 Stat. 958, as amended (7 U.S.C. 2011–2027)

277.1 General purpose and scope.

(a) *Purpose.* This Part establishes uniform requirements for the management of administrative funds provided to State agencies and sets forth principles for claiming costs of activities paid with administrative funds under the Food Stamp Program, and the Food Distribution Program and Food Stamp Program on Indian Reservations.

(b) *Scope and Applicability.* Upon compliance with the provisions of this Part, payments to State agencies will be made for cost(s) incurred for administration of the Food Stamp Program and for administration of the Food Distribution Program on Indian Reservations. To ensure maximum practical uniformity, deviation(s) by a State agency from this Part may be authorized only when necessary to meet program objectives, to conserve program funds, or when essential to the public interest. However, any deviations from this Part must be authorized by the Administrator of FNS.

§ 277.2 Definitions.

For the purpose of this Part the term:

"Accrued Expenditures" means the charges incurred by the State agency during a given period for liabilities incurred, benefits received or for goods and services used during this period.

"Accrued Income" means the net value of earnings during a given period resulting from services and goods provided whether or not payment has been realized.

"Acquisition Cost" refers to nonexpendable personal property acquired by purchase and means the net invoice price of the property including any attachments, accessories or auxiliary apparatus necessary to make the property usable for the purpose for which it was acquired. Ancillary charges such as taxes, duty, protection in-transit insurance, freight or installation shall be included in or excluded from acquisition cost in accordance with the State agency's regular accounting practices.

"Approval or Authorization by FNS" means documentation evidencing consent prior to incurring specific costs.

"Applicable Credits" refer to those receipts or reduction of expenditure-type transactions which offset or reduce expense items allocable to programs as direct or indirect costs. Examples of such transactions are: purchase discounts; rebates or allowances; recoveries or indemnities on losses; sale of publications, equipment, and scrap; income from personal or incidental services; and adjustments of overpayments or erroneous charges.

"Disbursements" refers to the transfer of funds by the state agency to pay for Program costs resulting from purchased or expired goods and services.

"Expendable Personal Property" means all tangible personal property other than nonexpendable property.

"Program Funds" means money, or property provided in lieu of money, paid for or furnished by FNS to a State agency.

"Funds Available to the State Agency" may include contributions from third parties including other Federal agencies.

"In-kind Contributions" refers to the value of noncash contributions. Only when authorized by Federal legislation may property purchased with Federal funds be considered as a State agency's in-kind contribution. In-kind contributions may be for the value of real and/or nonexpendable personal property or the value of goods and services provided specifically to the project or program.

"Nonexpendable Personal Property" means tangible personal property having a useful life of more than one year and an acquisition cost of more than $300 per unit. A State agency may use its own definiton of nonexpendable personal property provided that such definition would at least include all tangible personal property as defined herein.

"Obligations" are the amounts of orders placed, contracts awarded, services received, and similar transactions during a given period which require payment.

"Offset" means a method to recover funds due FNS through use of the Letter of Credit system. Recovery is accomplished by accounting adjustments to increase Federal funds on hand or disbursed.

"OMB" means the Office of Management and Budget.

"Personal Property" means property of any kind except real property. It may be tangible (having physical existence) or intangible (having no physical existence) such as patents, inventions and copyrights.

"Program" means both the Food Stamp Program and the Food Distribution Program on Indian Reservations.

"Program Closeout" means the process by which FNS determines that all applicable administrative and financial processes have been completed by the State agency and FNS terminates the program in the affected project area or areas.

"Project Costs" are allowable costs as set forth in this Part.

"Real Property" means land, land improvements, structure and appurtenances thereto, excluding movable machinery and equipment.

"State Agency" means the organization as defined in 7 CFR Part 271.1.

"State Agency Costs" means the State agency outlays from its funds available for program administration. Unless authorized by Federal legislation, costs charged to other Federal grants or to other Federal contracts may not be considered as State agency costs reimbursable under this authority.

"Subagency" means the organization or person to which a State agency makes any payment for acquisition of goods, materials or services for use in administering the program and which is accountable to the State agency for the use of funds provided.

"Terms and Conditions" means legal requirements imposed by the Federal Government under statute, regulations, contracts, agreements or otherwise.

"Unliquidated Obligation" represents the amount of obligations not yet paid.

"Unobligated Balance" means the portion of the Federal funds authorized less all allowable costs and unpaid obligations of the State agency.

§ 277.3 Budgets and budget revision procedures.

The preparation, content, submittal, and revision requirements for the State Food Stamp Program Budget shall be as specified in § 272.2. The application for funds and budget requirements for the Food Distribution Program on Indian Reservations shall be as specified in § 283.9. State agencies must submit a budget to FNS as part of the State Plan each fiscal year. Upon approval of the budget by FNS, administrative funds will be provided.

§ 277.4 Funding.

(a) *General.* This section sets allowable cost standards for activities of State agencies in administering the Food Stamp Program and Food Distribution Program on Indian Reservations.

(b) *Federal Reimbursement Rate.* The base percentage for Federal payment shall be 50 percent of State agencies' allowable Food Stamp Program administrative costs.

(1) A 75 percent Federal reimbursement of Food Stamp Program allowable costs incurred for State fraud investigations, prosections, and fraud hearings upon presentation and approval of a State Plan Addendum as outlined in § 277.15.

(2) [Reserved.]

(3) Funding of demonstration projects approved by FNS will be at a rate agreed to by FNS in accordance with the requirements outlined in Part 282.

(4) The reimbursement of administrative costs to State agencies administering the program on Indian reservations shall be in accordance with the requirements of Parts 281 and 283.

(5) [Reserved.]

(c) *Matching Costs.* State agency costs for Federal matching funds may consist of:

(1) Charges reported on a cash or accrual basis by the State agency as project costs.

(2) Project costs financed with cash contributed or donated to the State agency by other non-Federal public agencies and institutions.

(3) Project costs represented by services and real or personal property donated by other non-Federal public agencies and institutions.

(d) All cash or in-kind contributions except as provided in paragraph (e) of this section shall be allowable as part of the State agency's share of program costs when such contributions:

(1) Are verifiable;

(2) Are not contributed for another federally-assisted program, unless authorized by Federal legislation;

(3) Are necessary and reasonable for accomplishment of project objectives;

(4) Are charges that would be allowable under this Part;

(5) Are not paid by the Federal Government under another assistance agreement unless authorized under the other agreement and its subject laws and regulations; and

(6) Are in the approved budget.

(e) The value of services rendered by volunteers or the value of goods contributed by third parties, exclusive of the State and Federal agencies, are unallowable for reimbursement purposes under the Food Stamp Program. The value of services rendered by volunteers shall be allowable only to meet any matching administrative costs requirements for the Food Distribution Program on Indian Reservations.

§ 277.5 Methods of payment.

(a) This section sets forth FNS methods for authorizing funds for State agencies.

(b) The "Letter of Credit" (LOC) (SF–1193A) is the document by which an official of FNS authorizes a State agency to draw funds from the United States Treasury. This shall be the preferred method of payment for State agencies which receive at least $120,000 per year and meet the requirements prescribed in OMB Circular A–102, Attachment J.

(c) State agencies shall request payment(s) by submitting Request for Payment on Letter of Credit and Status of Funds Report (Treasury Form SF–183) to the appropriate United States Treasury Regional Disbursing Office with a copy to FNS.

(d) State agencies not meeting the requirements for the LOC method of payment or failing to meet LOC reporting requirements, including those requiring adjustments to cash balances to liquidate amounts owed to FNS, shall be provided funds by Treasury check in accordance with the provisions of Department of the Treasury Circular 1075.

(e) Payments for proper charges incurred by State agencies will not be withheld unless such payments are suspended or disallowed pursuant to § 277.16. When a payment is withheld, payment adjustments will be made in accordance with § 277.16. When FNS collects an indebtedness, whether due to a disallowance or an offset for amounts which the State agency has been billed but which it has failed to pay without cause acceptable to FNS, FNS shall provide reasonable notice to the State agency, and shall require appropriate accounting adjustment to cash balances for which the State agency is accountable to the Federal government to liquidate the indebtedness.

§ 277.6 Standards for financial management systems.

(a) *General.* This section prescribes standards for financial management systems in administering program funds by the State agency and its subagencies or contractors.

(b) *Responsibilities.* Financial management systems for program funds in the State agency shall provide for:

(1) Accurate, current, and complete disclosure of the financial results of program activities in accordance with Federal reporting requirements.

(2) Records which identify the source and application of funds for FNS or State agency activities supporting the administration of the Program. These records shall show authorizations, obligations, unobligated balances, assets, liabilities, outlays and income of the State agency, its subagencies and agents.

(3) Records which identify unallowable costs and offsets resulting from FNS or other determinations as specified in § 277.16 and the disposition of these amounts. Accounting procedures must be in effect to prevent a State agency from claiming these costs under ongoing program administrative cost reports.

(4) Effective control and accountability by the State agency for all program funds, property, and other assets acquired with program funds. State agencies shall adequately safeguard all such assets and shall assure that they are used solely for program authorized purposes unless disposition has been made in accordance with § 277.13.

(5) Controls which minimize the time between the receipt of Federal funds from the United States Treasury and their disbursement for program costs. In the Letter of Credit system, the State agency shall make drawdowns from the U.S. Treasury through a U.S. Treasury Regional Disbursing Office as nearly as possible to the time of making the disbursements.

(6) Procedures to determine the reasonableness, allowability, and allocability of costs in accordance with the applicable provisions prescribed in Appendix A to this Part.

(7) Support and source documents for costs.

(8) An audit trail including identification of time periods, initial and summary accounts, cost determination and allocation procedures, cost centers or other accounting procedures to support any costs claimed for program administration.

(9) Periodic audits by qualified individuals who are independent of those who maintain Federal program funds as prescribed in § 277.17.

(10) Methods to resolve audit findings and recommendations and to follow up on corrective or preventive actions.

(11) [Reserved]

(c) The standards in § 277.6(b) apply to subagencies or contractors involved with program funding.

§ 277.7 Cash depositories.

(a) The term "cash depositories" refers to banks or other institutions which maintain accounts where Food Stamp Program funds are deposited and from which withdrawals are made to meet administrative costs of the State agency.

(b) State agencies are encouraged to use minority owned banks to expand opportunities for minority enterprises.

(c) FNS shall not:

(1) Require physical segregation in a cash depository of program funds from other State agency funds.

(2) Establish any eligibility requirements for cash depositories in which program funds are deposited by the State agency.

§ 277.8 Bonding and insurance.

(a) *General.* In administering FNS program funds, State agencies shall observe their regular requirements and practices with respect to bonding and insurance. FNS will not impose additional bonding and insurance requirements, including fidelity bonding, above those normally required by the State agency.

(b) *Loan Guarantees.* FNS makes no guarantee of any loan or payment of money borrowed by a State agency for administering the program. State agencies shall not make any assurances to any lender or contractor that FNS will furnish funds for loan payments.

§ 277.9 Administrative costs principles.

(a) This section prescribes specific policies and procedures governing State agencies for funding under this Part.

(b) Any cost related to determining the Food Stamp eligibility of AFDC cases shall be included as part of the AFDC determination costs and claims. They are not allowable costs for FNS reimbursement.

(c) When costs for administering the program are claimed for reimbursement, the audit trail must identify the specific activities, locations, or time periods as defined in this section.

(1) *Direct Cost.* Allowable direct costs may be charged to the Food Stamp Program at the 50 percent or higher funding level as specified in this part.

(2) *Indirect Cost.* Allowable indirect costs may also be claimed at the 50 percent or higher reimbursement funding level as specified in this Part and Appendix A.

(3) Direct and indirect costs claimed for program cost reimbursement must be incurred for the time periods, the activities or for the locations for which the rates are approved by FNS.

(d) All State agency Cost Allocation Plans for determining the costs of administering the program must be approved by the cognizant Federal agency. All Cost Allocation Plans involving program funds shall be submitted to FNS for review.

§ 277.10 Program income.

(a) Program income is gross income resulting from activities financed with program funds. Such earnings exclude interest income but include income from service fees, usage or rental fees, sale of assets purchased with program funds, and royalties on patents and copyrights.

(b) Interest earned on advances of program administrative funds shall be remitted to FNS except for interest earned on advances to States or instrumentalities of a State as provided by the Intergovernmental Cooperation Act of 1968 (Pub. L. 90–577) and advances to tribal organizations under the Indian Self-Determination Act (Sections 102–104).

(c) Income resulting from the sale of real and personal property whose acquisition cost was borne in whole or in part with Program funds shall be remitted to FNS or applied to the Federal share of current program costs in accordance with §277.13. All other sales proceeds will be handled in accordance with § 277.13.

(d) Unless there is a prior agreement between FNS and the State agency, the State agency shall have no obligation to FNS with respect to royalties received from copyrights or patents produced as a result of activities financed with program administrative funds.

(e) Any other income earned under activities supported by program administrative funds may be retained by the State agency if they are deducted from the gross program administrative costs for the purposes of determining net costs and FNS's share of net cost.

(f) State agencies shall record the receipt and expenditure of revenues such as taxes, special assessments, levies, fines, etc., as a part of program fund transactions when such revenues are specifically earmarked for program fund projects.

§ 277.11 Financial reporting requirements.

(a) *General.* This section prescribes requirements for the State agencies to report financial information to FNS.

(b) *Authorized Forms and Instructions.* (1) Only forms specified by this Part, or other forms authorized by FNS, may be used for obtaining financial information from State agencies for the program.

(2) All instructions for use in connection with the form specified in § 277.11(c) shall be followed. FNS may prescribe supplementary instructions.

(3) State agencies shall submit the original and two copies of forms required by this section unless FNS approves a waiver of this requirement.

(4) The forms and instructions in this Part shall be available to the State agency and to the public upon request to FNS Regional Offices as set out in § 271.6(b).

(c) *Financial Status Report.* (1) *Form.* State agencies shall use the standard Financial Status Report (Form SF–269) to report program costs.

(2) *Freqency.* The report (Form SF–269) shall be required quarterly.

(3) *Exceptions.* Those State agencies that receive payments under the U.S. Treasury check system shall submit to FNS a Quarterly Report of Federal Cash Transactions (Form SF–272).

(4) *Due Dates.* Quarterly reports shall be due April 30 (for the period January–March), July 30 (April–June), October 30 (July–September), January 30 (October–December). Final reports are due December 30 for all completed Federal fiscal years (October 1–September 30) or 90 days after termination of Federal financial support. Requests from State agencies for extension of reporting due dates may be approved, if necessary.

§ 277.12 Retention and custody of records.

(a) *Retention Period.* All financial records, supporting documents, statistical records, negotiated contracts, and all other records pertinent to program funds shall be maintained for three years from the date of submission of the annual financial status report of the relevant fiscal year to which they apply except that:

(1) If any litigation, claim, or audit is started before the expiration of the three-year period, the applicable records shall be retained until these have been resolved.

(2) In the case of a payment by a State agency to a subagency or contractor using program funds, the State agency, USDA, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any book, documents, papers

and records of the subagency or contractor which the State agency, USDA, or the Comptroller General of the United States or any of their duly authorized representatives, determine are pertinent to administration of the specific FNS program funds, for the purpose of making audit, examination, excerpts, and transcripts.

(b) *Restrictions on Public Access.* Unless required by laws, FNS will not place restrictions on State agencies which limit public access to their records or the records of their subagencies or contractors that are pertinent to the administrative funding provided by FNS except when the State agency can demonstrate that such records must be kept confidential and would have been excepted from disclosure pursuant to the Freedom of Information Act (5 U.S.C. 552) if the records had belonged to FNS.

§ 277.13 Property.

(a) *General.* This section prescribes policies and procedures governing title, use, disposition of real and personal property for which acquisition costs were borne, in whole or in part, as a direct charge to FNS funds, and ownership rights or intangible personal property developed, in whole or in part, with FNS funds. State agencies may follow their own property management policies and procedures provided they observe the requirements of this section. With respect to property covered by this section, FNS may not impose on State agencies any requirement (including property reporting requirements) not authorized by this section unless specifically required by Federal laws.

(b) *Nonexpendable Personal Property.* (1) *Title.* Title to nonexpendable personal property whose acquisition cost is borne, in whole or in part, by FNS shall vest in the State agency upon acquisition, and shall be subject to the restrictions on use and dispositions set forth in this section.

(2) *Use.* (i) The State agency shall use the property in the program as long as there is a need for such property to accomplish the purpose of the program.

(ii) When there is no longer a need for the property to accomplish the purpose of the program, the State agency shall use the property where needed in administration of other programs in the following order of priority:

(A) Other federally-funded programs of FNS.

(B) Other federally-funded programs of USDA.

(C) Other federally-funded programs.

(iii) When the State agency no longer has need for such property in any of its federally financed activities, the property may be used for the State agency's own official activities in accordance with the following standards:

(A) If the property had a total acquisition cost of less than $1,000, the State agency may use the property without reimbursement to FNS.

(B) For all such property not covered under paragraph (b)(2)(iii)(A) of this section, the State agency may retain the property for its own use, provided a fair compensation is made to FNS for the FNS share of the property. The amount of compensation shall be computed by applying the percentage of FNS participation in the cost of the property to the current fair market value of the property.

(3) *Disposition.* If the State agency has no need for the property, disposition of the property shall be made as follows:

(i) If the property had a total acquisition cost of less than $1,000 per unit, the State agency may sell the property and retain the proceeds.

(ii) If the property had an acquisition cost of $1,000 or more per unit, the State agency shall:

(A) If instructed to ship the property elsewhere, the State agency shall be reimbursed with an amount which is computed by applying the percentage of the State agency's participation in the cost of the property to the current fair market value of the property, plus any shipping or interim storage costs incurred.

(B) If instructed to otherwise dispose of the property, the State agency shall be reimbursed by FNS for the cost incurred in such disposition.

(C) If disposition or other instructions are not issued by FNS within 120 days of a request from the State agency, the State agency shall sell the property and reimburse FNS an amount which is computed by applying the percentage of FNS participation in the cost of the property to the sales proceeds. The State agency may, however, deduct and retain from FNS's share $100 or 10 percent of the proceeds, whichever is greater, for the State agency selling and handling expenses.

(c) *Transfer of Title to Certain Property.* (1) Where FNS determines that an item of nonexpendable personal property with an acquisition cost of $1,000 or more which is to be wholly borne by FNS is unique, difficult, or costly to replace, FNS may reserve the right to require the State agency to transfer title of the property to the Federal Government or to a third party named by FNS.

(2) Such reservation shall be subject to the following:

(i) The right to require transfer of title may be reserved only by means of an expressed special condition under which funds were authorized for acquisition of the property, or, if approval for the acquisition of the property is given after the funds are awarded, by means of a written stipulation at the time such approval is given.

(ii) The property must be sufficiently described to enable the State agency to determine exactly what property is involved.

(3) FNS may not exercise the right to reserve until the State agency no longer needs the property in the activity for which it was acquired. Such need shall be assumed to end with termination of the activity in which the property was used unless the State agency continues to use the property in other program-related activities after the termination date and demonstrates to FNS a continued need for such use in the program.

(4) To exercise the right, FNS must issue disposition instructions to the State agency not later than 120 days after the State agency no longer needs the property in the activity for which it was acquired. If instructions are not issued within that time, FNS's right shall lapse, and the State agency shall act in accordance with the applicable standards in paragraph (b)(2) and (b)(3) of this section.

(5) The State agency shall be entitled to reimbursement with an amount which is computed by applying the percentages of the State agency's participation in the acquisition cost of the property to the current fair market value of the property, and for any reasonable shipping and interim storage costs it incurs pursuant to FNS's disposition instructions.

(d) *Property Management Standards.* State agencies' property management standards for nonexpendable personal property covered by this section shall include the following procedural requirements:

(1) Property records shall be maintained accurately and provide for:

(i) A description of the property.

(ii) Manufacturer's serial number or other identification number.

(iii) Acquisition date and cost.

(iv) Source of the property.

(v) Percentage of FNS funds used in the acquisition of the property, or sufficient information to be able to compute the percentage, if and when the property is disposed of.

(vi) Location, use and condition of the property.

(vii) Ultimate disposition data including sales price or the method used

to determine current fair market value if the State agency reimburses FNS for its share.

(viii) Trade-in value of any property purchased with Federal funds where their trade-in value reduces the acquisition cost of new property.

(2) A physical inventory of property shall be taken and the results reconciled with the property records at least once every two years to verify the existence, current utilization, and continued need for the property.

(3) A control system shall be in effect to ensure adequate safeguards to prevent loss, damage, or theft to the property. Any loss, damage, or theft of nonexpendable personal property shall be investigated and properly documented.

(4) Adequate maintenance procedures shall be implemented to keep the property in good condition.

(5) Proper sales procedures shall be implemented to keep the property in good condition.

(e) *Expendable personal property.* (1) *Title.* Title to expendable personal property, whose acquisition cost was borne in whole or in part by FNS, shall vest in the State agency.

(2) *Use.* The State agency shall use the property in the program as long as there is a need for such property to accomplish the purpose of the program.

(3) *Disposition.* When there is no longer a need for the property in the program and there is a residual inventory exceeding $1,000 the State agency shall:

(i) Use the property in other federally sponsored projects or programs;

(ii) Retain the property for use on nonfederally sponsored activities; or,

(iii) Sell it.

(4) *Compensation.* FNS must be compensated for its share if the alternative in paragraph (e) (3) (i) of this section is not followed. The amount of compensation shall be computed in the same manner as for nonexpendable personal property.

(f) *Patents and Inventions.* If any program activity produced patents, patent rights, processes or inventions in the course of work aided by FNS, such fact shall be promptly and fully reported to FNS. Unless there is prior agreement between the State agency and FNS on disposition of such items, FNS shall determine whether protection on such invention or discovery shall be sought and how the rights in the invention or discovery—including rights under any patent issued thereon—shall be disposed of and administered in order to protect the public interest consistent with "Government Patent Policy" (President's Memorandum for Heads of Excecutive Departments and Agencies, August 23, 1971), and State of Government Patent Policy as printed in Title 37 CFR, Chapters I and II.

(g) *Copyrights.* When a program activity results in a book or other copyrightable materials, the author or State agency is free to copyright the work, but FNS reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish or otherwise use and to authorize others to use the work for government purposes. This includes copyrights on ADP software as specified in Appendix A.

§ 277.14 Procurement standards.

(a) *General.* This section establishes standards and guidelines for the procurement of supplies, equipment, construction and other services whose cost is borne in whole or in part by FNS program funds. These standards ensure that such materials are obtained in an effective and economical manner and in compliance with the provisions of applicable Federal law and Executive Orders. No additional procurement standards will be imposed by FNS upon State agencies unless specifically required by Federal law, or Executive Orders, or authorized by the Administrator for Federal Procurement Policy, Office of Management and Budget.

(1) These standards do not relieve the State agency of any contractual responsiblities under its contracts. The State agency is responsible, in accordance with good administrative practice and sound business judgment, for the settlement of all contractural and administrative issues arising out of procurements entered into in support of the program. These include but are not limited to sources evaluations, protests, disputes and claims. FNS shall not substitute its judgment for that of the State agency unless the matter is primarily a Federal concern. Violations of laws shall be referred to the local, State or Federal authority having jurisdiction.

(2) State agencies shall use their own procurement procedures provided that procurements paid in whole or in part with FNS program funds meet the standards set forth in this Part.

(b) *Review of Proposed Contracts.* State agencies shall submit proposed contracts and related procurement documents to FNS for preaward review and approval when:

(1) The procurement is expected to exceed $10,000 and is to be awarded without competition or only one bid or offer is received in response to solicitation;

(2) The procurement expected to exceed $10,000 specifies a "brand name" product; or

(3) FNS has determined that the State agency's procurement procedures or operation fails to comply with one or more significant aspects of this section.

(c) *Code of Conduct.* The State agency shall maintain a written code or standards of conduct which shall govern the performance of its officers, employees, or agents engaged in the award and administration of contracts borne in whole or in part with FNS program funds. No employee, officer, or agent of the State agency shall participate in the selection, or in the award or administration of a contract supported in whole or in part by FNS program funds if a conflict of interest, real or apparent, would be involved. Such conflict would arise when:

(1) The employee, officer, or agent;

(2) Any member of his/her immediate family;

(3) His or her partner; or

(4) An organization which employs, or is about to employ, any of the above, has a financial or other interest in the firm selected for award. The State agency's officers, employees, or agents shall neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, potential contractors, or parties to subagreements. State agencies may set minimum rules where the financial interest is not substantial or the gift is an unsolicited item of nominal intrinsic value. To the extent permitted by State or local law or regulations, such standards of conduct shall provide for penalties, sanctions, or other disciplinary actions for violations of such standards by the State agency's officers, employees, or agents, or by contractors or their agents.

(d) *Procurement Procedures.* The State agency shall establish procurement procedures which provide that proposed procurement actions shall be reviewed by State agency officials to avoid the purchase of unnecessary or duplicative items. Consideration should be given to consolidation or dividing the purchase into smaller units, to obtain a more economical purchase. Where appropriate, an analysis shall be made of lease versus purchase alternatives, and any other appropriate analyses, to determine which approach would be the most economical. To foster greater economy and efficiency, State agencies are encouraged to enter into State and local intergovernmental agreements for procurement or use of common goods and services.

(e) *Contracting with Small and Minority Firms, Women's Business Enterprises and Labor Surplus Area*

Firms. (1) It is FNS policy to award a fair share of contracts to small and minority business firms. State agencies must take affirmative steps to assure that small and minority businesses are utilized when possible as sources of supplies, equipment, construction and services. State agency affirmative steps shall include the following:

(i) Including qualified small and minority businesses on solicitation lists.

(ii) Assuring that small and minority businesses are solicited whenever they are potential sources.

(iii) When economically feasible, dividing total requirements into smaller tasks or quantities so as to permit maximum small and minority business participation.

(iv) Where the requirement permits, establishing delivery schedules which will encourage participation by small and minority business.

(v) Using the services and assistance of the Small Business Administration, the Office of Minority Business Enterprise of the Department of Commerce and the Community Services Administration, as appropriate.

(vi) If any subcontracts are to be let, requiring the prime contractor to take the affirmative steps in paragraphs (e)(1)(i) through (v) of this section.

(2) State agencies shall take similar appropriate affirmative action in support of women's business enterprises.

(3) State agencies are encouraged to procure goods and services from labor surplus areas, as defined by the Department of Labor.

(4) FNS shall impose no additional regulations or requirements in the foregoing areas unless specifically mandated by law or Executive order.

(f) *Selection Procedures.* All State agency procurement transactions shall be conducted in a manner that provides maximum open and free competition with this section. Procurement procedures shall not contain features which restrict or eliminate competition. The State agency shall have written selection procedures which shall provide, as a minimum, the following procedural requirements:

(1) Solicitation of offers, whether by competitive sealed bid or competitive negotiation, shall contain a clear and accurate description of the technical requirements for the material, product, or service desired. Descriptions shall not, in competitive procurements, contain features which unduly restrict competition. Descriptions may include a statement of the qualitative nature of the material, product or service desired and, when necessary, shall set forth those minimum essential characteristics and standards to which it must conform if it is to satisfy its intended use. When it is impractical or uneconomical to describe clearly and accurately the technical requirements, a "brand name or equal" description may be used to define the performance or requirements of the material, product or service desired. The specific features of the named brand which must be met by offerors shall be clearly stated. State agencies shall clearly set forth all requirements which offerors must fulfill and all other factors to be used in evaluating bids or proposals.

(2) State agencies shall make awards only to responsible contractors that possess the potential ability to perform successfully under the terms and conditions of a proposed procurement. Consideration shall be given to such matters as contractor integrity, compliance with public policy, record of past performance, and financial and technical resources.

(g) *Procurement Methods.* State agency procurements made in whole or in part with program funds shall be by one of the following methods:

(1) *Small Purchase Procedures* are those relatively simple and informal procurement methods that are sound and appropriate for a procurement of services, supplies, or other property, costing in the aggregate not more than $10,000. State agencies shall comply with State or local small purchase dollar limits under $10,000. If small purchase procedures are used for a procurement under the program, price or rate quotations shall be obtained from an adequate number of qualified sources.

(2) In *competitive sealed bids* (formal advertising), sealed bids are publicly solicited and a firm-fixed-price contract (lump sum or unit price) is awarded to the responsible bidder whose bid, conforming with all the material terms and conditions of the invitation for bids, is lowest in price.

(i) In order for the State agency to use this method of procurement the following conditions, as a minimum, must prevail:

(A) A complete, adequate, and realistic specification or purchase description is available.

(B) Two or more responsible suppliers are willing and able to compete effectively for the State agency's business.

(C) The procurement lends itself to a firm-fixed-price contract, and selection of the successful bidder can appropriately be made principally on the basis of price.

(ii) If formal advertising is used for a procurement under a grant, the following requirements shall apply:

(A) A sufficient time prior to the date set for opening of bids, bids shall be solicited from an adequate number of known suppliers. In addition, the invitation shall be publicly advertised.

(B) The invitation for bids, including specifications and pertinent attachments, shall clearly define the items or services needed in order for the bidders to properly respond to the invitation.

(C) All bids shall be opened publicly at the time and place stated in the invitation for bids.

(D) A firm-fixed-price contract award shall be made by written notice by the State agency to that responsible bidder whose bid, conforming to the invitation for bids, is lowest. Where specified in the bidding documents, factors such as discounts, transportation costs and life cycle costs shall be considered in determining which bid is lowest. Payment discounts may only be used to determine low bid when prior experience of the State agency indicates that such discounts are generally taken.

(E) Any or all bids may be rejected by the State agency when there are sound documented business reasons in the best interest of the program.

(3) In *competitive negotiation,* proposals are requested from a number of sources and the Request for Proposal is publicized, negotiations are normally conducted with more than one of the sources submitting offers, and either a fixed-price or cost-reimbursable type contract is awarded, as appropriate. Competitive negotiation may be used if conditions are appropriate for the use of formal advertising. If competitive negotiation is used for procurement under a grant, the following requirements shall apply:

(i) Proposals shall be solicited from an adequate number of qualified sources to permit reasonable competition consistent with the nature and requirements of the procurement. The Request for Proposals shall be publicized and reasonable requests by other sources to compete shall be honored to the maximum extent practicable.

(ii) The Request for Proposal shall identify all significant evaluation factors, including price or cost where required and their relative importance.

(iii) The State agency shall provide procedures for technical evaluation of the proposals received, determinations of responsible offerors for the purpose of written or oral discussions, and selection for contract award.

(iv) Award may be made to the responsible offeror whose proposal will be most advantageous to the State agency, price and other factors

considered. Unsuccessful offerors should be notified promptly.

(v) State agencies may utilize competitive negotiation procedures for procurement of architectural/engineering professional services whereby competitors' qualifications are evaluated and the most qualified competitor is selected subject to negotiation of fair and reasonable compensation.

(4) *Noncompetitive negotiation* is procurement through solicitation of a proposal from only one source, or after solicitation of a number of sources, competition is determined inadequate. Noncompetitive negotiation may be used when the award of a contract is infeasible under small purchase, competitive bidding (formal advertising) or competitive negotiation procedures. Awards of contracts by noncompetitive negotiation are limited to the following:

(i) The item is available only from a single source;

(ii) Public exigency or emergency when the urgency for the requirement will not permit a delay incident to competitive procurement;

(iii) FNS authorizes noncompetitive procurement; or

(iv) After solicitation of a number of sources, competition is determined inadequate.

(h) *Contract Pricing.* The cost plus a percentage of cost and percentage of construction cost method(s) of contracting may not be used by a State agency. State agencies shall perform some form of cost or price analysis in connection with every procurement action including contract modifications. Costs or prices based on estimated costs for contracts, paid in whole or in part by FNS program funds, shall be allowed only to the extent that costs incurred or cost estimates included in negotiated prices are consistent with Federal cost principles.

(i) *State Agency Procurement Records.* State agencies shall maintain records sufficient to detail the significant history of a procurement. These records shall include, but are not neccessarily limited to, information pertinent to the rationale for the method of procurement, the selection of contract type, the contract selection or rejection, and the basis for the cost or price.

(j) *Contract provisions.* In addition to provisions defining a sound and complete procurement contract, State agencies shall include the following contract provisions or conditions in all procurement contracts and subcontracts as required by this provision, Federal law, or FNS:

(1) Contracts other than small purchases shall contain provisions or conditions which will allow for administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, and provide for such sanctions and penalties as may be appropriate.

(2) All contracts in excess of $10,000 shall contain suitable provisions for termination by the State agency including the manner by which it will be effected and the basis for settlement. In addition, such contracts shall describe conditions under which the contract may be terminated for default as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor.

(3) All contracts awarded in excess of $10,000 by State agencies and their contractors or subagencies shall contain a provision requiring compliance with Executive Order 11246, entitled "Equal Employment Opportunity," as amended by Executive Order 11375, and as supplemented in Department of Labor regulations (29 CFR Part 60).

(4) All contracts and subcontracts for construction or repair shall include a provision for compliance with the Copeland "Anti-Kickback" Act (18 USC 874) as supplemented in Department of Labor regulations (29 CFR Part 3). This Act provides that each contractor or subagency shall be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he is otherwise entitled. The State agency shall report all suspected or reported violations to FNS.

(5) Where applicable, all contracts awarded by State agencies and subagencies in excess of $2,000 for construction contracts in excess of $2,500 for other contracts which involve the employment of mechanics or laborers shall include a provision for compliance with sections 103 and 107 of the Contract Work Hours and Safety Standards Act (40 USC 327–330) as supplemented by Department of Labor regulations (29 CFR Part 5). Under section 103 of the Act, each contractor shall be required to compute the wages of every mechanic and laborer on the basis of a standard work day of 8 hours and a standard work week of 40 hours. Work in excess of the standard work day or work week is permissible provided that the work is compensated at a rate of not less than 1½ times the basic rate for all hours worked in excess of 8 hours in any calendar day or 40 hours in the work week. Section 107 of the Act is applicable to construction work and provides that no laborer or mechanic shall be required to work in surroundings or under working conditions which are unsanitary, hazardous, or dangerous to his health and safety as determined under construction, safety, and health standards promulated by the Secretary of Labor. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence.

(6) The contract shall include notice of FNS requirements and regulations pertaining to reporting and print rights under any contract involving research, developmental, experimental, or demonstration work with respect to any discovery or invention which arises or is developed in the course of or under such contract, and of FNS requirements and regulations pertaining to copyrights and rights to data so derived.

(7) All negotiated contracts (except those awarded by small purchases procedures) awarded by State agencies shall include a provision to the effect that the State agency, FNS, the Comptroller General of the United States, or any of their duly authorized representatives, shall have access to any books, documents, papers, and records of the contractor which are directly pertinent to that specific contract, for the purpose of making audit, examination, excerpts, and transcriptions. State agencies shall require contracts to maintain all required records for three years after the State agency makes final payments or all other pending matters are closed, whichever is last.

(8) Contracts, subcontracts, and subgrants of amounts in excess of $100,000 shall contain a provision which requires compliance with all applicable standards, orders, or requirements issued under Section 306 of the Clean Air Act, Section 508 of the Clean Water Act, Executive Order 11738, and Environmental Protection Agency (EPA) regulations, which prohibit the use under nonexempt Federal contract, grants, or loans of facilities included on the EPA List of Violating Facilities. The provision shall require reporting of violations to the FNS and to the USEPA Assistant Administrator for Enforcement.

(9) Contracts shall recognize mandatory standards and policies relating to energy efficiency which are contained in the State energy conservation plan issued in compliance with the Energy Policy and Conservation Act (Pub. L. 94–165).

(k) *Contract Administration.* State agencies shall maintain a contract administration system insuring that contractors perform in accordance with

the terms, conditions, and specifications of their contracts or purchase orders.

§ 277.15 Food stamp investigations and prosecutions.

(a) *General.* This section establishes the standards and procedures for Federal funding of State and local costs of Food Stamp Program Fraud investigations, prosecutions and fraud hearings.

(b) *Funding.* Upon submission to and approval by FNS of a budget revision and the information required by paragraph (c) of this section, State agencies will be funded at 75 percent of all allowable direct and indirect costs in accordance with the requirements contained in this section. This higher rate may apply retroactively beginning October 1, 1978 and carry forward to the current period. In no case will 75 percent funding apply prior to October 1, 1978. In cases where an agency other than the State welfare agency is or will be involved, an information statement shall be submitted by each State agency to include this operation.

(c) *State Agency Descriptions.* Concurrent with the budget revision required in paragraph (d) of this section, the State agency shall submit the following information:

(1) Identification of the organizational units, with a brief description of the fraud hearing, investigation or prosecution function assigned, that is claimed at the 75 percent rate;

(2) A copy of the statutes or court decisions under which food stamp fraud cases are prosecuted;

(3) A detailed description of the coordination between the investigative units and the prosecuting units, and the process by which prosecuting officials present indictments regarding food stamp fraud cases;

(4) Agreement that investigative reports, prepared by the investigation or prosecution units, and other related records will be made available to USDA upon request; and

(5) Assurance that the fraud hearing activity claimed under this part is conducted in accordance with § 273.17.

(d) *Budget Revision.* The State agency shall prepare and submit a budget revision in compliance with §§ 272.2 and 277.3 to FNS for approval.

(e) *Eligible Activity.* The following activities performed at the State or local level shall be eligible for funding at 75 percent of the costs if they are an integral element of food stamp investigations, prosecutions, and fraud hearings.

(1) *Direct charges.* Direct charges are costs which may be directly attributable to employees assigned specifically to the food stamp fraud investigation and prosecution functions. Such employees need not be assigned full time, but in the event they are employed less than full time, time sheets or time records must be used to document the amount of time spent on these functions.

(i) For investigation function, only employees whose State or local job title is "Investigator" or a similar descriptive title shall be eligible for the increased funding. Exceptions shall be granted based on adequate justification that the majority of the job duties are specifically related to the investigative function.

(ii) Costs related to the investigative or prosecutive function which are performed by agencies other than the State agency shall be based on a formal agreement between the State or local agency and provider agency. These interagency agreements shall meet the requirements of this Part in regard to allowable charges. Funding under these interagency agreements shall be provided by the State agency from their funds and funds made available by FNS.

(iii) Costs relating to the establishment and collection of claims, when performed by investigators or prosecutors or by any separate unit having claims establishment or collection as its primary function, shall be eligible for the increased funding.

(2) *Indirect charges.* Indirect charges are, in general, those costs which are attributable through allocation to the food stamp fraud investigation and prosecution functions.

(3) *Documentation.* The requirements of appendix A, Part 277, Section (2)(E), and (2)(F) will be followed for the classification and documentation of costs by the State or local agency.

(f) *Ineligible Activity.* The following activities, whether performed at the State or local level, shall be allowable only at the 50 percent funding level, and shall be ineligible for funding at the 75 percent level.

(1) Administrative reviews, such as fair hearings as required per 7 CFR 273 or Performance Reporting System reviews required per 7 CFR 275.

(2) Investigations of authorized retail or wholesale food concerns except when performed in coordination with USDA Office of Inspector General and FNS.

(3) Investigations or establishing claims against households by workers whose regular duties include the determination of a household's eligibility for participation in the Food Stamp Program, except as may be granted under the provisions of (e)(1)(i).

(4) Verification of eligibility information provided by the household for the purpose of making an eligibility determination, and

(5) Audits.

§ 277.16 Suspension, disallowance and program closeout.

(a) *Suspension.* When a State agency has materially failed to comply with any of the provisions contained in the Act, regulations, or FNS-approved State Plan of Operation, FNS may, after written notification to the State agency, temporarily withhold some or all Federal reimbursements for costs of administration of the Food Stamp Program in accordance with § 276.4. Adjustments will be made either by adjusting the Letter of Credit authorization or by not allowing the State agency to withdraw funds.

(b) *Disallowance.* (1) FNS may disallow costs in accordance with Section 276 and effect nonpayment for some or all costs incurred by a State agency which are normally allowable but are determined by FNS to be nonreimbursable because the State agency has failed to comply with any of the provisions contained in the Act, regulations, or FNS-approved State Plan of Operation.

(2) FNS may also disallow costs and institute recovery of Federal funds when a State agency fails to adhere to the cost principles of this Part and Appendix "A".

(c) *Offsets to the Letter of Credit.* (1) FNS may recover funds when owed by the State agency to FNS through offsets to the Letter of Credit. Offsets shall include:

(i) Costs determined by FNS to be disallowed under the provisions of this Part;

(ii) Unallowable costs resulting from audit or investigation findings; or

(iii) Amounts owed which have been billed to the State agency and which the State agency has failed to pay without cause acceptable to FNS.

(2) The amounts recovered through the offset procedure should be in one lump sum. If recovery of funds through the offset procedure is not possible in one lump sum, FNS shall make appropriate adjustments to recover the funds in not more than three fiscal years.

(d) *Program Transfer or Termination.* (1) When termination or transfer of a State program has been agreed upon by FNS, the following closeout procedure shall be observed:

(i) Upon request, FNS shall make or arrange for prompt payment to the State agency for allowable costs not covered by previous payments.

(ii) The State agency shall immediately refund to FNS any

unobligated balance of cash withdrawn by the State agency for the administration of the program in the affected State or Indian reservation.

(iii) The State agency shall submit to FNS within 90 days after the date of termination of the program, all required financial, performance, and other reports. FNS may grant extensions when requested by the State agency.

(iv) FNS shall adjust the amount authorized by the Letter of Credit in order to effect payment of any amounts due the State agency, and if appropriate, shall bill the State agency for any amounts due to FNS. The amounts of such billings shall be promptly remitted to FNS.

(v) In the event a final audit has not been performed prior to the closeout of the program, FNS shall retain the right to disallow costs or recover funds resulting from the final audit findings.

(2) Provisions of § 277.13 apply for any property acquired with program funds or received from the Federal Government in connection with the program and which was in use in the affected project area or areas.

§ 277.17 Audit requirements.

(a) *General.* This section sets forth the audit requirements for State agencies that receive FNS program funds. Audits shall be conducted on an organization-wide basis. Such audits are to determine whether:

(1) Financial operations are conducted properly;

(2) The financial statements are presented fairly;

(3) The organization has complied with laws and regulations affecting the expenditure of Federal funds;

(4) Internal procedures have been established to meet the objectives of Federally assisted programs; and

(5) Financial reports to the Federal Government contain accurate and reliable information.

Except where required by law, no additional requirements for audit will be imposed by FNS unless approved by the Office of Management and Budget (OMB). The provisions of this section do not limit the authority of FNS to make audits of State agencies, their subdivisions, and subcontracts. However, if independent audits arranged for by State agencies meet the requirements prescribed herein, FNS shall rely on them, and any additional audit work already done.

(b) *Audit Standards.* (1) State agencies shall use their own procedures to arrange for independent audits, and to prescribe the scope of audits, provided that the audits comply with the requirements set forth in this section. Where contracts are awarded for audit services, the contracts shall include a reference to OMB Circular A–102, Attachment P.

(2) Audits shall be made in accordance with the General Accounting Office "Standards for Audit of Governmental Organizations, Programs, Activities, and Functions, the Guidelines for Financial and Compliance Audits of Federally Assisted Program," and any compliance supplements approved by OMB, and generally accepted auditing standards established by the American Institute of Certified Public Accountants.

(c) *Purpose of Audit.* Audits will include, at a minimum, an examination of the systems of internal control, systems established to ensure compliance with laws and regulations affecting the expenditure of Federal funds, financial transactions and accounts, and financial statements and reports of State agencies. These examinations are to determine whether:

(1) There is effective control over and proper accounting for revenues expenditures, assets, and liabilities.

(2) The financial statements are presented fairly in accordance with generally accepted accounting principles.

(3) The Federal financial reports (including Financial Status Reports, Cash Reports, and claims for advances and reimbursements) contain accurate and reliable financial data; and are presented in accordance with the terms of applicable agreements, and in accordance with Attachment H of OMB Circular A–102.

(4) Federal funds are being expended in accordance with the terms of applicable agreements and those provisions of Federal law or regulations that could have a material effect on the financial statements or on the awards tested.

(d) *Audit Coverage.* A representative number of charges to Federal funds shall be tested. The test shall be representative of:

(1) The universe of Federal funds received, and

(2) All cost categories that materially affect the award. The test is to determine whether the charges:

(i) Are necessary and reasonable for the proper administration of the program;

(ii) Conform to any limitations or exclusions in the award;

(iii) Were given consistent accounting treatments and applied uniformly to both Federally assisted and other activities of the State agency;

(iv) Were net of applicable credits;

(v) Did not include costs property chargeable to other Federally assisted programs;

(vi) Were properly recorded (i,e., correct amount, date) and supported by source documentation;

(vii) Were approved in advance, if subject to prior approval in accordance with Financial Management Circular 74–4;

(viii) Were incurred in accordance with competitive purchasing procedures, if covered by OMB Circular A–102, Attachment O; and

(ix) Were allocated equitably to benefiting activities, including non-Federal activities.

(3) Audits usually will be made annually, but not less frequently than every two years.

(4) If the auditors become aware of irregularities in the State agency, subagency or subcontractor, the auditor shall promply notify the cognizant agency and State agency management officials above the level of involvement. Irregularities include such matters as conflict of interest, falsification of records or reports, and misappropriation of funds and other assets.

(e) *Audit Report.* The audit report shall include:

(1) Financial statements, including footnotes, of the State agency, subagency, or subcontractor organization.

(2) The auditor's comments on the financial statements which should:

(i) Identify the statements examined and the period covered.

(ii) Identify the various programs under which the organization received Federal funds, and the amounts received for each program.

(iii) State that the audit was done in accordance with paragraph (d) above.

(iv) Express an opinion as to whether the financial statements are fairly presented in accordance with generally accepted accounting principles. If an unqualified opinion cannot be expressed, state the nature of the qualification.

(3) The auditor's comments on compliance and internal control which should:

(i) Include comments on weaknesses in and noncompliance with the systems of internal control, separately identifying material weaknesses.

(ii) Identify the nature and impact of any noted instances of noncompliance with the terms of agreements and those provisions of Federal law or regulation that could have a material effect on the financial statements and reports.

(iii) Contain an expression of positive assurance with respect to compliance

with requirements for tested items, and negative assurance for untested items.

(4) Comments on the accuracy and completeness of financial reports and claims for advances or reimbursements to Federal agencies.

(5) Comments on corrective action taken or planned by the State agency.

(f) *Record Retention.* Work paper and reports shall be retained for a minimum of three years from the date of the audit report unless the auditor is notified in writing by the cognizant agency of the need to extend the retention period. The audit workpapers shall be made available upon request to the cognizant agency or its designees and the General Accounting Office or its designees.

(g) *Cognizant Agency Responsibilities.* The cognizant agency shall have the following responsibilities:

(1) Obtain or make quality assessment reviews of the work of non-Federal audit organizations, and provide the results to other interested audit agencies. If a non-Federal audit organization is responsible for audits of State agencies that have different cognizant audit agencies, a single quality assessment review will be arranged.

(2) Assure that all audit reports of State agencies that affect Federally assisted programs are received, reviewed, and distributed to appropriate Federal audit officials. These officials will be responsible for distributing audit reports to their program officials.

(3) Whenever significant inadequacies in an audit are disclosed, the State agency will be advised and the auditor will be called upon to take corrective action. If corrective action is not taken, the cognizant agency shall notify the State agency and Federal awarding agencies of the facts and its recommendation. Major inadequacies or repetitive substandard performance of independent auditors shall be referred to appropriate professional bodies.

(4) Assure that satisfactory audit coverage is provided in a timely manner and in accordance with the provisions of this section.

(5) Provide technical advice and act as a liaison between Federal agencies, independent auditors and State agencies.

(6) Maintain a followup system on audit findings and investigative matters to assure that audit findings are resolved.

(7) Inform other affected audit agencies of irregularities uncovered. The audit agencies, in turn, shall inform all appropriate officials in their agencies. State or local government law enforcement and prosecuting authorities shall also be informed of irregularities within their jurisdiction.

(8) Recipients shall require subrecipients that are local governments of Indian tribal governments to adopt the requirements in paragraph (d) through (f). The recipient shall ensure that the subrecipient audit reports are received as required, and shall submit the reports to the cognizant agency. The cognizant agency will have the responsibility for those reports described in paragraph (g).

Appendix A—Principles for Determining Costs Applicable to Administration of the Food Stamp Program by State Agencies

This appendix sets forth the procedures implementing uniform requirements for the negotiations and approval of cost allocation plans with State agencies, in accordance with the provisions of Federal Management Circular (FMC) 74–4 and OASC–10, "Cost Principles and Procedures for Establishing Cost Allocation Plans and Indirect Cost Rates for Grants and Contracts with the Federal Government," U.S. Department of Health, Education, and Welfare. This material is adapted substantially from the circular; changes have been made only when necessary in order to conform with legislative constraints.

A. Purpose and scope.

(1) Objectives. This Appendix sets forth principles for determining the allowable costs of administering the Food Stamp Program by State agency under FNS approved State Plans of Operation. The principles are for the purpose of cost determination and are not intended to identify the circumstances or dictate the extent of Federal and State or local participation in the financing of the Program. They are designed to provide that all federally assisted programs bear their fair share of costs recognized under these principles, except where restricted or prohibited by law. No provision for profit or other increment above cost is intended.

(2) Policy guides. The application of these principles is based on the fundamental premises that:

(a) State agencies are responsible for the efficient and effective administration of the Food Stamp Program through the application of sound management practice.

(b) The State agency assumes the responsibility for seeing that Food Stamp Program funds have been expended and accounted for consistent with underlying agreements and program objectives.

(c) Each State agency, in recognition of its own unique combination of staff facilities and experience, will have the primary responsibility for employing whatever form of organization and management techniques as may be necessary to assure proper and efficient administration.

(3) Application. These principles will be applied by FNS in determining costs incurred by State agencies receiving FNS payments for administering the Food Stamp Program.

(B) Definitions. Approval or authorization by FNS means documentation evidencing consent prior to incurring specific costs.

Cognizant Federal Agency means the Federal agency recognized by OMB as having the predominate interest in terms of program dollars.

Cost allocation plan means the documentation identifying, accumulating, and distributing allowable costs of program administration together with the allocation methods used.

Cost, as used herein, means cost as determined on a cash, accrual, or other basis acceptable to FNS as a discharge of the State agency's accountability for FNS funds.

Cost center means a pool, summary account, objective or area established for the accumulation of costs. Such areas include objective organizational units, functions, objects or items of expense, as well as ultimate cost objective(s) including specific costs, products, projects, contracts, programs and other operations.

Federal agency means FNS and also any department, agency, commission, or instrumentality in the executive branch of the Federal Government which makes grants to or contracts with State or local governments.

Payments for administrative costs means reimbursement or advances for costs to State agencies pursuant to any agreement whereby FNS provides funds to carry out programs, services, or activities in connection with administration of the Food Stamp Program. The principles and policies stated in this Appendix as applicable to program payments in general also apply to any State agency obligations under a cost reimbursement type of agreement performed by a subagency, including contracts and subcontracts.

Food Stamp Program administration means those activities and operations of the State agency which are necessary to carry out the purposes of the Food Stamp Act, including any portion of the Program financed by the State agency.

Local unit means any political subdivision of government below the State level.

Other agencies of the State means departments or agencies of the State or local unit which provide goods, facilities, and services to a State agency.

Subagencies means the organization or person to which a State agency makes any payment for acquisition of goods, materials or services for use in administering the Food Stamp Program and which is accountable to the State agency for the use of the funds provided.

Service, as used herein, means goods and facilities, as well as services.

Supporting services means auxiliary functions necessary to sustain the direct effort of administering the Program. These services may be centralized in the State agency or in some other agency, and include procurement, payroll, personnel functions, maintenance and operation of space, data processing, accounting, budgeting, auditing, mail and messenger service, and the like.

(C) Basic guidelines.

(1) Factors affecting allowability of costs. To be allowable under the Program, costs must meet the following general criteria:

(a) Be necessary and reasonable for proper and efficient administration of the Program, be allocable thereto under these principles, and, except as specifically provided herein,

not be a general expense required to carry out the overall responsibilities of State or local governments.

(b) Be authorized or not prohibited under State or local laws or regulations.

(c) Conform to any limitations or exclusions set forth in these principles, Federal Laws, or other governing limitations as to types or amounts of cost items.

(d) Be consistent with policies, regulations, and procedures that apply uniformly to both federally assisted and other activities of the unit of government of which the State agency is a part.

(e) Be accorded consistent treatment through application of generally accepted accounting principles appropriate to the circumstances.

(f) Not be allocable to or included as a cost to any other federally financed program in either the current or a prior period.

(g) Be the net of all applicable credits.

(2) Allocable costs.

(a) A cost allocable to a particular cost objective to the extent of benefits received by such objective.

(b) Any cost allocable to a particular program or cost objective under these principles may not be shifted to other Federal programs to overcome fund deficiencies, avoid restrictions imposed by law or grant agreement, or for other reasons.

(c) Where an allocation of joint cost will ultimately result in charges to the Program, an allocation plan will be required as prescribed in Section 1 of these principles.

(3) Applicable credits.

(a) Applicable credits refer to those receipts or reduction of expenditure-type transactions which offset or reduce expense items allocable to programs as direct or indirect costs. Examples of such transactions are: Purchase discounts; rebates or allowances; recoveries or indemnities on losses; sale of publications, equipment, and scrap; income from personal or incidental services; and adjustments of overpayments or erroneous charges.

(b) Applicable credits may also arise when Federal funds are received or are available from sources other than FNS to finance operations or capital items donated or financed by the Federal Government to fulfill matching requirements under another program. These types of credits should likewise be used to reduce related expenditures in determining the rates or amounts applicable to a given program.

(D) Composition of cost.

(1) Total cost. The total cost of a program is comprised of the allowable direct cost incident to its performance, plus its allocable portion of allowable indirect costs, less applicable credit.

(2) Classification costs. There is no universal rule for classifying certain costs as either direct or indirect under every accounting system. A cost may be direct with respect to some specific service or function, but indirect with respect to a program or other ultimate cost objective. However, it is essential that each item of cost be treated consistently either as a direct or an indirect cost. Specific guides for determining direct and indirect costs allocable under the Program are provided in the section which follows.

(E) Direct costs.

(1) General. Direct costs are those that can be identified specifically with a particular cost objective. These costs may be charged directly to the Program, contracts, or to other programs against which costs are finally lodged. Direct costs may also be charged to cost objectives used for the accumulation of costs pending distribution in the course to programs and other ultimate costs objectives.

(2) Application. Typical direct costs chargeable to the Program are:

(a) Compensation of employees for the time and effort devoted specifically to the administration of the Program.

(b) Cost of materials acquired, consumed, or expended specifically for the purpose of the Program.

(c) Equipment and other approved capital expenditures.

(d) Other items of expense incurred specifically for efficiently and effectively administering the Program.

(e) Service furnished specifically for the Program by other agencies, provided such charges are consistent with criteria outlined in Section G of these principles.

(F) Indirect costs.

(1) General. Indirect costs are those (a) incurred for a common or joint purpose benefiting more than one cost objective, and (b) not readily assignable to the cost objectives specifically benefited, without effort disproportionate to the result achieved. The term indirect cost as used herein applies to costs of this type originating in the State agency, as well as those incurred by other departments in supplying goods, services, and facilities, to the State agency. To facilitate equitable distribution of indirect expenses to the cost objectives served, it may be necessary to establish a number of pools of indirect costs within a State agency or in other agencies providing services to a State agency. Indirect cost pools should be distributed to benefiting cost objectives on bases which will produce an equitable result in consideration of relative benefits derived.

(2) State agency indirect costs. All State agency indirect costs, including the various levels of supervision, are eligible for allocation to the program provided they meet the conditions set forth in their principles. In lieu of determining the actual amount of State agency indirect cost allocable to the program the following methods may be used:

(a) Predetermined fixed rates for indirect costs. A predetermined fixed rate for computing indirect costs applicable to program administration may be negotiated annually in situations where the cost experience and other pertinent facts available are deemed sufficient to enable the parties to reach an informed judgment (1) as to the probable level of indirect costs in the State agency during the period to be covered by the negotiated rate, and (2) that the amount allowable under the predetermined rate would not exceed actual indirect costs.

(b) Negotiated lump sum for overhead. A negotiated fixed amount in lieu of indirect costs may be appropriate under circumstances where the benefits derived from a State agency's indirect services cannot be readily determined as in the case of a small self-contained or isolated activity. When this method is used, a determination should be made that the amount negotiated will be approximately the same as the actual indirect cost that may be incurred. Such amounts negotiated in lieu of indirect costs will be treated as an offset to total indirect expenses of the State agency before allocation to remaining activities. The base on which such remaining expenses are allocated should be appropriately adjusted.

(3) Limitation on indirect costs.

(a) Some Federal programs may be subject to laws that limit the amount of indirect cost that may be allowed. Agencies that sponsor programs of this type will establish procedures which will assure that the amount actually allowed for indirect costs under each such program does not exceed the maximum allowable under the statutory limitation or the amount otherwise allowable under these principles, whichever is the smaller.

(b) When the amount allowable under a statutory limitation is less than the amount otherwise allocable as indirect costs under these principles, the amount not recoverable as indirect costs under a program may not be shifted to another federally sponsored program or contract.

(G) Cost incurred by other agencies of the State.

(1) General. The cost of service provided by other agencies may only include allowable direct costs of the service plus a pro rata share of allowable supporting costs and supervision directly required in performing the service, but not supervision of a general nature such as that provided by the head of a department and his staff assistants not directly involved in operations. However, supervision by the head of a department or agency whose sole function is providing the service furnished would be an eligible cost. Supporting costs include those furnished by other units of the supplying department or by other agencies.

(2) Alternative methods of determining indirect cost. In lieu of determining actual indirect cost related to a particular service furnished by other agencies of the State, either of the following alternative methods may be used provided only one method is used for a specific service during the fiscal year involved.

(a) Standard indirect rate. An amount equal to ten percent of direct labor cost in providing the service performed by other agencies of the State (excluding overtime, shift, or holiday premiums, and fringe benefits) may be allowed in lieu of actual allowable indirect cost for that service.

(b) Predetermined fixed rate. A predetermined fixed rate for indirect cost of the unit or activity providing service may be negotiated as set forth in section F(2)(a) of these principles.

(H) Cost incurred by State agency for others. The principles provided in section G will also be used in determining the cost of services provided by the State agency to another agency.

(I) Cost Allocation Plan

(1) A cost allocation will be required to support the distribution of any indirect costs. All costs allocable to the Food Stamp Program under cost allocation plans will be supported by formal accounting records

which will substantiate the propriety of eventual charges.

(2) There are two types of cost allocation plans:

(a) Statewide or central service cost allocation plan identifies and distributes the cost of services provided by support organizations to those departments or units participating in Federal programs.

(b) Indirect cost proposals distribute the administrative or joint costs incurred by the State agency and the cost of service allocable to it under the Statewide or central service cost allocation plan in a ratio to all work performed by the State agency. The process involves applying a percentage relationship of indirect cost to direct cost.

(3) Requirements. The cost allocation plan of the State agency shall cover all allocated costs of the department as well as costs to be allocated under plans of other agencies or organizational units which are to be included in the costs of federally sponsored programs. The cost allocation plans of all the agencies rendering services to the State agency, to the extent feasible, should be presented in a single document.

(4) Instructions for preparation of cost allocation plans. The Department of Health and Human Services, in consultation with the other Federal agencies concerned, will be responsible for developing and issuing the instructions for use by State agencies in preparation of cost allocation plans. This responsibility applies to both central support services at the State and local government level and indirect cost proposals of individual State agencies.

(5) Submitting Plans for Approval

(a) Responsibility for approving cost allocation plans for individual State agencies has been assigned by the Office of Management and Budget to the cognizant Federal agency.

(b) State cost allocation plans must be submitted to the cognizant Federal agency within six months after the last day of the State's fiscal year. Upon request by the State agency, an extension of time for submittal of the cost allocation plan may be granted by the cognizant Federal agency. It is essential that cost allocation plans be submitted in a timely manner. Failure to submit the plans when required will cause the State agency to become delinquent. In the event a State becomes delinquent, FNS will not provide for the recovery of central service and indirect costs, and such costs already made and claimed against Food Stamp Program funds will be subject to disallowance.

(6) Negotiation and Approval of Cost Allocation Plans for States. The cognizant Federal agency, in collaboration with Federal agencies concerned, will be responsible for negotiation, approval, and audit of cost allocation plans.

(7) Negotiation and Approval of Cost Allocation Plans for Local Governments. Cost allocation plans will be retained at the local government level for audit by the cognizant Federal agency except in those cases where that agency requests that cost allocation plans be submitted to it for negotiation and approval.

(8) A current list of cognizant Federal agencies is maintained by the Office of Management and Budget.

(9) Resolution of problems. The Office of Management and Budget will lend assistance in resolving problems encountered by Federal agencies on cost allocation plans.

(10) Approval by FNS. FNS reserves the right to disapprove costs not meeting the general criteria outlined in Section C of these principles. FNS shall promptly notify the State agency in writing of the disapproval, the reason for the disapproval and the effective date. Costs incurred by State agencies after disapproval may not be charged to FNS unless if FNS subsequently approves the cost.

Standards for Selected Items of Cost

A. *Allowable Cost.* Standards for allowability of costs are established by Federal Management Circular 74–4. These standards will apply regardless of whether a particular item of cost is treated as direct or indirect. Failure to mention a particular item of cost in these standards is not intended to imply that it is either allowable or unallowable. Rather, determination of allowability in each case should be based on the treatment of standards provided for similar or related items of cost. The allowability of the selected items of cost is subject to the general policies and principles as stated in Attachment A to Federal Management Circular 74–4.

(1) *Accounting.* The cost of establishing and maintaining accounting and other information systems required for the management of the Food Stamp Program is allowable. This includes costs incurred by central service agencies of the State government for these purposes. The cost of maintaining central accounting records required for overall State or local government purposes, such as appropriation and fund accounts by the Treasurer, Comptroller, or similar officials, is considered to be a general expense of government and is not allowable.

(2) *Advertising.* Advertising media includes newspapers, magazines, radio and television programs, direct mail, trade papers, and the like. The advertising costs allowable are those which are solely for:

(a) Recruitment of personnel required for the Program;

(b) Solicitation of bids for the procurement of goods and services required;

(c) Disposal of scrap or surplus materials acquired in the performance of the agreement; and

(d) Other purposes specifically provided for by FNS regulations or approved by FNS in the administration of the Food Stamp Program.

(3) *Advisory Councils.* Costs incurred by State advisory councils or committees established to carry out Food Stamp Program goals are allowable. The cost of like organizations is allowable when used to improve the efficiency and effectiveness of the Program.

(4) *Audit Service.* The cost of audits necessary for the administration and management of functions related to the Program is allowable.

(5) *Bonding.* Costs of premiums on bonds covering employees who handle Food Stamp Program funds or food coupons are allowable. The amount of allowable coverage shall be limited to the anticipated maximum amount of food stamp funds or food coupons handled at one time by that employee.

(6) *Budgeting.* Costs incurred for the development, preparation, and execution of budgets are allowable. Costs for services of a central budget office are generally not allowable since these are costs of general government. However, where employees of the central budget office actively participate in the State agency's budget process, the cost of services identifiable to the Food Stamp Program are allowable.

(7) *Building Lease Management.* The administrative cost for lease management which includes review of lease proposals, maintenance of a list of available property for lease, and related activities is allowable.

(8) *Central Stores.* The cost of maintaining and operating a central stores organization for supplies, equipment, and materials used either directly or indirectly for the Food Stamp Program is allowable.

(9) *Communications.* Communication costs incurred for telephone calls or service, telegraph, teletype service, wide area telephone service (WATS), centrex, telpak (tie lines), postage, messenger service and similar expenses are allowable.

(10) *Compensation For Personal Services.*

(a) *General.* Compensation for personal services includes all remuneration, paid currently or accrued, for services rendered during the period of performance in the administration of the program including but not necessarily limited to wages, salaries, and supplementary compensation and benefits as defined in Section A (13) of these principles. The costs of such compensation are allowable to the extent that total compensation for individual employees: is reasonable for the services rendered; follows an appointment made in accordance with State or local government laws and rules and which meets Federal Merit System or other requirements, where applicable; and is determined and supported as provided in Section A of these principles. Compensation for employees engaged in federally-assisted activities will be considered reasonable to the extent that it is consistent with that paid for similar work in other activities of the State or local government. In cases where the kinds of employees required for the Food Stamp Program activities are not found in the other activities of the State or local government, compensation will be considered reasonable to the extent that it is comparable to that paid for similar work in the labor market in which the employing government competes for the kind of employees involved. Compensation surveys providing data representative of the labor market involved will be an acceptable basis for evaluating reasonableness.

(b) *Payroll and distribution of time.* Amounts charged to the program for personal services, regardless of whether treated as direct or indirect costs, will be based on payrolls documented and approved in accordance with the generally accepted practice of the State or local agency. Payrolls must be supported by time and attendence or equivalent records for individual employees. Distribution of salaries and wages of employees chargeable to more than one

program or other cost objective will be supported by appropriate time reports or approved time study methodologies. The method used should be included in the cost allocation plan and should be approved by FNS.

(11) *Depreciation and Use Allowance.*

(a) State agencies may be compensated for the use of buildings, capital improvements, and equipment through use allowances or depreciation. Use allowances are the means of providing compensation in lieu of depreciation or other equivalent costs. However, a combination of the two methods may not be used in connection with a single class of fixed assets.

(b) The computation of depreciation or use allowances will be based on acquisition cost. Where actual cost records have not been maintained, a reasonable estimate of the original acquisition cost may be used in the computation. The computation will exclude the cost of any portion of the cost of buildings and equipment donated or borne directly or indirectly by the Federal Government through charges to Federal programs or otherwise, irrespective of where title was originally vested or where it presently resides. In addition, the computation will also exclude the cost of acquisition of land. Depreciation or a use allowance on idle or excess facilities is not allowable, except when specifically authorized by FNS.

(c) Where the depreciation method is followed, adequate property records must be maintained, and any generally accepted method of computing depreciation may be used. However, the method of computing depreciation must be consistently applied for any specific asset or class of assets for all affected federally sponsored programs and must result in equitable charges considering the extent of the use of the assets for the benefit of such programs.

(d) In lieu of depreciation, a use allowance for buildings and improvements may be computed at an annual rate not exceeding two percent of acquisition cost. The use allowance for equipment (excluding items properly capitalized as building cost) will be computed at an annual rate not exceeding six and two-thirds percent of acquisition cost of usable equipment.

(e) No depreciation or use charge may be allowed on any assets that would be considered as fully depreciated, provided, however, that reasonable use charges may be negotiated for any such assets if warranted after taking into consideration the cost of the facility or item involved, the estimated useful life remaining at time of negotiation, the effect of any increased maintenance charges or decreased efficiency due to age, and any other factors pertinent to the utilization of the facility or item for the purpose contemplated.

(12) *Disbursing Service.* The cost of disbursing program funds by the State Treasurer or other designated officer is allowable. Disbursing services cover the processing of checks or warrants, from preparation to redemption, including the necessary records of accountability and reconciliation of such records with related cash accounts.

(13) *Employee Fringe Benefits.* Costs identified are allowable to the extent that total compensation for employees is reasonable as defined in paragraph (10)(a) of these principles.

(a) Employee benefits in the form of regular compensation paid to employees during periods of authorized absences from the job, such as for annual leave, sick leave, court leave, military leave, and the like, if they are provided pursuant to an approved leave system, and the cost thereof is equitably allocated to all related activities, including federally-assisted programs.

(b) Employee benefits in the form of employers' contributions or expense for social security, employees' life and health insurance plans, unemployment insurance coverage, workers' compensation insurance, pension plans, severance pay, and the like, provided such benefits are granted under approved plans and are distributed equitably to programs and to other activities.

(14) *Employee Morale, Health And Welfare Costs.* The costs of health or first-aid clinics and/or infirmaries, recreational facilities, employees' counseling services, employee information publications, and any related expenses incurred in accordance with general State or local policy, are allowable. Income generated from any of these activities will be offset against expenses.

(15) *Exhibits.* Costs of exhibits relating specifically to the Food Stamp Program are allowable.

(16) *Legal Expenses.* The cost of legal expenses required in the administration of the program is allowable. Legal services furnished by the chief legal officer of a State or local government or his staff solely for the purpose of discharging his general responsibilities as legal officer are unallowable. Legal expenses for the prosecution of claims against the Federal Government is unallowable.

(17) *Maintenance and Repair.* Costs incurred for necessary maintenance, repair, or upkeep of property which neither add to the permanent value of the property nor appreciably prolong its intended life, but keep it in an efficient operating condition, are allowable.

(18) *Materials and Supplies.* The cost of materials and supplies necessary to carry out the program is allowable. Purchases made specifically for the program should be charged thereto at their actual prices after deducting all cash discounts, trade discounts, rebates, and allowances received by the State agency. Withdrawals from general stores or stockrooms should be charged at cost under any recognized method of pricing consistently applied. Incoming transportation charges are a proper part of material cost.

(19) *Memberships, Subscriptions and Professional Activities.*

(a) The *cost of membership* in civic, business, technical, and professional organizations is allowable, provided:

(i) The benefit from the membership is related to the program,

(ii) The expenditure is for agency membership,

(iii) The cost of the membership is reasonably related to the value of the services or benefits received, and

(iv) The expenditure is not for membership in an organization which devotes a substantial part of its activities to influencing legislation.

(b) *Reference material.* The cost of books, and subscriptions to civic, business, professional, and technical periodicals is allowable when related to the program.

(c) *Meetings and conferences.* Costs are allowable when the primary purpose of the meeting is the dissemination of technical information relating to the program and they are consistent with regular practices followed for other activities of the State agency.

(20) *Motor pools.* The costs of a service organization which provides automobiles to user State agencies at a mileage or fixed rate and/or provides vehicle maintenance, inspection and repair services are allowable.

(21) *Payroll preparation.* The cost of preparing payrolls and maintaining necessary wage records is allowable.

(22) *Personnel administration.* Costs for the recruitment, examination, certification, classification, training, establishment of pay standards, and related activities for the program are allowable.

(23) *Printing and reproduction.* Cost for printing and reproduction services necessary for program administration including but not limited to forms, reports, manuals, and information literature, is allowable. Publication costs of reports or other media relating to program accomplishments or results are allowable.

(24) *Procurement service.* The cost of procurement service, including solicitation of bids, preparation and award of contracts, and all phases of contract administration in providing goods, facilities and services for the program is allowable.

(25) *Taxes.* In general, taxes or payments in lieu of taxes which the State agency is legally required to pay are allowable.

(26) *Training and education.* The cost of in-service training, customarily provided for employee development which directly or indirectly benefits the program is allowable. Out-of-service training involving extended periods of time is allowable only when specifically authorized by FNS.

(27) *Transportation.* Costs incurred for freight, cartage, express, postage, and other transportation costs relating either to goods purchased, delivered, or moved from one location to another are allowable.

(28) *Travel.* Travel costs are allowable for expenses for transportation, lodging, subsistence, and related items incurred by employees who are in travel status on official business incident to the program. Such costs may be charged on an actual basis, on a per diem or mileage basis in lieu of actual costs incurred, or on a combination of the two. The charges must be consistent with those normally allowed in like circumstances in nonfederally sponsored activities. The difference in cost between first-class air accommodations and less-than-first-class air accommodations is unallowable except when less-than-first-class air accommodations are not reasonably available. Notwithstanding the provisions of paragraphs C (7) and (10), travel costs of officials covered by those paragraphs, when specifically related to grant programs, are allowable with the prior approval of a grantor agency.

B. *Costs allowable with approval of FNS*

(1) *General-Acquisition requirement.* A State shall obtain prior written approval from FNS when it plans to acquire ADP equipment or services that it anticipates will have total acquisition costs of $100,000 or more in Federal and State funds over a 12-month period, or $200,000 or more in Federal or State funds for the total acquisition. A State shall also obtain prior written approval from FNS when it plans to acquire noncompetitively from a commercial source ADP equipment or services that cost more than $25,000 in Federal and State funds. A State shall notify FNS when it plans to acquire ADP equipment or services that will cost $25,000 to $100,000 over a 12-month period in Federal and State funds. The State shall send the prior notice of acquisition to FNS 60 days before the planned acquisition.

(2) *Definitions.*

(a) *"Acceptance documents"* means written evidence of satisfactory completion of an approved phase of work or contract, and acceptance thereof by the State agency.

(b) *"Advance Planning Document" or "APD"* means a written plan of action to acquire the proposed APD services, system, or equipment. The APD must contain a statement of needs and objectives:

(i) The feasibility study;

(ii) A preliminary cost/benefit analysis including lease/purchase options;

(iii) A personnel resource statement indicating availability of qualified and adequate staff including a project director to accomplish the project objectives;

(iv) A detailed description of the nature and scope of the activities to be undertaken and the methods to be used;

(v) A proposed schedule;

(vi) A proposed budget; and

(vii) A statement indicating the period of time for which the services, system, or equipment described are expected to be used; for integrated computer systems, a statement of the percentage allocated to FNS and a breakdown or explanation of how the percentage was determined.

(c) *"Automatic Data Processing" or "ADP"* means data processing performed by a system of electronic or electrical machines so interconnected and interacting as to minimize the need for human assistance or intervention.

(d) *"Automatic Data Processing equipment" or "ADP equipment"* means:

(i) Electronic digital computers, regardless of size, capacity, or price, that accept data input, store data, perform calculations, and other processing steps, and prepare information;

(ii) All peripheral or auxiliary equipment used in support of electronic computers whether selected and acquired with the computer or separately;

(iii) Data transmission or communications equipment that is selected and acquired solely or primarily for use with a configuration of ADP equipment which includes an electronic computer; and

(iv) "Data input equipment" means equipment used to enter data directly or indirectly into an electronic digital computer; peripheral or auxiliary equipment; or data transmission or communication equipment.

(e) *"Automatic Data Processing services" or "ADP services"* means:

(i) Services to operate ADP equipment, either by private sources, or by employees of the State agency, or by State or local organizations other than the State agency; and/or

(ii) Services provided by private sources or by employees of the State agency or by State and local organizations other than the State agency to perform such tasks as feasibility studies, system studies, system design efforts, development of system specifications, system analysis, programming and system implementation.

(f) *"Data processing"* means the preparation of source media containing data or basic elements of information and the use of such source media according to precise rules of procedures to accomplish such operations as classifying, sorting, calculating, summarizing, recording and transmitting.

(g) *"Feasibility study"* means a preliminary study to determine whether it is sufficiently probable that effective and efficient use of ADP equipment or systems can be made to warrant the substantial investment of staff, time, and money. The study shall project for a three year period the requirements for ADP equipment, services, and systems.

(h) *"Request for proposal" or "RFP"* means the document used for public solicitations of competitive proposals from qualified sources as outlined in 7 CFR 277.14.

(i) *"Service agreement"* means a document signed by the State or local agency and a second State or local organization providing ADP services to the State or local agency which: (i) Identifies those ADP services to be provided by the provider agency;

(ii) Includes, preferably as an amendable attachment, a schedule of changes for each identified ADP service, and a certification that these charges apply equally to all users;

(iii) Includes a description of the method(s) of accounting for the services rendered under the agreement and computing services changes;

(iv) Includes assurances that services provided shall be timely and satisfactory; and

(v) Requires the provider agency to obtain prior State agency approval and to follow competitive procurement procedures equivalent to those contained in 7 CFR 277.14 for the acquisition of any ADP services in support of or in addition to the service agreement.

(j) *"Software"* means a set of computer programs, procedures, and associated documentation by which ADP equipment is used and operated.

(k) *"System design"* means the putting together of a new or more efficient ADP system which avoids the deficiencies and discrepancies in the old system.

(l) *"System specifications"* means information about the new ADP system—such as workload descriptions, input data, information to be maintained and processed, data processing techniques, and output data which is required to determine the ADP equipment and software necessary to implement the system design.

(m) *"System study"* means the examination of existing information flow and operational procedures within an organization to determine how to provide more timely, accurate, and meaningful information for management decision-making and to develop new or improved ADP systems to service, control and coordinate the activities of the organization to improve operational efficiency. The study essentially consists of three basic phases: data gathering or investigation of the present system and new information requirements; analysis of the data gathered in the investigation; and synthesis, or refitting, of the parts and relationships uncovered through the analysis into an efficient system.

(3) *Obtaining approval.* Prior approval by FNS is required for costs of ADP equipment or ADP services in support of the Food Stamp Program which exceed $100,000 in combined Federal and State funds per project. Requests for Approvals must be forwarded through the State agency prior to submittal to FNS. Approval by FNS will be based on a review of the studies conducted by or for the agency that will justify the acquisition of the proposed ADP equipment or ADP services. Written approval or the Advance Planning Document must be obtained from FNS by the State agency prior to entering into contractual agreements or making any other commitment for acquisition of ADP equipment or ADP services.

(4) *Approval by the State agency.* Approval by the State agency is required for all documents specified in this regulation prior to submittal for FNS approval. In addition, State agency approval is also required for those acquisitions of ADP equipment and ADP services not requiring prior approval by FNS.

(5) *Competitive procurement.* Acquisition of ADP equipment and purchase of ADP services shall be based on competitive procurement procedures specified in 7 CFR 277.14 when Food Stamp Program funds are involved. State agency officials responsible for such procurement will ensure that formal advertising is the method of procurement unless the conditions for negotiation in 7 CFR 277.14 are met. Notwithstanding the existence of circumstances justifying negotiation, competitive procurement shall be obtained to the maximum extent practicable. The competitive procurement policy shall be applicable except for ADP services provided by the agency itself, or by other State or local agencies.

(6) *Submittal of documents.*

(a) Prior to claiming funding under the Food Stamp Program the State agency will be required to submit:

(i) The Advance Planning Document;

(ii) The Service Agreement (when data processing services are to be provided by a State central data processing facility or by another State or local agency);

(iii) The Request for Proposal, prior to its issuance when service or equipment proposals are being solicited from commercial sources; and

(iv) The Contract, prior to signature of the contracting officer when services or equipment are to be acquired commercially.

(b) Voluntary submittal, or when requested by FNS, will be made of:

(i) The system study,

(ii) The system design,

(iii) The system specifications,

(iv) The acceptance document.

(7) *Methods for charging costs.* Methods and procedures for properly charging the

costs of all systems whether acquired from public or private sources shall be in accordance with this regulation and applicable FNS instructions.

(8) *Access.* Access to the system by FNS in all of its aspects, including design, development, and operation, including work performed by any source, and including cost records of contractors and subcontractors, shall be made available by the State at intervals as are deemed necessary by FNS to determine whether the conditions for approval are being met and to determine the efficiency, economy and effectiveness of the system. Failure to provide full access by appropriate State and Federal representatives to all parts of the system shall result in termination of Food Stamp Program funds in the costs of the system and its operation.

(9) *Ownership rights.*

(a) *Software.* The State will have all ownership rights in software or modification thereof and associated documentation designed, developed or installed with Food Stamp Program funds except that FNS reserves a royalty-free, nonexclusive license to reproduce, publish, or otherwise use, and to authorize others to do so, such software, modification and documentation. Proprietary software which is provided at established catalog or market prices and sold or leased to the general public shall not be subject to the ownership provisions of this section.

(b) *Automatic data processing equipment.* The policies and procedures governing title, use and disposition of property purchased with Food Stamp Program funds, which are covered in 7 CFR 277.13 are applicable to automatic data processing equipment.

(10) *Use of ADP system.* ADP systems designed, developed or installed with Food Stamp Program funds shall be used for a period of time consistent with the Advance Planning Document as approved, or which FNS shall determine is sufficient to justify the Federal funds invested.

(11) *Basis for continued Federal Financial Participation.* Periodic onsite surveys and reviews of State and local agency ADP methods and practices may be conducted by or for FNS to determine the adequacy of such methods and practices and to assure that ADP equipment and services are utilized for the purposes for which Federal funds were authorized. Such surveys may include:

(a) *Pre-installation readiness.* A pre-installation survey including an onsite evaluation of the physical site and the State agency's readiness to use the proposed ADP services, equipment or system when installed and operational.

(b) *Post-installation.* A review conducted after installation of ADP equipment or systems to assure that the objectives for which Federal Financial Participation was approved is being accomplished.

(c) *Utilization.* A continuing review of ADP facilities to determine whether or not the ADP equipment or services are being efficiently and effectively utilized in support of the Food Stamp Program. Should FNS determine from such surveys or reviews or otherwise that the State agency has improperly used Food Stamp Program funds, funding may be invoked. Such termination would be limited to the costs of the data processing services or equipment in question as specified in the written notification of termination by FNS.

(12) *Application of this Section.* The conditions of this section apply for initial and continuing authority to claim Food Stamp Program funding for automatic data processing services and equipment. Due to the nature of the procurement of ADP equipment and services, approved cost allocation plans will not be valid unless documentation required under B(1) of this Section is submitted and approvals are obtained.

(13) *Building space and related facilities.* The cost of space in privately or publicly owned buildings used for the benefit of the Program is allowable subject to the following conditions.

(a) The total cost of space, whether in a privately or publicly owned building, may not exceed the rental cost of comparable space and facilities in a privately owned building in the same locality.

(b) The cost of space may not be charged to FNS for periods of nonoccupancy, without authorization of FNS.

(i) *Rental Cost.* The rental cost of space in a privately-owned building is allowable.

(ii) *Maintenance and operation.* The cost of utilities, insurance, security, janitorial services, elevator service, upkeep of grounds, normal repairs and alterations and the like, are allowable to the extent they are not otherwise included in rental or other charges for space.

(iii) *Rearrangements and alterations.* Costs incurred for rearrangement and alteration of facilities required specifically for the program or those that materially increase the value or useful life of the facilities (Section B(3) of these principles) are allowable when specifically approved by FNS.

(iv) *Depreciation and use allowances on publicly owned buildings.* These costs are allowable as provided in paragraph A(11) of these principles.

(v) *Occupancy of space under rental-purchase or a lease with option-to-purchase agreement.* The cost of space procured under such arrangements is allowable when specifically approved by FNS.

(14) *Capital expenditures.* The cost, net of any credits, of facilities, equipment, other capital assets, and repairs which materially increase the value or useful life of capital assets, and/or of nonexpendable personal property, having a useful life of more than one year and a net acquisition costy of more than $5,000 per unit after allocation to FNS as projected for one year after purchase, is allowable when such procurement is specifically approved by FNS. No such approval shall be granted unless the State agency shall demonstrate to FNS that such a cost is:

(a) Necessary and reasonable for proper and efficient administration of the program, and allocable thereto under the principles provided herein; and

(b) That procurement of such item or items has been or will be made in accordance with the standards set out in 277.14. In no case shall such a cost become a program charge against FNS prior to approval in writing by FNS of the procurement and the cost. When assets acquired with Food Stamp funds are (i) sold, (ii) no longer available for use in a Federally-sponsored program, or (iii) used for purposes not authorized by FNS, FNS's equity in the asset will be refunded in the same proportion as Federal participation in its cost. In case any assets are traded on new items, only the net cost of the newly acquired assets is allowable.

(15) *Insurance.*

(a) Cost of insurance to secure the State agency against financial losses involved in the acceptance, storage, and issuance of food coupons and ATP cards is allowable with FNS approval.

(b) Costs of other insurance in connection with the general conduct of activities are allowable subject to the following limitations:

(i) Types and extent and cost of coverage will be in accordance with general State or local government policy and sound business practice.

(ii) Costs of insurance or contributions to any reserve covering the risk of loss of, or damage to, Federal government property are unallowable except to the extent that FNS approves such cost.

(16) *Management Studies.* The cost of management studies to improve the effectiveness and efficiency of program management for the Food Stamp Program is allowable. However, FNS must approve cost in excess of $2,500 for studies performed by outside consultants or agencies other than the State agency.

(17) *Preagreement costs.* Costs incurred prior to the effective date of approval of the amended indirect cost proposal or the revised Statewide cost allocation plan, whether or not they would have been allowable thereunder if incurred after such date, are allowable only when subsequently provided for in the plan or approved indirect cost proposal.

(18) *Professional services.* Cost of professional services rendered by individuals or organizations not a part of the State agency is allowable. Prior authorization must be obtained from FNS for cost exceeding a total of $2,500.

(19) *Proposal costs.* Costs of preparing indirect cost proposals or amendments for allocating, distributing, and implementing provisions for payment of portions of the costs of administering the Food Stamp Program by the State agency are allowable.

(20) *Cost incurred by Agencies other than the State.* The cost of services provided by

other agencies (including municipal governments) may only include allowable direct costs plus a pro rata share of allowable supporting costs and supervision directly required in performing the service. Allowable supporting costs are those services which may be centralized and includes such functions as procurement, payroll, personnel services, maintenance and operation of space, data processing, accounting, budgeting, auditing, mail and messenger service and the like. Supervision costs will not include supervision of a general nature such as that provided by the head of a department and his staff assistants not directly involved in the operation of the program. In lieu of determining actual indirect cost related to a particular service performed by another agency, either of the following alternative methods may be used during the fiscal year involved and is specifically provided for in the indirect cost proposal:

(a) Standard indirect rate equal to ten percent of direct labor cost in providing the service (excluding overtime, shift or holiday premiums, and fringe benefits) may be allowed in lieu of actual allowable cost.

(b) A predetermined fixed rate for indirect cost of the unit or activity providing service may be negotiated.

C. *Unallowable costs.* The following costs shall not be allowable:

(1) Costs of determining Food Stamp eligibility incidental to the determination of AFDC eligibility are not chargeable to FNS.

(2) Bad debts. Any losses arising from uncollectable accounts or other claims, and related costs, are unallowable.

(3) Contingencies. Contributions to a contingency reserve or any similar provision for unforeseen events are unallowable.

(4) Contributions and donations. Unallowable.

(5) Entertainment. Costs whose purpose is for amusement, social activities, and incidental costs relating thereto, such as meals, beverages, lodgings, rentals, transportation, and gratuities are unallowable.

(6) Fines and penalties. Costs resulting from violations of or failure to comply with Federal, State and local laws and regulations are unallowable.

(7) Governor's expenses. The salaries and expenses of the Office of the Governor of a State or the chief executive of a political subdivision are considered a cost of general State or local government and are unallowable. However, for a federally-recognized Indian tribal government, only that portion of the salaries and expenses of the office of the chief executive that is a cost of general government is unallowable. The portion of salaries and expenses directly attributable to managing and operating programs is allowable.

(8) Indemnification. The cost of indemnifying the State against liabilities to third parties and other losses not compensated by insurance is unallowable.

(9) Interest and other financial costs. Interest on borrowings, bond discounts, cost of financing and refinancing operations, and legal and professional fees paid in connection therewith, are unallowable.

(10) Legislative expenses. Salaries and other expenses of the State legislature or similar local governmental bodies are unallowable.

(11) Losses. Losses which could have been covered by permissible insurance are unallowable.

(12) Underrecovery of cost under agreements. Any excess of cost over Federal contribution under one agreement is unallowable under another agreement.

(13) The acquisition of land or buildings is an unallowable cost.

Note.—The reporting and recordkeeping requirement contained in this rule are being submitted for approval by the Office of Management and Budget in accordance with the Federal Reports Act of 1942. The reporting and recordkeeping requirements may be subject to revision prior to implementation if the requirements as presently formulated are not approved without change by OMB.

(91 Stat. 958 (7 U.S.C. 2011–2027))

(Catalog of Federal Domestic Assistance Program No. 10551 Food Stamp)

Dated: December 22, 1980.

Carol Tucker Foreman,

Assistant Secretary.

[FR Doc. 80-40407 Filed 12-29-80; 8:45 am]

BILLING CODE 3410-30-M

Agricultural Marketing Service

7 CFR Part 910

[Lemon Regulation 285]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Serices, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market during the period December 28–January 3, 1981. Such action is needed to provide for orderly marketing of fresh lemons for this period due to the marketing situation confronting the lemon industry.

EFFECTIVE DATE: December 28, 1980.

FOR FURTHER INFORMATION CONTACT: Malvin E. McGaha, 202–447–5975.

SUPPLEMENTARY INFORMATION: *Findings.* This regulation is issued under the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The action is based upon the recommendations and information submitted by the Lemon Administrative Committee, and upon other information. It is hereby found that this action will tend to effectuate the declared policy of the act.

This action is consistent with the marketing policy for 1980–81 which was designated significant under the procedures of Executive Order 12044. The marketing policy was recommended by the committee following discussion at a public meeting on July 8, 1980. A final impact analysis on the marketing policy is available from Malvin E. McGaha, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202–447–5975.

The committee met again publicly on December 22, 1980, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons is good.

It is further found that there is insufficient time between the date when information became available upon which this regulation is based and when the action must be taken to warrant a 60 day comment period as recommended in E.O. 12044, and that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553). It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

Section 910.585 is added as follows:

§ 910.585 Lemon Regulation 285.

(a) The quantity of lemons grown in California and Arizona which may be handled during the period December 28, 1980, through January 3, 1981, is established at 210,000 cartons.

(b) As used in this section, "handled" and "carton(s)" mean the same as defined in the marketing order.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: December 23, 1980.

Charles R. Brader,

Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 80-40454 Filed 12-23-80; 2:00 pm]

BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

9 CFR Part 78

Brucellosis Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: These amendments add the county of Lipscomb in Texas, to the list of Modified Certified Brucellosis Areas and delete it from the list of Certified Burcellosis-Free Areas because it has been determined that this county now qualifies only as a Modified Certified Brucellosis Area. The effect of this action will provide for more restrictions on cattle moved interstate from this area. These amendments also add the county of Vernon in Missouri to the list of Modified Certified Brucellosis Areas and delete such county from the list of Noncertified Areas because it has been determined that this county now qualifies as a Modified Certified Brucellosis Area. The effect of this action will provide for less restrictions on cattle moved interstate from this area.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: Dr. A. D. Robb, USDA, APHIS, VS, Room 805, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8713.

SUPPLEMENTARY INFORMATION: A complete list of Brucellosis Areas was published in the **Federal Register** (45 FR 44253-44256) effective July 1, 1980. These amendments update the complete list. These amendments add the county of Lipscomb in Texas to the list of Modified Certified Brucellosis Areas in § 78.21 and delete it from the list of Certified Brucellosis-Free Areas in § 78.20, because it has been determined that it now qualifies only as a Modified Certified Brucellosis Area as defined in § 78.1(m) of the regulations. These amendments add the county of Vernon in Missouri to the list of Modified Certified Brucellosis Areas in § 78.21 and delete such county from the list of Noncertified Areas in § 78.22 because it has been determined that such county now qualifies as a Modified Certified Brucellosis Area.

Accordingly, §§ 78.20, 78.21, and 78.22 of Part 78, Title 9, Code of Federal Regulations, designating Certified Brucellosis-Free Areas, Modified Certified Brucellosis Areas, and Noncertified Areas, respectively, are revised to read as follows:

§ 78.20 Certified Brucellosis-Free Areas.

The following states, or specified portions thereof, are hereby designated as Certified Brucellosis-Free Areas:

(a) *Entire States.*

Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Iowa, Indiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Vermont, Vriginia, Washington, West Virginia, Wisconsin, Wyoming, Virgin Islands.

(b) *Specific Counties Within States.*

Alabama. Dale, Geneva.

Arkansas. Baxter, Bradley, Columbia, Crittenden, Dallas, Drew, Fulton, Garland, Grant, Jefferson, Marion, Monroe, Montgomery, Newton, Ouachita, Stone, Union, Woodruff.

Florida. Baker, Bay, Calhoun, Citrus, Dixie, Franklin, Holmes, Jackson, Leon, Liberty, Monroe, Okaloosa, Santa Rosa, Seminole, St. Johns, Taylor, Wakulla, Walton.

Georgia. Appling, Atkinson, Bacon, Banks, Brantley, Bryan, Bulloch, Burke, Butts, Camden, Candler, Charlton, Chatham, Chattahoochee, Clarke, Clayton, Cook, Crawford, De Kalb, Echols, Effingham, Evans, Fannin, Franklin, Glascock, Glynn, Greene, Habersham, Jeff Davis, Johnson, Lanier, Laurens, Liberty, Long, McIntosh, Monroe, Peach, Rabun, Richmond, Screven, Stephens, Taylor, Toombs, Treutlen, Twiggs, Upson, Ware, Wayne, Wheeler, White, Wilkinson.

Idaho. Ada, Adams, Bannock, Bear Lake, Benewah, Bingham, Blaine, Boise, Bonner, Bonneville, Boundary, Butte, Camas, Canyon, Caribou, Clark, Clearwater, Custer, Elmore, Gem, Idaho, Kootenai, Latah, Lemhi, Lewis, Minidoka, Nez Perce, Owyhee, Payette, Power, Shoshone, Teton, Valley, Washington.

Illinois. Adams, Alexander, Bond, Boone, Brown, Bureau, Calhoun, Carroll, Cass, Champaign, Christian, Clark, Clay, Clinton, Coles, Cook, Crawford, Cumberland, De Kalb, DeWitt, Douglas, Du Page, Edgar, Edwards, Effingham, Fayette, Ford, Franklin, Fulton, Gallatin, Greene, Grundy, Hamilton, Hancock, Hardin, Henderson, Henry, Iroquois, Jackson, Jasper, Jefferson, Jersey, Johnson, Kane, Kankakee, Kendall, Knox, Lake, La Salle, Lawrence, Lee, Livingston, Logan, Macon, Macoupin, Madison, Marion, Marshall, Mason, Massac, McDonough, McHenry, McLean, Menard, Mercer, Monroe, Montgomery, Morgan, Moultrie, Ogle, Peoria, Perry, Piatt, Pike, Pope, Pulaski, Putnam, Randolph, Richland, Rock Island, St. Clair, Saline, Sangamon, Schuyler, Scott, Shelby, Stark, Stephenson, Tazewell, Union, Vermilion, Wabash, Warren, Washington, Wayne, White, Whiteside, Will, Williamson, Winnebago, Woodford.

Kansas. Anderson, Barber, Bourbon, Brown, Chase, Chautauqua, Cherokee, Cheyenne, Clark, Coffey, Comanche, Crawford, Decatur, Dickinson, Doniphan, Douglas, Edwards, Ellsworth, Finney, Ford, Geary, Gove, Graham, Grant, Gray, Greeley, Hamilton, Harvey, Haskell, Hodgeman, Jewell, Johnson, Kearney, Kingman, Kiowa, Labette, Lane, Leavenworth, Lincoln, Logan, Marion, Marshall, Meade, Miami, Mitchell, Ness, Norton, Osage, Osborne, Pawnee, Phillips, Pottawatomie, Pratt, Rawlins, Republic, Riley, Rooks, Rush, Saline, Scott, Seward, Shawnee, Sheridan, Sherman, Smith, Stanton, Stevens, Sumner, Thomas, Trego, Wabaunsee, Wallace, Washington, Wichita, Wilson, Woodson, Wyandotte.

Kentucky. Bell, Breathitt, Campbell, Clay, Floyd, Harlan, Johnson, Kenton, Knott, Knox, Lawrence, Lee, Leslie, Letcher, Lewis, Magoffin, Martin, McCreary, Minifee, Morgan, Owsley, Pendleton, Perry, Pike, Robertson, Trimble, Whitley, Wolfe.

Mississippi. Harrison.

Missouri. Audrain, Dunklin, Gasconade, Hickory, Lewis, Moniteau, Montgomery, Perry, Platte, Pulaski, St. Louis, Schuyler, Shelby.

Nebraska. Banner, Box Butte, Burt, Chase, Cheyenne, Clay, Colfax, Cuming, Dakota, Deuel, Dodge, Douglas, Dundy, Franklin, Hitchcock, Jefferson, Lancaster, Nuckolls, Perkins, Saline, Seward, Sioux, Stanton, Thayer, Thurston, Washington, Wayne.

New Mexico. Catron, Colfax, De Baca, Dona Ana, Grant, Guadalupe, Harding, Hidalgo, Lincoln, Los Alamos, Luna, McKinley, Mora, Otero, Quay, Rio Arriba, Sandoval, San Juan, San Miguel, Santa Fe, Sierra, Socorro, Taos, Torrance, Union, Valencia.

Oklahoma. Alfalfa, Cimarron, Custer, Ellis, Jackson, Woodward.

South Dakota. Aurora, Beadle, Bennett, Bon Homme, Brookings, Brown, Brule, Buffalo, Butte, Campbell, Charles Mix, Clark, Clay, Codington, Corson, Custer, Davison, Day, Deuel, Dewey, Douglas, Edmunds, Fall River, Grant, Gregory, Haakon, Hamlin, Hand, Hanson, Harding, Hughes, Hutchison, Hyde, Jackson, Jerauld, Kingsbury, Lake, Lawrence, Lincoln, Lyman, Marshall,

McCook, McPherson, Meade, Mellette, Miner, Minnehaha, Moody, Pennington, Perkins, Potter, Roberts, Sanborn, Shannon, Spink, Sully, Todd, Tripp, Turner, Union, Walworth, Washabaugh, Yankton, Ziebach.

Tennessee. Anderson, Blount, Campbell, Carter, Claiborne, Fentress, Grainger, Hamblen, Hancock, Johnson, Knox, Lake, Lewis, Meigs, Morgan, Perry, Polk, Roane, Robertson, Scott, Sequatchie, Sevier, Sullivan, Unicoi, Union, Van Buren.

Texas. Armstrong, Bandera, Borden, Brewster, Childress, Comal, Crane, Culberson, Ector, Gillespie, Glasscock, Gray, Hansford, Hartley, Hempill, Hudspeth, Hutchinson, Irion, Jeff Davis, Kendall, Kerr, Kimble, Llano, Loving, Martin, Mason, Menard, Midland, Moore, Newton, Ochiltree, Pecos, Presidio, Reagan, Real, Roberts, Schleicher, Sherman, Sterling, Sutton, Terrell, Tom Green, Val Verde, Ward, Winkler, Yoakum.

Utah. Beaver, Cache, Carbon, Daggett, Davis, Duchesne, Emery, Grand, Iron, Juab, Kane, Millard, Morgan, Piute, Rich, Salt Lake, San Juan, Sanpete, Sevier, Summit, Tooele, Uintah, Utah, Wasatch, Washington, Wayne, Weber.

Puerto Rico. Adjuntas, Aguada, Aguadilla, Aguas Buenas, Aibonito, Anasco, Arroyo, Barceloneta, Barranquitas, Bayamon, Cabo Rojo, Caguas, Canovanas (Loiza), Catano, Cayey, Ceiba, Ciales, Cidra, Coamo, Comerio, Corozal, Culebra, Dorado, Fajardo, Guanica, Guayama, Guaynabo, Guayanilla, Hormigueros, Humacao, Jayuya, Juana Diaz, Juncos, Lajas, Leres, Las Marias, Luquillo, Manati, Maricao, Maunabo, Mayaguez, Moca, Naranjito, Orocovis, Patillas, Penuelas, Ponce, Rincon, Rio Grande, Rio Piedras, Sabana Grande, Salinas, San German, San Juan, San Lorenzo, Santa Isabel, Toa Alta, Toa Baja, Trujillo Alto, Utuado, Vega Alta, Vega Baja, Vieques, Villalba, Yabucoa, Yauco.

§ 78.21 Modified Certified Brucellosis Areas.

The following States, or specified portions thereof, are hereby designated as Modified Certified Brucellosis Areas:

(a) *Entire States.* Alaska.

(b) *Specific Counties Within States.*

Alabama. Autauga, Baldwin, Barbour, Bibb, Blount, Bullock, Butler, Calhoun, Chambers, Cherokee, Chilton, Choctaw, Clarke, Clay, Cleburne, Coffee, Colbert, Conecuh, Coosa, Covington, Crenshaw, Cullman, Dallas, De Kalb, Elmore, Etowah, Escambia, Fayette, Franklin, Greene, Hale, Henry, Houston, Jackson, Jefferson, Lamar, Lauderdale, Lawrence, Lee, Limestone, Lowndes, Macon, Madison, Marengo, Marion, Marshall, Mobile, Monroe, Montgomery, Morgan, Perry, Pickens, Pike, Randolph, Russell, St. Clair, Shelby, Sumter, Talladega, Tallapoosa, Tuscaloosa, Walker, Washington, Wilcox, Winston.

Arkansas. Arkansas, Ashley, Benton, Boone, Calhoun, Carroll, Chicot, Clark, Clay, Cleburne, Cleveland, Conway, Craighead, Crawford, Cross, Desha, Faulkner, Franklin, Greene, Hempstead, Hot Spring, Howard, Independence, Izard, Jackson, Johnson, Lafayette, Lawrence, Lee, Lincoln, Little River, Logan, Lonoke, Madison, Miller, Mississippi, Nevada, Perry, Phillips, Pike, Poinsett, Polk, Pope, Prairie, Pulaski, Randolph, Saline, Scott, St. Francis, Searcy, Sebastian, Sevier, Sharp, Van Buren, Washington, White, Yell.

Florida. Alachua, Bradford, Brevard, Broward, Clay, Collier, Columbia, Dade, De Sota, Duval, Escambia, Flagler, Gadsden, Gilichrist, Glades, Gulf, Hamilton, Hendry, Hernando, Hillsborough, Indian River, Jefferson, Lafayette, Lake, Lee, Levy, Madison, Manatee, Marion, Martin, Nassau, Orange, Osceola, Palm Beach, Pasco, Pinellas, Polk, Putnam, St. Lucie, Sarasota, Sumter, Suwanee, Union, Volusia, Washington.

Georgia. Baker, Baldwin, Barrow, Bartow, Ben Hill, Berrien, Bibb, Bleckley, Brooks, Calhoun, Carroll, Catoosa, Chattooga, Cherokee, Clay, Clinch, Cobb, Coffee, Colquitt, Columbia, Coweta, Crisp, Dade, Dawson, Decatur, Dodge, Dooly, Dougherty, Douglas, Early, Elbert, Emanuel, Fayette, Floyd, Forsyth, Fulton, Gilmer, Gordon, Grady, Gwinnett, Hall, Hancock, Haralson, Harris, Hart, Heard, Henry, Houston, Irwin, Jackson, Jasper, Jefferson, Jenkins, Jones, Lamar, Lee, Lincoln, Lowndes, Lumpkin, Macon, Madison, Marion, McDuffie, Meriwether, Miller, Mitchell, Montgomery, Morgan, Murray, Muscogee, Newton, Oconee, Oglethorpe, Paulding, Pickens, Pierce, Pike, Polk, Pulaski, Putnam, Quitman, Randolph, Rockdale, Schley, Seminole, Spalding, Stewart, Sumter, Talbot, Taliaferro, Tattnall, Telfair, Terrell, Thomas, Tift, Towns, Troups, Turner, Union, Walker, Walton, Warren, Washington, Webster, Whitfield, Wilcox, Wilkes, Worth.

Idaho. Cassia, Franklin, Fremont, Gooding, Jefferson, Jerome, Lincoln, Madison, Oneida, Twin Falls.

Illinois. Jo Daviess.

Kansas. Allen, Atchison, Barton, Butler, Cloud, Cowley, Elk, Ellis, Franklin, Greenwood, Harper, Jackson, Jefferson, Linn, Lyon, McPherson, Montgomery, Morris, Morton, Nemaha, Neosho, Ottawa, Reno, Rice, Russell, Sedgwick, Stafford.

Kentucky. Adair, Allen, Anderson, Ballard, Barren, Bath, Boone, Bourbon, Boyd, Boyle, Bracken, Breckinridge, Bullitt, Butler, Caldwell, Calloway, Carlisle, Carroll, Carter, Casey, Christian, Clark, Clinton, Crittenden, Cumberland, Daviess, Edmonson, Elliott, Estill, Fayette, Fleming, Franklin, Fulton, Gallatin, Garrard, Grant, Graves, Grayson, Green, Greenup, Hancock, Hardin, Harrison, Hart, Henderson, Henry, Hickman, Hopkins, Jackson, Jefferson, Jessamine, Larue, Laurel, Lincoln, Livingston, Logan, Lyon, Madison, Marion, Marshall, Mason, McCracken, McLean, Meade, Mercer, Metcalfe, Monroe, Montgomery, Muhlenberg, Nelson, Nicholas, Ohio, Oldham, Owen, Powell, Pulaski, Rockcastle, Rowan, Russell, Scott, Shelby, Simpson, Spencer, Taylor, Todd, Twigg, Union, Warren, Washington, Wayne, Webster, Woodford.

Louisiana. Acadia, Allen, Ascension, Assumption, Avoyelles, Beauregard, Bienville, Bossier, Caddo, Calcasieu, Caldwell, Catahoula, Claiborne, Concordia, De Soto, East Baton Rouge, East Carroll, East Feliciana, Evangeline, Franklin, Grant, Iberia, Iberville, Jackson, Jefferson, Jefferson Davis, Lafayette, La Salle, Lincoln, Livingston, Madison, Morehouse, Natchitoches, Orleans, Ouachita, Plaquemines, Pointe Coupee, Rapides, Red River, Richland, Sabine, St. Bernard, St. Charles, St. Helena, St. James, St. John The Baptist, St. Landry, St. Martin, St. Mary, St. Tammany, Tangipahoa, Tensas, Terrebonne, Union, Vermilion, Vernon, Washington, Webster, West Baton Rouge, West Carroll, West Feliciana, Winn.

Mississippi. Adams, Alcorn, Amite, Attala, Benton, Bolivar, Calhoun, Carroll, Chickasaw, Choctaw, Claiborne, Clarke, Clay, Coahoma, Copiah, Covington, De Soto, Forrest, Franklin, George, Greene, Grenada, Hancock, Hinds, Holmes, Humphreys, Issaquena, Itawamba, Jackson, Jasper, Jefferson, Jefferson Davis, Jones, Kemper, Lafayette, Lamar, Lauderdale, Lawrence, Leake, Lee, LeFlore, Lincoln, Lowndes, Madison, Marion, Marshall, Monroe, Montgomery, Neshoba, Newton, Noxube, Oktibbeha, Panola, Pearl River, Perry, Pike, Pontotoc, Prentiss, Quitman, Rankin, Scott, Sharkey, Simpson, Smith, Stone, Sunflower, Tallahatchie, Tate, Tippah, Tishimingo, Tunica, Union, Walthall, Warren, Washington, Wayne, Webster, Wilkinson, Winston, Yalobusha, Yazoo.

Missouri. Adair, Andrew, Atchinson, Barry, Barton, Bates, Benton, Bollinger, Boone, Buchanan, Butler, Caldwell, Callaway, Camden, Cape Girardeau,

Carroll, Carter, Cass, Cedar, Chariton, Christian, Clark, Clay, Clinton, Cole, Cooper, Crawford, Dade, Dallas, Daviess, DeKalb, Dent, Douglas, Franklin, Gentry, Greene, Grundy, Harrison, Henry, Holt, Howard, Howell, Iron, Jackson, Jasper, Jefferson, Johnson, Knox, Laclede, Lafayette, Lawrence, Lincoln, Linn, Livingston, Macon, Madison, Maries, Marion, McDonald, Mercer, Miller, Mississippi, Monroe, Morgan, New Madrid, Newton, Nodaway, Oregon, Osage, Ozark, Pemiscot, Pettis, Phelps, Pike, Polk, Putnam, Ralls, Randolph, Ray, Reynolds, Ripley, St. Charles, St. Clair, St. Francois, St. Genevieve, Saline, Scotland, Scott, Shannon, Stoddard, Stone, Sullivan, Taney, Texas, Vernon, Warren, Washington, Wayne, Webster, Worth, Wright.

Nebraska. Adams, Antelope, Arthur, Blaine, Boone, Boyd, Brown, Buffalo, Butler, Cass, Cedar, Cherry, Custer, Dawes, Dawson, Dixon, Fillmore, Frontier, Furnas, Gage, Garden, Garfield, Gosper, Grant, Greeley, Hall, Hamilton, Harlan, Hayes, Holt, Hooker, Howard, Johnson, Kearney, Keith, Keya Paha, Kimball, Knox, Lincoln, Logan, Loup, Madison, McPherson, Merrick, Morrill, Nance, Nemaha, Otoe, Pawnee, Phelps, Pierce, Platte, Polk, Redwillow, Richardson, Rock, Sarpy, Saunders, Scotts Bluff, Sheridan, Sherman, Thomas, Valley, Webster, Wheeler, York.

New Mexico. Bernalillo, Chaves, Curry, Eddy, Lea, Roosevelt.

Oklahoma. Adair, Atoka, Beaver, Beckham, Blaine, Bryan, Caddo, Canadian, Carter, Cherokee, Choctaw, Cleveland, Coal, Comanche, Cotton, Craig, Creek, Delaware, Dewey, Garfield, Garvin, Grady, Grant, Greer, Harmon, Harper, Haskell, Hughes, Jefferson, Johnson, Kay, Kingfisher, Kiowa, Latimer, Le Flore, Lincoln, Logan, Love, Major, Marshall, Mayes, McClain, McCurtain, McIntosh, Murray, Muskogee, Noble, Nowata, Okfuskee, Oklahoma, Okmulgee, Osage, Ottawa, Pawnee, Payne, Pittsburg, Pontotoc, Pottawatomie, Pushmataha, Roger Mills, Rogers, Seminole, Sequoyah, Stephens, Texas, Tillman, Tulsa, Wagoner, Washington, Washita, Woods.

South Dakota. Faulk, Jones, Stanley.

Tennessee. Bedford, Benton, Bledsoe, Bradley, Cannon, Carroll, Cheatham, Chester, Clay, Cocke, Coffee, Crockett, Cumberland, Davidson, Decatur, DeKalb, Dickson, Dyer, Fayette, Franklin, Gibson, Giles, Greene, Grundy, Hamilton, Hardeman, Hardin, Hawkins, Haywood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Jefferson, Lauderdale, Lawrence, Lincoln, Loudon, Macon, Madison, Marion, Marshall, Maury, McMinn, McNairy, Monroe, Montgomery, Moore, Obion, Overton, Pickett, Putnam, Rhea, Rutherford, Shelby, Smith, Stewart, Sumner, Tipton, Trousdale, Warren, Washington, Wayne, Weakley, White, Williamson, Wilson.

Texas. Anderson, Andrews, Angelina, Aransas, Archer, Atascosa, Austin, Bailey, Bastrop, Baylor, Bee, Bell, Bexar, Blanco, Bosque, Bowie, Brazoria, Brazos, Briscoe, Brooks, Brown, Burleson, Burnet, Caldwell, Calhoun, Callahan, Cameron, Camp, Carson, Cass, Castro, Chambers, Cherokee, Clay, Cochran, Coke, Coleman, Collin, Collingsworth, Colorado, Comanche, Concho, Cooke, Coryell, Cottle, Crockett, Crosby, Dallam, Dallas, Dawson, Deaf Smith, Delta, Denton, De Witt, Dickens, Dimmitt, Donley, Duval, Eastland, Edwards, Ellis, El Paso, Erath, Falls, Fannin, Fayette, Fisher, Floyd, Foard, Fort Bend, Franklin, Freestone, Frio, Gaines, Galveston, Garza, Goliad, Gonzales, Grayson, Gregg, Grimes, Guadalupe, Hale, Hall, Hamilton, Hardeman, Hardin, Harris, Harrison, Haskell, Hays, Henderson, Hidalgo, Hill, Hockley, Hood, Hopkins, Houston, Howard, Hunt, Jack, Jackson, Jasper, Jefferson, Jim Hogg, Jim Wells, Johnson, Jones, Karnes, Kaufman, Kenedy, Kent, King, Kinney, Kleberg, Knox, Lamar, Lamb, Lampasas, La Salle, Lavaca, Lee, Leon, Liberty, Limestone, Lipscomb, Live Oak, Lubbock, Lynn, McCulloch, McLennan, McMullen, Madison, Marion, Matagorda, Maverick, Medina, Milam, Mills, Mitchell, Montague, Montgomery, Morris, Motley, Nacogdoches, Navarro, Nolan, Nueces, Oldham, Orange, Palo Pinto, Panola, Parker, Parmer, Polk, Potter, Rains, Randall, Red River, Reeves, Refugio, Robertson, Rockwall, Runnels, Rusk, Sabine, San Augustine, San Jacinto, San Patricio, San Saba, Scurry, Shackelford, Shelby, Smith, Somervell, Starr, Stephens, Stonewall, Swisher, Tarrant, Taylor, Terry, Throckmorton, Titus, Travis, Trinity, Tyler, Upshur, Upton, Uvalde, Van Zandt, Victoria, Walker, Waller, Washington, Webb, Wharton, Wheeler, Wichita, Wilbarger, Willacy, Williamson, Wilson, Wise, Wood, Young, Zapata, Zavala.

Utah. Box Elder, Garfield.

Puerto Rico. Arecibo, Camuy, Carolina, Gurabo, Hatillo, Isabela, Las Piedras, Morovis, Naguabo, Quebradillas, San Sebastian.

§ 78.22 Noncertified Areas.

The following States, or specified portions thereof, are hereby designated as Noncertified Bruellosis Areas:

(a) *Entire States.*

Yellowstone National Park.

(b) *Specific Counties Within States.*

Florida. Charlotte, Hardee, Highlands, Okeechobee; *Louisiana.* Cameron, Lafourche.

(Secs. 4–7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791–792, as amended; sec. 3, 33 Stat. 1265, as amended; sec. 2, 65 Stat. 693; and secs. 3 and 11, 76 Stat. 130, 132, 21 U.S.C. 111–113, 114a–1, 115, 117, 120, 121, 125, 134b, 134f; 37 FR 28464, 28477; 38 FR 19141, 9 CFR 78.25)

The amendment designating an areas as a Modified Certified Brucellosis Area imposes restrictions presently not imposed on cattle moved from that area in interstate commerce. The restrictions are necessary in order to prevent the spread of brucellosis from such area.

Therefore, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this final rule are impracticable and contrary to the public interest and good cause is found for making this final rule effective less than 30 days after publication of this document in the **Federal Register.**

Further, this final rule has not been designated as "significant," and is being published in accordance with the emergency procedures in Executive Order 12044 and Secretary's Memorandum 1955. It has been determined by Paul Becton, Director, National Brucellosis Eradication Program, APHIS, VS, USDA, that the emergency nature of this final rule warrants publication without the opportunity for public comment and preparation of an impact analysis statement at this time.

This final rule will be scheduled for review under provisions of Executive Order 12044 and Secretary's Memorandum 1955.

Done at Washington, D.C., this 22nd day of December 1980.

Norvan L. Meyer,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 80–40408 Filed 12–29–80; 8:45 am]

BILLING CODE 3410–34–M

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9 CFR Part 92

Cattle Imported Through Harry S Truman Animal Import Center; Procedures

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document amends the regulations concerning the procedures to be used for the allotment of quarantine space for cattle to be imported through

the Harry S Truman Animal Import Center (HSTAIC). This amendment provides:

1. That at least 60 days prior to any drawing notice will be given in the **Federal Register** of the date, time and place of the drawing. The notice shall also designate the geographic areas from which animals will be considered for importation and shall include the fee schedule for the proposed importation.

2. That the application to import animals shall be accompanied by a certified check or money order in the amount of $1,000 for each animal requested and that the application be received by the Department at least 5 days prior to the date of the drawing.

3. That the applicant, or their designated legal agent or representative, be present at the drawing at which time the cooperative agreement shall be executed and the financial responsibility shall be assumed by the successful applicants.

4. Editorial changes are provided to clarify the procedures and the importers' financial responsibility.

These changes are believed necessary to better administer the facility and help insure that the facility is fully utilized.

EFFECTIVE DATE: December 23, 1980.

FOR FURTHER INFORMATION CONTACT: Dr. D. E. Herrick, USDA, APHIS, VS, Federal Building, Room 819, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–8170. The Final Impact Statement describing the options considered in developing this final rule and the impact of implementing each option is available on request from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, 301–436–8695.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been classified as "not significant".

Dr. Milton J. Tillery, Director, National Program Planning Staffs, has determined that an emergency situation exists which warrants that this final rule become effective less than 30 days after publication in the **Federal Register**, because the lottery for the third importation of animals imported into the United States through the HSTAIC will be on January 6, 1981, and the procedures required by this amendment concern the application process and system of allocation of space at HSTAIC. Potential applicants should be notified of these procedures as soon as possible. Further, these procedures should result in a substantial cost savings to the Federal Government and should facilitate the allocation of space for the HSTAIC. Therefore, they should be implemented for the third importation.

On Friday, June 6, 1980, there was published in the **Federal Register** (45 FR 38036–38038) an amendment that provided a method of selecting alternate applicants to replace applicants originally selected who have not delivered the required cooperative agreement and the required funds, payment bond or letter of credit to the Department. The intended effect of that action was to achieve maximum utilization of all available quarantine space at HSTAIC.

A period of 60 days was provided for receipt of comments, which expired August 5, 1980. No comments were received. The amendment was determined to be essential in order to allow the Department to better coordinate and allocate personnel and materials to the facility and to provide maximum utilization of the facility. However, the procedures were time consuming, were difficult to administer and did not provide the desired results.

On Tuesday, October 14, 1980, there was published in the **Federal Register** (45 FR 67669–67673) a proposed amendment to the regulations of § 92.41 (9 CFR 92.41) concerning the procedures to be used for the allotment of quarantine space for cattle to be imported through the Harry S Truman Animal Import Center which, among other provisions, proposed to amend the procedures of the Friday, June 6, rulemaking.

A period of 30 days was provided for receipt of comments which expired November 13, 1980. Only one comment was received. It stated that the cost schedule would make it prohibitive to import any more animals through HSTAIC, that even if affordable, it would be impossible to bring a letter of credit at the time of the drawing, and suggesting a meeting be held with interested importers to resolve these matters.

The costs associated with the operation of the Harry S Truman Animal Import Center are to be borne by the importers using this facility and will vary in accordance with the actual number of animals utilizing the facility during a given importation period. Each importer who has been authorized a special permit in the drawing, must sign a cooperative agreement which, among other things, sets forth the payment requirements prior to being awarded a special permit to import cattle into HSTAIC.

The regulations also presently require that the selected applicants deliver the cooperative agreement set forth in § 92.41(c) and the payment required under such agreement to the Department within a specified time. This has resulted in the Department not being able to determine if the applicants selected by lottery are going to exercise their right to obtain a special permit. This could result in less than full utilization of the HSTAIC for a particular importation. Therefore, it is essential that the importers, prior to issuance of the special permits, assume fiscal responsibility of the expenses to be incurred. Due to the unusual nature of the service and the need to have adequate funds available to the Department for the cost of the services which will be performed in connection with the importation of animals into the HSTAIC in accordance with the provisions of section 1 of the Act of May 6, 1970 (21 U.S.C. 135), the Department requires either advance payment, a payment bond or a letter of credit, meeting the requirements specified in the cooperative agreement, be deposited with the Service (Veterinary Services) at the time of the drawing. The Department believes that while it could require only cash advance payment of the entire fee, alternative mechanisms for payment are necessary to provide the importer ways to participate in the importation process without "tying up" an importer's cash reserve from the outset of the importation process. The alternative methods of payment are believed to be workable alternatives to requiring that funds be deposited in cash at the outset of the importation process. If the letter of credit option does not prove feasible, the importer may rely on either the advance payment in cash or the use of a bond to cover the cost of the service.

Further, the Department has found that the formula for the fees prescribed for the quarantine period that are based upon full utilization of the facility do not provide for all contingencies. If there is less than full utilization of the facility during the quarantine period, then it will not be self-supporting to the fullest extent possible as Congress intended. However, whether or not the facility will actually be fully utilized depends on several factors, the first of which is the ability of all prospective importers to obtain the necessary financing to enter into the required cooperative agreement. If a prospective importer cannot obtain such financing, the facility will not be fully utilized, unless there is time for another importer to be offered the space in accordance with the regulations and he has time to make all the necessary

financial and pre-entry quarantine arrangements.

Therefore, in order to provide sound financial management both for the prospective importers and the Department, it is essential that the importers, prior to the approval and issuance of the special permits, assume fiscal responsibility for the expenses to be incurred.

The suggestion that the Department meet with prospective importers is rejected since, as stated previously, the lottery for the third importation will be on January 6, 1981, and there is not sufficient time to advise interested persons and schedule such a meeting. Therefore, since this amendment concerns the application process, the proposed amendment is adopted without change.

The Animal and Plant Health Inspection Service (APHIS) is quite concerned about the escalating cost of importing cattle through HSTAIC. APHIS is committed to analyzing its procedures for HSTAIC and to try to identify and implement cost-cutting measures in the operation of the Center. Along with this, APHIS is also exploring the legality and practical feasibility of alternative uses of the facility, or portions thereof in the event that there is less than maximum utilization of the Center during a given importation period, in order to cut costs associated with the importation of cattle through HSTAIC.

Accordingly, Part 92, Title 9, Code of Federal Regulations is amended in the following respects:

1. Sections 92.41 (a) and (b) are revised to read:

§ 92.41 Requirements for the importation of animals into the United States through the Harry S Truman Animal Import Center.

(a) *Special authorization.* Because of the extended period of time required to process cattle intended for importation from countries affected with exotic diseases not otherwise eligible for importation into the United States, including foot-and-mouth disease, through the Harry S Truman Animal Import Center, (HSTAIC), special authorization shall be required before any animal may enter the facility for quarantine. Such authorization will be issued on a lottery basis in accordance with the following procedures:

(1) *Drawing; contents of applications and deposits.* For each importation of animals into the HSTAIC, a drawing will be held of the names of applicants who desire to import animals into the facility at that particular time. Each applicant shall complete an application for importing animals through the HSTAIC which shall be received by Veterinary Services at least 5 days prior to the date of the drawing.[14] The applicant shall state on the application the number of animals he desires to import into the HSTAIC and their country of origin. Each application shall be accompanied by a certified check or money order payable to the United States Department of Agriculture, Animal and Plant Health Inspection Service, in the amount of one thousand dollars ($1,000), for each animal for which special authorization is requested on the application. In the event the applicant does not receive special authorization for animals for which he has applied, the amount deposited with the application for each animal not so authorized will be returned. If the applicant receives special authorization, the deposited amount shall be applied against the total cost of importation of each animal. At least 60 days prior to any drawing, notice will be given in the **Federal Register** of the date, time and place of the drawing for interested persons to submit an application. The notice shall also designate the geographic areas from which animals will be considered for importation into the HSTAIC and shall also include the fee schedule for the proposed importation. All applicants, or their designated legal agents or representatives, shall be required to appear in person at the drawing. Such designated legal agent or representative shall have a notarized statement of authority signed by the applicant.

(2) *Drawing for special authorization.* At the time, date, and places specified in the Notice of Drawing, if there are more than 400 applicants, a Department employee shall consecutively draw the names of applicants, until a maximum of 400 names have been selected to receive special authorization to qualify one animal for entry into the United States through the HSTAIC. If there are less than 400 applicants for 400 animals or more, the procedure for the consecutive drawings for spaces shall be as follows: A drawing will be held of the names of those applicants seeking to import at least one animal into the HSTAIC. Then a drawing will be held on the names of applicants wishing to import at least two animals. If after these names have been selected, available space in the HSTAIC still exists, a drawing will be held of the names of those applicants seeking to import at least three animals into the center. This selection process shall continue in the same manner until no available space exists for importing animals into the HSTAIC. However, if the total applications received are for less than 400 animals, each applicant shall receive special authorization for the number requested on their application in acordance with the provisions of subparagraph (4) of this paragraph (a). Further, if available space at the HSTAIC still exists at the designated time of the drawing, each of the applicants shall be offered an opportunity to request additional space(s). If the requests for additional space(s) exceed the space(s) available, a lottery drawing shall be conducted for the additional spaces in the same manner as provided above from those interested applicants. Each applicant shall receive special authorization for the additional space(s) in accordance with the provisions of subparagraph (4) of this paragraph (a). At the end of the drawing when the total number of animals has been determined, the fee will be established in accordance with the graduated fee scale. If any person selected to receive a special authorization declines acceptance, the other applicants will be offered the opportunity to receive the special authorization as provided above in this subparagraph. If any such additional authorization is not requested, the fee per animal shall increase in accordance with the graduated fee schedule: *Provided,* That if the total number of animals for which special authorizations are requested is not at least 50, there shall not be a lottery or importation and the deposits shall be refunded to the applicants.

(3) *Area of origin; limitations.* All applications received will be carefully reviewed prior to the public drawing. In the event applications are received for the importation of cattle which originate from areas in which conditions are considered to be unacceptable as specified in § 92.4(a)(3), the applicant will be so advised in writing and the money submitted with the application will be returned.

(4) *Requirements for special authorization.* On the day of the drawing applicants selected to receive special authorization for cattle to be qualified for importation through the HSTAIC, or their designated legal agents or representatives shall be required to execute a cooperative agreement described in § 92.41(c) and pay the required fee in accordance with the provisions of the cooperative agreement. Authorization to qualify cattle into the United States through

[14] Application forms may be obtained upon request from and completed applications should be sent to Import-Export Animals and Products Staff, Veterinary Services, APHIS, U.S. Department of Agriculture, 6505 Belcrest Road, Room 815, Hyattsville, MD 20782.

HSTAIC shall not be assigned or transferred, not shall any interest be assigned or transferred.

(b) *Fees.* (1) Cost associated with the maintenance and operation of the facility shall be borne by applicants who receive a special authorization under this section in accordance with the provisions of a cooperative agreement specified in paragraph (c) of this section.

(2) The Deputy Administrator is authorized to establish reasonable fees of the costs incurred by the Department in the maintenance and operation of the HSTAIC. Such fees shall include certain pre-entry services provided by the Department to prepare HSTAIC and animals for entry into that facility. Fees shall also include costs incurred while animals are in the facility and for a period of 30 days subsequent to the animals leaving the facility for costs incurred in its cleaning and disinfecting.

(3) The fees authorized in this section shall be based upon the following items:

(i) *Personnel.* The hourly rates including appropriate premium pay in accordance with 5 U.S.C. 5541–5549 for Veterinary Services' employees who perform the service.

(ii) *Travel.* The costs of travel and per diem of Veterinary Services' employees from their official duty station to their temporary duty station and return in order to qualify animals for entry into the facility. Travel costs shall also include costs to courier test samples from temporary duty stations overseas to Plum Island for testing.

(iii) *Utilities.* The cost of electricity, oil and water for operating the HSTAIC for the five month period of quarantine plus one month for cleaning and disinfection.

(iv) *Laboratory costs.* The cost of conducting three series of laboratory tests for each animal as authorized by the cooperative agreement and in accordance with a Veterinary Services protocol [14a] to qualify for importation into the Harry S Truman Animal Import Center.

(v) *Supplies.* The cost of supplies (feed, bedding, disinfectants, contact test animals and miscellaneous supplies for the animal care, maintenance, and testing at the facility) for the five month period of quarantine plus one month for cleaning and disinfection.

(vi) *Overhead.* A surcharge for overhead based on the most current historical data available showing the percentage of Animal and Plant Health Inspection Service funds expended for administrative support.

(4) Any test performed on animals in excess of the number of animals specified in a cooperative agreement is not included in the fees authorized in this section. The Deputy Administrator shall charge the importer for whom the service is performed the actual cost of conducting such test. Payment shall be due upon receipt by such person of a bill for the services from the Department.

(5) The cost of any additional laboratory tests deemed necessary by the Deputy Administrator to determine an animal's freedom from communicable disease is not included in the fees authorized in this section. Also, any treatment performed on animals while at the Harry S Truman Animal Import Center is not included in the fees authorized in this section. The Deputy Administrator shall charge the importer for whom the service is performed the actual cost of such testing or treatment. Payment shall be due upon receipt by that person of a bill for the services from the Department.

(6) The importer shall be reimbursed for any monies advanced for feed, bedding or laboratory tests for animals at the HSTAIC if such feed or bedding are not used or if such laboratory test for animals are not performed by Veterinary Services.

(7) Fees shall be based on the expected level of occupancy of the HSTAIC as determined by the number of cattle for which importers have been specially authorized to import the Center.

§ 92.41 [Amended]

2. In § 92.41(c) the first paragraph is revised to read:

* * * * *

(c) *Cooperative agreements.* Each applicant, or their legal agent or representative, selected to be specially authorized to qualify animals for importation through the HSTAIC shall enter into and abide by the provisions of the following cooperative agreement with the Department. Financial obligation for the amount detailed in the following cooperative agreement is to be provided at the time the cooperative agreement is signed.

* * * * *

3. In § 92.41(c) paragraph (A) of the "Cooperative Agreement" is amended in subparagraphs 4, 5, 6, and 7 by renumbering 5, 6, 7, and 8 respectively and adding a new subparagraph 4 to read:

* * * * *

(c) * * *

(A) * * *

4. To pay for all laboratory tests in addition to those identified in the Veterinary Services protocol for importing animals into the HSTAIC deemed necessary by the Department to determine freedom from communicable animal diseases.

* * * * *

(Sec. 1, Pub. L. 91–239 (21 U.S.C. 135); 37 FR 28464, 28477; 38 FR 19141)

Done at Washington, D.C., this 23d day of December, 1980.

Norvan L. Meyer,

Acting Deputy Administrator, Veterinary Services.

[FR Doc. 80-40511 Filed 12-23-80; 4:02 pm]

BILLING CODE 3410-34-M

[14a] A protocol concerning the requirements to be observed may be obtained upon request from Import-Export Animals and Products Staff, Veterinary Services, APHIS, VS, U.S. Department of Agriculture, 6505 Belcrest Road, Room 819, Hyattsville, MD 20782.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

Organization and Operations of Federal Credit Unions; Share, Share Draft and Share Certificate Accounts

AGENCY: National Credit Union Administration.

ACTION: Final rule.

SUMMARY: On November 14, 1980, the National Credit Union Administration (NCUA) published for public comment a proposed rule concerning a premium or gift given by a Federal Credit Union for establishing an account, renewing an account or adding to an existing account. The proposed rule would consider such a premium or gift a promotional or advertising expense, and not a dividend for purposes of 12 CFR 701.35(h), f (1) the premium or gift is given only at the time of the opening of a new account or an addition to, or renewal of, an existing account; (2) no more than two premiums per account are given within a 12-month period; and (3) the value of the premium or gift (including shipping, warehousing, packaging and handling) does not exceed $10 for share purchases of less than $5,000 or $20 for share purchases of $5,000 or more. The costs of the premium may not be averaged. Prior to the beginning of a premium program, an official of the credit union must certify that the total cost of the premium or gift, including shipping, warehousing, packaging and handling does not exceed the applicable $10/20 limitations and that no portion of the total cost of any premium has been attributed to development, advertising, promotional or other expenses. Certification and supporting documents must be retained in the files of the Federal credit union until the next examination and be made available to NCUA upon request.

The period for comments expired on December 10, 1980. After reviewing and considering all comments received and views expressed, the NCUA Board has decided to adopt the proposed regulation as a final regulation with the exception of the requirement that only two premiums may be given per account in any 12 month period.

EFFECTIVE DATE: December 31, 1980.

ADDRESS: National Credit Union Administration, 1776 G Street, NW., Washington, D.C. 20456.

FOR FURTHER INFORMATION CONTACT: James J. Engel, Assistant General Counsel or Todd A. Okun, Assistant General Counsel, both at above address; telephone (202) 357–1030.

SUPPLEMENTARY INFORMATION: Of the approximately 20 comments received, nearly all from Federal credit unions, the vast majority expressed the belief that there was no evidence of abuse to justify the proposed rule and that the proposal represented a burdensome and unnecessary new regulation and not a deregulation, which is the mandate of the Depository Institutions Deregulation Committee (Committee) whose regulation is the parallel for NCUA's proposal.

It is the view of the NCUA Board that the concurrent establishment of a dividend earning account (or renewal of, or addition to, an account) and the giving of a gift or premium of value could lead to impermissibly exceeding the dividend limitations on Federal credit union accounts prescribed at 12 CFR 701.35(h). Therefore, there is an obligation on the NCUA Board to assure that this does not occur. Coupled with this duty is the knowledge that premiums have, in fact, been valuable to Federal credit unions in attracting new funds. Previous policy in this area, common to all financial regulatory agencies, delineated *de minimus* amounts that could be given as premiums but that would not be considered as dividends. The final rule recognizes that economic conditions have changed since 1970 and, hence, it doubles the permissible value of premiums that may be given without being considered dividends.

The NCUA Board does not consider the rule to be burdensome except for the requirement that only two premiums may be given per account in any twelve month period. This requirement would impose a confusing and burdensome recordkeeping requirement and would inhibit a Federal credit union board of directors in its decision as to the proper timing and form of a premium campaign. It could serve to stifle innovation and preclude the use of a badly needed premium campaign if the limit imposed by this requirement has already been reached. Therefore, the NCUA Board has deleted this requirement from the final regulation.

While Federal credit unions are not bound by rules promulgated by the Committee, the NCUA Board believes that, in this case, parallel rules as to the value of permissible premiums that will not be considered dividends are appropriate. All financial regulatory agencies have, since 1970, promulgated parallel rules or policies in this area. Because of this fact and the belief of the NCUA Board that the substance of the regulation itself is not overly restrictive or burdensome, the proposed rule as to amounts is adopted as final. The NCUA Board believes that, within the rule's guidelines, innovative and effective promotional programs can be undertaken while retaining the integrity of the dividend limitations.

One commenter asked about the applicability of the proposed rule to a promotional program wherein establishment of accounts and renewals of, or additions to, accounts are rewarded with changes of winning a television set or automobile through a random drawing. It has been, and continues to be, NCUA policy that the nominal value of each chance need not be considered in relation to the applicable dividend guidelines. In addition, the value of the ultimate prize awarded at the drawing is not considered a dividend to the recipient. The prize should be of reasonable value, as determined by the board of directors. Before initiating such a program, however, a Federal credit union would be well advised to consult with an attorney to determine whether any given program might run afoul of either Federal or state lottery laws.

Another commenter asked about the use of such "goodwill" items as pens, calendars, luggage tags and the like. These items need not be considered dividends unless they are specifically offered, and only given, in connection with the establishment of, addition to, or renewal of a Federal credit union account. That same commenter suggested that the proposed rule should apply to promotional activities designed to induce loans. However, the purpose of the rule is to ensure that the dividend guidelines in connection with share purchases are not exceeded. Premiums to induce loans are not covered by the final rule and are within the discretion of a board of directors.

Inadvertently omitted from the proposed rule was the fact that required certification would not have to be kept on file beyond the next examination of the credit union. The regulation now reflects this requirement.

Accordingly § 701.35 is amended by a adding a new paragraph (m) to read as set forth below.

Rosemary Brady,

Secretary to the Board, National Credit Union Administration.

December 22, 1980.

(Sec. 107(6), 94 Stat. 132 (12 U.S.C. 1757(6)), sec. 120, 73 Stat. 635 (12 U.S.C. 1766) and Sec. 209, 84 Stat. 1104 (12 R.S.C. 1789)).

§ 701.35 Share Accounts and Share Certificate Accounts.

* * * * *

(m) *Premiums.* (1) Premiums given by a Federal credit union, whether in the form of merchandise or cash, are regarded as an advertising or promotional expense rather than the payment of a dividend if:

(i) The premium is given only at the time of the establishment of a new account or an addition to, or renewal of, an existing account; and

(ii) The value of a premium, including shipping, warehousing, packaging and handling costs does not exceed $10 for share purchases of less than $5,000 or $20 for share purchases of $5,000 or more; and

(iii) The costs of premiums are not averaged; and

(iv) An official of the credit union, prior to the inception of a premium program, certifies in writing that the total cost of a premium, including shipping, warehousing, packaging and handling cost does not exceed the applicable $10/20 limitations and that no portion of the total cost of the premium has been attributed to development, advertising, promotional or other expenses. The certification and supporting documents must be maintained in the Federal credit union files until the next examination of the credit union.

[FR Doc. 80-40342 Filed 12-29-80; 8:45 am]

BILLING CODE 7535-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. 80N-0345]

Public Hearing Before a Public Advisory Committee; Advisory Committee Annual Reports

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to delete the provision that requires advisory committees which meet entirely in open session to issue annual reports. This provision is no longer necessary.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: Richard L. Schmidt, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 12, 1980 (45 CFR 60449), FDA published a proposal to eliminate annual reports from committees which meet entirely in open session and invited public comment through November 12, 1980. No comments were received.

Section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463) requires that any advisory committee that holds a closed meeting issue a report at least annually setting forth a summary of its activities as would be informative to the public. FDA's regulations implemented this requirement (21 CFR 14.60(d)) and further extended this obligation to all agency advisory committees whether or not they held any closed sessions (21 CFR Part 14.60(e)). The purpose of the report was to inform the public of the advisory committees' membership, functions, recommendations, and other actions. In light of the public accessibility to this information (21 CFR 14.75), particularly for committees which meet entirely in open session, § 14.60(e) is no longer necessary. Thus, with this change, FDA's regulations conform to Federal Advisory Committee Act requirements of reports only for committees that have held closed sessions.

§ 14.60 [Amended]

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 14 is amended in § 14.60 *Minutes and reports of advisory committee meetings* by deleting paragraph (e).

Effective date. December 29, 1980.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)).)

Dated: December 12, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-0284 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Parts 73 and 81

[Docket No. 80N-0447]

Postponement of Closing Date for Provisional Listing of Lead Acetate; Notice of Stay of Regulations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of lead acetate for use as a color additive in cosmetics that color the hair on the scalp. A new closing date of March 3, 1981 is being established to complete the agency's evaluation of objections received in response to the final regulation approving the petition for the permanent listing of lead acetate. The regulation that permanently lists lead acetate and deletes lead acetate from the provisional list is stayed until final agency action is taken on the objections.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: The current closing date of December 31, 1980, for the color additive provisional listing of lead acetate was established by a regulation published in the **Federal Register** of October 31, 1980 (45 FR 72117). The December 31, 1980, closing date for lead acetate was established to provide for receipt and evaluation of any objections received in response to the final regulation approving the petition for the permanent listing of lead acetate.

After the review and evaluation of the data relevant to the color additive petition for lead acetate used in hair dyes, the agency concluded that lead acetate was safe and suitable for that use. Therefore, FDA issued a regulation that would permanently list lead acetate. The listing regulation was published in the **Federal Register** of October 31, 1980 (45 FR 72112). It was stated in the text of the listing regulation that the regulation shall become effective December 1, 1980, except as to provisions that may be stayed by filing of proper objections.

FDA has received several objections to the listing regulation. Because of the objections the agency is staying the regulations that permanently lists lead acetate and that delete lead acetate from the color additive provisional list until the agency can rule upon the objections. It is expected that the agency will need only a brief period of time to complete the evaluation of the objections and publish a final decision concerning them in the **Federal Register.** Therefore, the agency concludes that a brief postponement is necessary, and the regulation set forth below will postpone the December 31, 1980, closing date for the provisional listing of that color additive until March 3, 1981.

Because the current closing date expires on December 31, 1980, FDA has concluded that the use of a notice and public procedure on this regulation is impracticable. Moreover, good cause exists for issuing this postponement as a final rule and such action is consistent with the protection of the public health since the agency has previously concluded that lead acetate is safe for its intended use under the Color Additive Amendments of 1960. This regulation will permit the uninterrupted use of this color additive until March 3, 1981. To prevent any interruption in the provisional listing of lead acetate, and in accordance with 5 U.S.C. 553(d) (1) and (3), this regulation is being made effective on December 30, 1980.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701(e), 706(b), (c), and (d), 70 Stat. 919 as amended, 74 Stat. 399–403 (21 U.S.C. 371(e), 376(b), (c), and (d))) and the Transitional Provisions of the Color Additive Amendments (Title II, Pub. L. 86–618, sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

§ 73.2396 [Stayed]

1. Part 73 is amended by staying § 73.2396 *Lead acetate.*

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

2. Part 81 is amended as follows:

§ 81.1 [Amended]

a. In § 81.1 *Provisional lists of color additives* the amendment in paragraph (g) of deleting the entry "Lead acetate" is stayed, and the entry "Lead acetate" and its closing date, "March 3, 1981", are added.

§ 81.27 [Amended]

b. In § 81.27 *Conditions of provisional listing of additives,* the closing date for

"Lead acetate" in paragraph (b) is revised to read "March 3, 1981."

Effective date. This regulation is effective December 30, 1980.

(Secs. 701(e), 706(b), (c), and (d), 70 Stat. 919 as amended, 74 Stat. 399–403 (21 U.S.C. 371(e), 376(b), (c), and (d)); (sec. 203, 74 Stat. 404–407 (21 U.S.C. 376, note))

Dated: December 22, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–40580 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 173

[Docket No. 76F–0371]

Secondary Direct Food Additives Permitted in Food for Human Consumption; 1–Hydroxyethylidene–1,1–Diphosphonic Acid and its Sodium and Potassium Salts

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the food additive regulations to provide for the safe use of 1–hydroxyethylidene–1, 1–diphosphonic acid and its sodium and potassium salts as boiler water additive used in the preparation of steam that will contact food. The agency is taking this action in response to a petition filed by Monsanto Co.

DATES: Effective December 30, 1980.; objections by January 29, 1981.

ADDRESS: Written objections to the Dockets Management Branch (formly the Hearing Clerk's office)(HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James B. Lamb, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 29, 1976 (41 FR 42970), FDA announced that a petition (FAP 6A3163) had been filed by Monsanto Co., 800 N. Lindbergh Blvd., St. Louis, MO 63166, proposing to amend § 173.310 *Boiler water additives* (21 CFR 173.310) to provide for the safe use of 1–hydroxyethylidene–1, 1–diphosphonic acid and its sodium and potassium salts as boiler water additives used in the preparation of steam that will contact food.

Having evaluated data in the petition and other relevent material, FDA concludes that the food additive regulations should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 173 is amended in § 173.310(c) by alphabetically inserting a new item in the list of substances to read as follows:

§ 173.310 Boiler water additives.

* * * * *

(c) * * *

Substances	Limitations
* * * *	
1–hydroxyethylidene–1,1–diphosphonic acid (CAS Reg. No. 2809–21–4) and its sodium and potassium salts.	
* * * *	

Any person who will be adversely affected by the foregoing regulation may at any time on or before January 29, 1981, submit to the Dockets Management Branch (formly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective December 30, 1980.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: December 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–40505 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 178

[Docket No. 80F–0169]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Antistatic and/or Antifogging Agents in Food-Packaging Materials

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the food additive regulations to provide for the safe use of sodium *n*-alkylsulfonate as an antistatic agent in polyolefin films intended for food-contact use. This action is in response to a petition filed by British Cellophane Ltd.

DATES: Effective December 30, 1980. Objections by January 29, 1981.

ADDRESS: Written objections to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 3, 1980 (45 FR 37524), FDA announced that a food additive petition (FAP 9B3476) had been filed by British Cellophane Ltd., Bath Rd., Bridgewater, Somerset TA6 4PA, England, proposing that the food additive regulations be amended to provide for the safe use of sodium *n*-alkylsulfonate as an antistatic agent in polyolefin films intended to contact food.

Having evaluated data in the petition and other relevant material, FDA concludes that the food additive regulations should be amended as set forth below.

The agency has considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that document may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers

Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 178 is amended in § 178.3130(b) by alphabetically inserting a new item in the list of substances to read as follows:

§ 178.3130 Antistatic and/or antifogging agents in food-packaging materials.

* * * * *

(b) * * *

List of substances	Limitations
* *	* * *
Sodium *n*-alkylsulfonate (alkyl group in the range of C_{10-18} with not less than 50 percent C_{14-16})..	For use only as an antistatic agent at levels not to exceed 0.1 percent by weight of polyolefin films that comply with § 177.1520 of this chapter: *Provided,* That the finished olefin polymers contact foods only of types I, II, III, IV, V, VI—A, VI–B, VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter, and under conditions of use E, F, and G described in table 2 of § 176.170(c) of this chapter.

Any person who will be adversely affected by the foregoing regulation may at any time on or before January 29, 1981 submit to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective December 30, 1980.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: December 19, 1980.

William F. Randolph

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–40506 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 510

Change of Sponsor Name; New Animal Drugs

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration amends the animal drug regulations to reflect change of sponsor for several new animal drug applications (NADA's) from Formica Laboratories to Mountaire Feeds & Vitamin Premixes, Division of Mountaire Corp., and to revise the list of sponsors of approved NADA's to reflect the name change.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: Robert S. Brigham, Bureau of Veterinary Medicine (HFV–238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6243.

SUPPLEMENTARY INFORMATION: Mountaire Feeds & Vitamin Premixes, Division of Mountaire Corp., 124 E. Fifth St., Little Rock, AR 72119, advised the agency of a change of sponsor name from Formica Laboratories. The Bureau of Veterinary Medicine is amending the regulations in 21 CFR 510.600 to reflect the change.

This action, the change of sponsor of several NADA's, does not involve changes in manufacturing facilities, equipment, procedures, or personnel. Under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), approval of this action does not require reevaluation of the safety and effectiveness data in the parent applications.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 510 is amended in § 510.600 by deleting the entry for "Formica Laboratories" in paragraph (c)(1) and adding a new sponsor alphabetically, and by deleting from paragraph (c)(2) in the numerical listing for "043734" the entry "Formica Laboratories," and inserting in its place "Mountaire Feeds & Vitamin Premixes, Division of Mountaire Corp.," to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Mountaire Feeds and Vitamin Premixes, Division of Mountaire Corp., 124 E. Fifth St., P.O. Box 5391, Little Rock, AR 72119..	043734

* * * * *

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
043734....	Mountaire Feeds and Vitamin Premixes, Division of Mountaire Corp., 124 E. Fifth St., P.O. Box 5391, Little Rock, AR 72119.

* * * * *

Effective date. December 29, 1980.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: December 16, 1980.

Max L. Crandall,

Associate Director for Surveillance and Compliance.

[FR Doc. 80–40283 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

CFR Part 607

[Docket No. 79N–0396]

Exemption of Certain Transfusion Services and Clinical Laboratories From Registration

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations to exempt transfusion services and clinical laboratories that are approved for Medicare reimbursement from FDA's registration and product listing requirements. This rule implements a Memorandum of Understanding concluded between the Public Health Service (PHS), including FDA, and the Health Care Financing Administration (HCFA). To avoid unnecessary

regulatory duplication, FDA has agreed not to conduct routine inspections of these exempted facilities.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: About this final rule: Steven F. Falter, Bureau of Biologics (HFB–620), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301–443–1306; about registration or for notification of a change in registration status: Herbert W. Dorsey, Bureau of Biologics (HFB–14), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301–443–5368.

SUPPLEMENTARY INFORMATION: In early October 1979, a Memorandum of Understanding (MOU) was concluded between PHS, including FDA, and HCFA. The MOU was approved by the Secretary on January 21, 1980. HCFA agreed to assume sole responsibility for the routine inspection (survey) of certain transfusion services and clinical laboratories approved for Medicare reimbursement. HCFA also agreed to assume responsibility for any other routine compliance activities that are necessary to ensure that these facilities are in compliance with FDA's technical and scientific standards. The MOU was published in the **Federal Register** of March 25, 1980 (45 FR 19316).

To implement this MOU, FDA proposed in the **Federal Register** of September 30, 1980 (45 FR 64601) to amend the biologics regulations to exempt the tranfusion services and clinical laboratories affected by the MOU from the registration and product listing requirements under Part 607 (21 CFR Part 607). Under section 510(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(h)), registered establishments must be inspected by FDA at least once every 2 years. Thus, an exemption from registration would also exempt the establishment from the requirement of biennial inspection by FDA, thereby fulfilling the objective of the MOU.

The proposal provided 30 days for public comment. Sixty-two letters, some containing more than one comment, were received in response to the proposed rule. A summary of the comments and FDA's response follow:

1. One comment requested that the proposed regulations be amended or withdrawn on the ground that they conflict with the requirements of the act. Specifically, the comment contended that:

a. Proposed § 607.65(f) violates section 510(g)(3) of the act (21 U.S.C. 360(g)(3)). Proposed § 607.65(f) would exempt certain transfusion services which "* * * neither routinely collect nor process blood and blood components * * *." Section 510(g)(3) exempts from registration only those manufactures of drugs and devices used solely "* * * in research, teaching, or chemical analysis and not for sale." The comment contended that the proposed rule provides for the limited (nonroutine) collection and processing by exempt facilities of a drug (blood) which is for sale and that this exemption expands upon 510(g)(3) of the act. The comment concluded that such legislative powers are beyond those delegated by Congress to an administrative agency such as FDA.

b. The expressions "neither routinely collect nor process," "emergency situation," and "responsible person" were not adequately defined in the proposal or MOU.

c. The effective enforcement of the act is impeded because, although FDA retains ultimate authority for enforcement of the act and, when necessary, will exercise this authority, HCFA has been delegated the responsibility for determining when enforcement of the act by FDA may be necessary.

d. No provision is made in proposed § 607.65(f) and (g) for FDA to inform HCFA inspectors of a fatal transfusion reaction reported by an exempt facility.

FDA disagrees with this comment. FDA's response to each contention within the comment is as follows:

a. Section 510(g)(3) of the act exempts from registration those manufacturers of drugs or devices for certain uses other than for sale. Conversely, it does not exempt this broad class of persons (i.e., manufacturers of drugs or devices) from registration if the products are offered for sale. However, section 510(g)(4) of the act does provide for the exemption of specific classes of persons upon a finding that registration "* * * is not necessary for the protection of the public health." FDA considers this paragraph to grant FDA the authority to exempt those classes of persons whose registration is not necessary for the protection of the public health but which could not be identified by Congress at the time of enactment. This authority does indeed extend beyond the specific exemptions granted in section 510(g) (1), (2) and (3) of the act. The lack of significant public comment on the question of the protection of the public health confirms FDA's (and HCFA's) finding the public health will continue to be adequately protected with the exemption of the subject facilities. Accordingly, FDA finds that the proposed regulations are consistent with section 510 of the act.

b. For clarification, the term, "routinely collect or process" means the collection or processing (see definition of "processing" under 21 CFR 606.3(i)) of blood or a blood component on a regular (nonemergency) basis. For the purpose of this regulation, "an emergency situation" is when a person with the authority for making such a determination, i.e., "a responsible person," determines that blood or a blood component is needed immediately, and the urgency of the situation prohibits the obtaining of the blood or blood component through routine channels, and the circumstances justifying the action are suitably documented in writing. The responsible person is, in effect, the same as the designated, qualified person described in § 606.20(a) (21 CFR 606.20(a)) as the person who shall exercise control of the establishment in all matters related to compliance with the biologics regulations. FDA believes that these terms are adequately understood by the affected facilities and no further clarification in the regulations is necessary.

c. The MOU provides for the joint survey (inspection) by HCFA and FDA of transfusion services or clinical laboratories to certify and document any alleged significant deficiency or deficiencies which would, if confirmed to be present, adversely affect the safety or efficacy of products, or the health and safety of a donor or patient. The initial determination of the possible significance of an alleged deficiency is the responsibility of HCFA; however, in cases where the possible significance is unclear, the district FDA office may be contacted by the HCFA representative for consultation and, if necessary, a joint inspection initiated. In view of the continuing high compliance rate of the subject facilities, few actions of this kind are anticipated. FDA finds this arrangement adequate for the proper enforcement of the act for the protection of the public health.

d. The MOU provides that exempt facilities continue to report to FDA fatal transfusion reactions, as required by § 606.170(b) (21 CFR 606.170(b)). The reports received by FDA from transfusion services or those involving fatalities resulting from errors and accidents in areas of a hospital unrelated to the collection or processing of blood or blood components are transmitted to HCFA for followup action. Because the procedures for notifying HCFA officials are adequately documented in the MOU no corresponding revision of § 607.65 (f) and (g) is necessary.

Accordingly, for the reasons stated in a. through d. above, the comment is rejected.

2. One comment, by a representative of HCFA, concerned the reference in § 607.65 (f) and (g) to "Medicare/Medicaid reimbursement." The comment noted that approval of laboratories for participation in the Medicaid program is the function of the local State agency administering the State's Medicaid program, and not HCFA. Consistently, the MOU made no mention of clinical laboratories approved solely for participation in the Medicaid program and the sole responsibility for routine compliance activities for such facilities has not been transferred to HCFA.

FDA agrees with the comment. The MOU did not relieve those facilities participating solely in the Medicaid program from FDA inspection nor was it intended in the proposed rules that these facilities be exempted from FDA registration. During the 1980 registration period (commencing November 1979), the potential status of all registering blood establishments was determined. Only those establishments participating, or those parts of a facility participating, in the Medicare program and otherwise qualified for exemption under the proposed rules were notified by letter that with the publication of this final rule they would be exempt from FDA registration and inspection. The remaining facilities, including those clinical laboratories participating solely in Medicaid, were notified that they must continue to register and be inspected by FDA. Therefore, the clinical laboratories participating in Medicaid but not Medicare are aware that, consistent with the terms of the MOU, they must continue to register with and be inspected by FDA. Accordingly, § 607.65 (f) and (g) are amended in the final rule by changing the term "Medicare/Medicaid/reimbursement" to read "Medicare reimbursement."

3. One comment by a HCFA representative on proposed § 607.65(f), noted that transfusion services per se are not approved by HCFA for Medicare reimbursement; rather, a hospital or independent laboratory, of which transfusion services may be a part, may be approved by HCFA for Medicare.

FDA agrees with the comment and for clarity § 607.65(f) is amended in the final rule to read "Transfusion services which are part of a facility approved for Medicare reimbursement and * * *."

4. The majority of the comments received requested that § 607.65(f) be amended also to exempt from registration those transfusion services approved for Medicare reimbursement that routinely process red blood cells from units of whole blood. The comments noted that this "packing" of red blood cells is an uncomplicated process involving minimal danger to the eventual recipient of the blood component. Furthermore, the process is essentially the same as that used for recovering plasma from whole blood, a procedure which, under the proposed rules, may be performed by exempt facilities. The comments argued that in view of the high compliance rate of the facilities and HCFA's extensive experience in the regulation of the facilities, the dual inspection of transfusion services routinely packing red blood cells is a regulatory burden which is unnecessary for the protection of the public health.

FDA advises that the exemption from registration of transfusion services packing red blood cells is beyond the scope of this final rulemaking. In the MOU a "transfusion service" was defined, in part, as a facility which "* * * is not engaged in the routine collection or processing of blood or plasma (except recovered plasma) * * *." As a result, facilities routinely processing red blood cells from whole blood are by definition not included in the transfer to HCFA of routine inspectional responsibilities. However, FDA believes the comment has merit and will explore the possibility of amending the MOU to provide for the transfer of these responsibilities to HCFA. Upon amendment of the MOU, FDA intends to publish a proposed rule for comment by all interested persons to exempt the additional transfusion services from FDA registration. Accordingly, the comment is rejected at this time.

5. A number of comments were received from persons who, in some manner, either routinely collect or routinely process blood or blood components requesting that they be exempt from FDA registration and inspection.

Exemption of additional classes of persons is beyond the scope of this document. Before exemption of these persons could be contemplated, the individual merits of each request must be considered by FDA to determine if alternatives to FDA registration and inspection are possible which will continue to ensure the adequate protection of the public health. In any event, further agreements for the transfer of inspectional responsibilities would be necessary before an exemption from FDA registration for any additional classes of persons could be considered. Accordingly, the comments are rejected at this time.

As noted in the proposal, FDA has reviewed the Forms FDA–2830, "Blood Establishment Registration and Product Listing" and related inspection records for the facilities registering for 1980. Those facilities notified by FDA as qualifying for exemption are exempt from FDA registration and inspection with the publication of this final rule. Approximately 3,500 facilities become exempt from registration by this final rule. FDA will continue to review the Forms FDA–2830 submitted each year and will identify those additional facilities qualified for exemption. Facilities should notify the Bureau of Biologics, FDA, at the address given above when a change in the registration status of the facility occurs, such as the commencement of the routine collection or processing of blood or blood components, so that the correct registration status may be determined.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 510, 710, 52 Stat. 1040–1042 as amended 1055–1056 as amended, 76 Stat. 794–795 as amended (21 U.S.C. 321, 360, 371)) and the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 607 is amended in § 607.65 by adding new paragraphs (f) and (g) to read as follows:

§ 607.65 Exemptions for blood product establishments.

* * * * *

(f) Transfusion services which are a part of a facility approved for Medicare reimbursement and engaged in the compatibility testing and transfusion of blood and blood components, but which neither routinely collect nor process blood and blood components. The collection and processing of blood and blood components in an emergency situation as determined by a responsible person and documented in writing, therapeutic collection of blood or plasma, and the preparation of recovered human plasma for further manufacturing use are not acts requiring such transfusion services to register.

(g) Clinical laboratories that are approved for Medicare reimbursement and are engaged in the testing of blood products in support of other registered blood establishments.

Effective date. This regulation becomes effective on December 30, 1980. This regulation both grants an exemption and relieves an unnecessary regulatory burden from the affected establishments. Accordingly, under § 10.40(c)(4)(i) (21 CFR 10.40(c)(4)(i)), the

agency finds that a delayed effective date is unnecessary.

(Secs. 201, 510, 710, 52 Stat. 1040–1042 as amended, 1055–1056 as amended, 76 Stat. 794–795 as amended (21 U.S.C. 321, 360, 371) and sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262).)

Dated: December 18, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80-40228 Filed 12-22-80; 10:57 am]

BILLING CODE 4110-03-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 7744]

Income Tax; Taxation of Political Organizations

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document provides final regulations relating to the taxation of political organizations. Changes to the applicable tax law were made by the Act of January 3, 1975. These regulations provide necessary guidance to political organizations for compliance with the law, and affect all political organizations that are entitled to receive special tax treatment.

DATE: Generally, except where otherwise provided, the regulations are effective for taxable years beginning after December 31, 1974.

FOR FURTHER INFORMATION CONTACT: Jason R. Felton of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224, Attention: CC:LR:T, 202–566–3289, not a toll-free call.

SUPPLEMENTARY INFORMATION:

Background

On November 24, 1976, the **Federal Register** published proposed amendments to the Income Tax Regulations (26 CFR Part I) under section 527 of the Internal Revenue Code of 1954, 41 FR 51840. The amendements were proposed to conform the regulations to section 10 (a) of the Act of January 3, 1975 (88 Stat. 2116). A public hearing was held on February 24, 1977. After consideration of all comments regarding the proposed amendments, those amendments are adopted as revised by this Treasury decision.

General Provisions

Section 527 provides special tax treatment for political organizations which are organized and operated primarily for an exempt function, such as supporting candidates for public office. Generally, organizations that qualify as political organizations as defined in section 527 are treated as exempt organizations. Thus, income such as contributions and dues is not taxed if segregated for use only for an exempt function. However, generally, the investment income of a political organization, such as interest income, is subject to tax.

1978 Statutory Changes

In 1978, Congress amended the definition of exempt function income to include proceeds from the conducting of any bingo game (as defined in section 512 (f)(2)). Act of October 21, 1978 (92 Stat. 1702). This amendment will be the subject of a notice of proposed rulemaking and thus is not reflected in these final regulations.

Operational Test

Generally, a political organization must be operated primarily to receive contributions or make expenditures for an exempt function. Under the proposed regulations, if more than an insubstantial amount of exempt function income was spent for nonexempt function purposes, the political organization could lose its exempt status. In response to a number of comments this position has been modified. Such expenditures will, generally, cause the political organization to lose its exempt status only if such organization is primarily engaged in nonexempt function activities. However, amounts of exempt function income expended for nonexempt function activities might result in the taxation of amounts remaining in the political organization's segregated fund. See § 1.527–2(b).

Exempt Function

Generally, the term "exempt function" means the function of receiving contributions or making expenditures for the purpose of influencing or attempting to influence the selection, nomination, election, or appointment of individuals for Federal, State, or local public office. The definition of exempt function has been clarified, and a number of examples have been added to illustrate the general principles. See § 1.527–2(c).

Certain Expenditures by Organizations Described in Section 501(c)

Generally, section 527(f) provides that an organization described in section 501(c) is subject to tax if it makes expenditures for an exempt function as defined in section 527(e)(1). Several commentators suggested that certain expenditures made by an organization described in section 501(c) should be treated differently from identical expenditures made by a political organization. These commentators state that activities that are not considered to be political activities under Federal or State election laws should not be treated as exempt function activities under section 527. In particular they argue that under the Federal Election Campaign Act (FECA) labor unions and trade associations, among others, may engage in certain activities that under the proposed regulations could result in taxation of expenditures for such activities. These activities are (1) communications with members about candidates for public office, (2) paying the costs of establishing a fund and soliciting contributions to such fund, and (3) engaging in certain nonpartisan activities during a political campaign such as voter registration drives. They therefore argue that those expenditures should not be considered an expenditure for an exempt function.

Paragraph (b) (2) and (3) of § 1.527–6 is reserved pending resolution of the relationship between section 527 and FECA and similar State statutes. When adopted as a Treasury decision, paragraph (b) (2) and (3) will apply on a prospective basis if the commentators' position is rejected and taxpayers are thereby adversely affected. The final regulations also adopt the position that under certain circumstances commenting on potential appointees for public office will not be considered an exempt function activity.

Deductible Expenditures

In response to several comments, the final regulations adopt the position that where an expenditure relates to an exempt function activity and to an activity to produce political organization taxable income, the expenditure is allocated between the two uses on a reasonable and consistent basis. See § 1.527–4(c).

Other Changes

The final regulations delete the substantially related test with respect to fund raising and entertainment events, and sale of campaign materials. However, in any such case, the event or sale must still relate to a political

activity of the organization aside from the need for funds or income in order for the proceeds to qualify as exempt function income. See § 1.527–3 (d) and (e).

Drafting Information

The principal author of this regulation is Jason R. Felton of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

Adoption of amendments to the regulations.

Accordingly, 26 CFR Part 1 is amended by adding §§ 1.527–1 through 1.527–8 as follows:

* * * * *

Sec.

Authority: Sec. 7805 of the Internal Revenue Code of 1954 (68A Stat. 917; (26 U.S.C. 7805)).

§ 1.527–1 Political organizations; Generally.

Section 527 provides that a political organization is considered an organization exempt from income taxes for the purpose of any law which refers to organizations exempt from income taxes. A political organization is subject to tax only to the extent provided in section 527. In general, a political organization is an organization that is organized and operated primarily for an exempt function as defined in § 1.527–2(c). Section 527 provides that a political organization is taxed on its political organization taxable income (see § 1.527–4) which, in general, does not include the exempt function income (see § 1.527–3) of the political organization. Furthermore, section 527 provides that an exempt organization, other than a political organization, may be subject to tax under section 527 when it expends an amount for an exempt function, see § 1.527–6. Finally, the taxation of newsletter funds is provided under section 527, see § 1.527–7.

§ 1.527–2 Definitions.

For purposes of section 527 and these regulations—

(a) *Political organization*—(1) *In general.* A "political organization" is a party, committee, association, fund, or other organization (whether or not incorporated) organized and operated primarily for the purpose of directly or indirectly accepting contributions or making expenditures for an exempt function activity (as defined in paragraph (c) of this section). Accordingly, a political organization may include a committee or other group which accepts contributions or makes expenditures for the purpose of promoting the nomination of an individual for an elective public office in a primary election, or in a meeting or caucus of a political party. A segregated fund (as defined in paragraph (b) of this section) established and maintained by an individual may qualify as a political organization.

(2) *Organizational test.* A political organization meets the organizational test if its articles of organization provide that the primary purpose of the organization is to carry on one or more exempt functions. A political organization is not required to be formally chartered or established as a corporation, trust, or association. If an organization has no formal articles of organization, consideration is given to statements of the members of the organization at the time the organization is formed that they intend to operate the organization primarily to carry on one or more exempt functions.

(3) *Operational test.* A political organization does not have to engage exclusively in activities that are an exempt function. For example, a political organization may—

(i) Sponsor nonpartisan educational workshops which are not intended to influence or attempt to influence the selection, nomination, election, or appointment of any individual for public office,

(ii) Pay an incumbent's office expenses, or

(iii) Carry on social activities which are unrelated to its exempt function,

provided these are not the organization's primary activities. However, expenditures for purposes described in the preceding sentence are not for an exempt function. See § 1.527–2 (c) and (d). Furthermore, it is not necessary that a political organization operate in accordance with normal corporate formalities as ordinarily established in bylaws or under state law.

(b) *Segregated fund*—(1) *General rule.* A "segregated fund" is a fund which is established and maintained by a political organization or an individual separate from the assets of the organization or the personal assets of the individual. The purpose of such a fund must be to receive and segregate exempt function income (and earnings on such income) for use only for an exempt function or for an activity necessary to fulfill an exempt function. Accordingly, the amounts in the fund must be dedicated for use only for an exempt function. Thus, expenditures for the establishment or administration of a political organization or the solicitation of political contributions may be made from the segregated fund, if necessary to fulfill an exempt function. The fund must be clearly identified and established for the pruposes intended. A savings or checking account into which only contributions to the political organization are placed and from which only expenditures for exempt functions are made may be a segregated fund. If an organization that had designated a fund to be a segregated fund for purposes of segregating amounts referred to in section 527(c)(3) (A) through (D), expends more than an insubstantial amount from the segregated fund for activities that are not for an exempt function during a taxable year, the fund will not be treated as a segregated fund for such year. In such a case amounts referred to in section 527(c)(3)(A)–(D), segregated in such fund will not be exempt function income. Further, if more than insubstantial amounts segregated for an exempt function in prior years are expended for other than an exempt function the facts and circumstances may indicate that the fund was never a segregated fund as defined in this paragraph.

(2) *Record keeping.* The organization or individual maintaining a segregated fund must keep records that are adequate to verify receipts and disbursements of the fund and identify the exempt function activity for which each expenditure is made.

(c) *Exempt function*—(1) *Directly related expenses.* An "exempt function", as defined in section 527(e)(2), includes all activities that are directly related to and support the process of influencing or attempting to influence the selection, nomination, election, or appointment of any individual to public office or office in a political organization (the selection process). Whether an expenditure is for an exempt function depends upon all the facts and circumstances. Generally, where an organization supports an

individual's campaign for public office, the organization's activities and expenditures in furtherance of the individual's election or appointment to that office are for an exempt function of the organization. The individual does not have to be an announced candidate for the office. Furthermore, the fact that an individual never becomes a candidate is not crucial in determining whether an organization is engaging in an exempt function. An activity engaged in between elections which is directly related to, and supports, the process of selection, nomination, or election of an individual in the next applicable political campaign is an exempt function activity.

(2) *Indirect expenses.* Expenditures that are not directly related to influencing or attempting to influence the selection process may also be an expenditure for an exempt function by a political organization. These are expenses which are necessary to support the directly related activities of the political organization. Activities which support the directly related activities are those which must be engaged in to allow the political organization to carry out the activity of influencing or attempting to influence the selection process. For example, expenses for overhead and record keeping are necessary to allow the political organization to be established and to engage in political activities. Similarly, expenses incurred in soliciting contributions to the political organization are necessary to support the activities of the political organization.

(3) *Terminating activities.* An exempt function includes an activity which is in furtherance of the process of terminating a political organization's existence. For example, where a political organization is established for a single campaign, payment of campaign debts after the conclusion of the campaign is an exempt function activity.

(4) *Illegal expenditures.* Expenditures which are illegal or are for a judicially determined illegal activity are not considered expenditures in furtherance of an exempt function, even though such expenditures are made in connection with the selection process.

(5) *Examples.* The following examples illustrate the principles of paragraph (c) of this section. The term "exempt function" when used in the following examples means exempt function within the meaning of section 527(e)(2).

(i) *Example (1).* A wants to run for election to public office in State X. A is not a candidate. A travels throughout X in order to rally support for A's intended candidacy. While in X, A attends a convention of an organization for the purpose of attempting to solicit its support. The amount expended for travel, lodging, food, and similar expenses are for an exempt function.

(ii) *Example (2).* B, a member of the United States House of Representatives, is a candidate for reelection. B travels with B's spouse to the district B represents. B feels it is important for B's reelection that B's spouse accompany B. While in the district, B makes speeches and appearances for the purpose of persuading voters to reelect B. The travel expenses of B and B's spouse are for an exempt function.

(iii) *Example (3).* C is a candidate for public office. In connection with C's campaign, C takes voice and speech lessons to improve C's skills. The expenses for these lessons are for an exempt function.

(iv) *Example (4).* D, an officeholder and candidate for reelection, purchases tickets to a testimonial dinner. D's attendance at the dinner is intended to aid D's reelection. Such expenditures are for an exempt function.

(v) *Example (5).* E, an officeholder, expends amounts for periodicals of general circulation in order to keep informed on national and local issues. Such expenditures are not for an exempt function.

(vi) *Example (6).* N is an organization described in section 501(c) and is exempt from taxation under section 501(a). F is employed as president of N. F, as a representative of N, testifies in response to a written request from a Congressional committee in support of the confirmation of an individual to a cabinet position. The expenditures by N that are directly related to F's testimony are not for an exempt function.

(vii) *Example (7).* P is a political organization described in section 527(e)(2). Between elections P does not support any particular individual for public office. However, P does train staff members for the next election, drafts party rules, implements party reform proposals, and sponsors a party convention. The expenditures for these activities are for an exempt function.

(viii) *Example (8).* Q is a political organization described in section 527(e)(2). Q finances seminars and conferences which are intended to influence persons who attend to support individuals to public office whose political philosophy is in harmony with the political philosophy of Q. The expenditures for these activities are for an exempt function.

(d) *Public office.* The facts and circumstances of each case will determine whether a particular Federal, State, or local office is a "public office." Principles consistent with those found under § 53.4946–1(g)(2) (relating to the definition of public office) will be applied.

§ 1.527–3 Exempt function income.

(a) *General rule*—(1) For purposes of section 527, exempt function income consists solely of amounts received as—

(i) Contributions of money or other property,

(ii) Membership dues, fees, or assessments from a member of a political organization, or

(iii) Proceeds from a political fund raising or entertainment event, or proceeds from the sale of political campaign materials, which are not received in the ordinary course of any trade or business,

but only to the extent such income is segregated for use only for exempt functions of the political organization.

(2) Income will be considered segregated for use only for an exempt function only if it is received into and disbursed from a segregated fund as defined in § 1.527–2(b).

(b) *Contributions.* The rules of section 271(b)(2) apply in determining whether the transfer of money or other property constitutes a contribution. Generally, money or other property, whether solicited personally, by mail, or through advertising, qualifies as a contribution. In addition, to the extent a political organization receives Federal, State, or local funds under the $1 "checkoff" provision (sections 9001–9013), or any other provision for financing of campaigns, such amounts are to be treated as contributions.

(c) *Dues, fees, and assessments.* Amounts received as membership fees and assessments from members of a political organization may constitute exempt function income to the political organization. Membership fees and assessments received in consideration for services, goods, or other items of value do not constitute exempt function income. However, filing fees paid by an individual directly or indirectly to a political party in order that the individual may run as a candidate in a primary election of the party (or run in a general election as a candidate of that party) are to be treated as exempt function income. For example, some States provide that a certain percentage of the first year's salary of the office sought must be paid to the State as a filing (or "qualifying") fee and party assessment. The State then transfers part of this fee to the candidate's party. In such a case, the entire amount transferred to the party is to be treated as exempt function income. Furthermore, amounts paid by an individual directly to the party as a qualification fee are treated similarly.

(d) *Fund raising events*—(1) *In general.* Amounts received from fund raising and entertainment events are eligible for treatment as exempt function income if the events are political in nature and are not carried on in the ordinary course of a trade or business. Whether an event is "political" in nature depends on all facts and circumstances. One factor that indicates an event is a political event is the extent to which the

event is related to a political activity aside from the need of the organization for income or funds. For example, an event that is intended to rally and encourage support for an individual for public office would be a political fund raising event. Examples of political events can include dinners, breakfasts, receptions, picnics, dances, and athletic exhibitions.

(2) *Ordinary course of any trade or business.* Whether an activity is in the ordinary course of a trade or business depends on the facts and circumstances of each case. Generally, proceeds from casual, sporadic fund raising or entertainment events are not in the ordinary course of a trade or business. Factors to be taken into account in determining whether an activity is a trade or business include the frequency of the activity, the manner in which the activity is conducted, and the span of time over which the activity is carried on.

(e) *Sale of campaign materials.* Amounts received from the sale of campaign materials are eligible for treatment as exempt function income if the sale is not carried on in the ordinary course of a trade or business (as defined in paragraph (d)(2) of this section), and is related to a political activity of the organization aside from the need of such organization for income or funds. Proceeds from the sale of political memorabilia, bumper stickers, campaign buttons, hats, shirts, political posters, stationery, jewelry, or cookbooks are related to such a political acitivity where such items can be identified as relating to distributing political literature or organizing voters to vote for a candidate for public office.

§ 1.527-4 Special rules for computation of political organization taxable income.

(a) *In general.* Political organization taxable income is determined according to the provisions of section 527(b) and the rules set forth in this section.

(b) *Limitation on capital losses.* If for any taxable year a political organization has a net capital loss, the rules of sections 1211(a) and 1212(a) apply.

(c) *Allowable deductions*—(1) *In general.* To be deductible in computing political organization taxable income, expenses, depreciation, and similar items must not only qualify as deductions allowed by chapter 1 of the Code, but must also be directly connected with the production of political organization taxable income.

(2) *"Directly connected with" defined.* To be "directly connected with" the production of political organization taxable income, an item of deduction must have a proximate and primary relationship to the production of such income and have been incurred in the production of such income. Items of deduction attributable solely to items of political organization taxable income are proximately and primarily related to such income. Whether an item of deduction is incurred in the production of political organization taxable income is determined on the basis of all the facts and circumstances of each case.

(3) *Dual use of facilities or personnel.* Expenses, depreciation, and similar items that are attributable to the production of exempt function income and political organization taxable income shall be allocated between the two on a reasonable and consistent basis. For example, where facilities are used both for an exempt function of the organization and for the production of political organization taxable income, expenses, depreciation, and similar items attributable to such facilities (for example, items of overhead) shall be allocated between the two uses of a reasonable and consistent basis. Similarly, where personnel are employed both for an exempt function and for the production of political organization taxable income, expenses and similar items attributable to such personnel (for example, items of salary) shall be allocated between the activities on a reasonable and consistent basis. The portion of any such item so allocated to the production of political organization taxable income is directly connected with such income and is allowable as a deduction in computing political organization taxable income to the extent that it qualifies as an item of deduction allowed by chapter 1 of the Code. Thus, for example, assume that X, a political organization, pays its manager a salary of $10,000 a year and that it derives political organization taxable income. If 10 percent of the manager's time during the year is devoted to deriving X's gross income (other than exempt function income), a deduction of $1,000 (10 percent of $10,000) would generally be allowable for purposes of computing X's political organization taxable income.

§ 1.527.5 Activities resulting in gross income to an individual or political organization.

(a) *In general*—(1) *General rule.* Amounts expended by a political organization for an exempt function are not income to the individual or individuals on whose behalf such expenditures are made. However, where a political organization expends any other amount for the personal use of any individual, the individual on whose behalf the amount is expended will be in receipt of income. Amounts are expended for the personal use of an individual where a direct or indirect financial benefit accrues to such individual. For example, if a political organization pays a personal legal obligation of a candidate for public office, such as the candidate's federal income tax liability, the amount paid is includible in such candidate's gross income. Similarly, if a political organization expends any amount of its exempt function income for other than an exempt function, and the expenditure results in a direct or indirect financial benefit to the political organization, it must include the amount of such expenditure in its gross income. For example, if a political organization expends exempt function income for making an improvement or addition to its facilities, or for equipment, which is not necessary for or used in carrying out an exempt function, the amount of the expenditure will be included in the political organization's gross income. However, if a political organization expends exempt function income to make ordinary and necessary repairs on the facilities the political organization uses in conducting its exempt function, such amounts will not be included in the political organization's gross income.

(2) *Expenditure for an illegal activity.* Expenditures by a political organization that are illegal or for an activity that is judicially determined to be illegal are treated as amounts not segregated for use only for the exempt function and shall be included in the political organization's taxable income. However, expenses incurred in defense of civil or criminal suits against the organization are not treated as taxable to the organization. Similarly, voluntary reimbursement to the participants in the illegal activity for similar expenses incurred by them are not taxable to the organization if the organization can demonstrate that such payments do not constitute a part of the inducement to engage in the illegal activity or part of the agreed upon compensation therefor. However, if the organization entered into an agreement with the participants to defray such expenses as part of the inducement, such payments would be treated as an expenditure for an illegal activity. Except where necessary to prevent the period of limitation for assessment and collection of a tax from expiring, a notice of deficiency will not generally be issued until after there has been a final determination of illegality by an appropriate court in a criminal proceeding.

(b) *Certain uses not treated as income to a candidate.* Except as otherwise

provided in paragraph (a) of this section, if a political organization—

(1) Contributes any amount to or for the use of any political organization described in section 527(e)(1) or newsletter fund described in section 527(g),

(2) Contributes any amount to or for the use of any organization described in paragraph (1) and (2) of section 509(a) which is exempt from taxation under section 501(a), or

(3) Deposits any amount in the general fund of the U.S. Treasury or in the general fund of any State or local government,

such amount shall not be treated as an amount expended for the personal use of a candidate or other person. No deduction shall be allowed under the Internal Revenue Code of 1954 for the contribution or deposit described in the preceding sentence.

(c) *Excess funds*—(1) *General rule.* Generally, funds controlled by a political organization or other person after a campaign or election are excess funds and are treated as expended for the personal use of the person having control over the ultimate use of such funds. However, such funds will not be treated as excess funds to the extent they are—

(i) Transferred within a reasonable period of time by the person controlling the funds in accordance with paragraph (b) of this section, or

(ii) Held in reasonable anticipation of being used by the political organization for future exempt functions.

(2) *Excess funds transferred at death.* Where excess funds are held by an individual who dies, and these funds go to the individual's estate or any other person (other than an organization or fund described in paragraph (b) of this section), the funds are income of the decedent and will be included in the decedent's gross estate unless the estate or other person receiving such funds transfers the funds within a reasonable period of time in accordance with paragraph (b) of this section.

This paragraph (c)(2) will not apply where the individual who dies provides that the funds be transferred to an organization or fund described in paragraph (b) of this section.

§1.527-6 Inclusion of certain amounts in the gross income of an exempt organization which is not a political organization.

(a) *Exempt organizations—General rule.* If an organization described in section 501(c) which is exempt from tax under section 501(a) expends any amount for an exempt function, it may be subject to tax. There is included in the gross income of such organization for the taxable year an amount equal to the lesser of—

(1) The net investment income of such organization for the taxable year, or

(2) The aggregate amount expended during the taxable year for an exempt function.

The amount included will be treated as political organization taxable income.

(b) *Exempt function expenditures*—(1) *Directly related expenses.* (i) Except as provided in this section, the term "exempt function" will generally have the same meaning it has in § 1.527-2(c). Thus, expenditures which are directly related to the selection process as defined in § 1.527-2(c)(1) are expenditures for an exempt function. Expenditures for indirect expenses as defined in § 1.527-2(c)(2), when made by a section 501(c) organization are for an exempt function only to the extent provided in paragraph (b)(2) of this section. Expenditures of a section 501 (c) organization which are otherwise allowable under the Federal Election Campaign Act or similar State statute are for an exempt function only to the extent provided in paragraph (b)(3) of this section.

(ii) An expenditure may be made for an exempt function directly or through another organization. A section 501(c) organization will not be absolutely liable under section 527(f)(1) for amounts transferred to an individual or organization. A section 501(c) organization is, however, required to take reasonable steps to ensure that the transferee does not use such amounts for an exempt function.

(2) *Indirect expenses.* [Reserved].

(3) *Expenditures allowed by Federal Election Campaign Act.* [Reserved].

(4) *Appointments or confirmations.* Where an organization described in paragraph (a) of this section appears before any legislative body in response to a written request by such body for the purpose of influencing the appointment or confirmation of an individual to a public office, any expenditure directly related to such appearance is not treated as an expenditure for an exempt function.

(5) *Nonpartisan activity.* Expenditures for nonpartisan activities by an organization to which paragraph (a) of this section applies are not expenditures for an exempt function. Nonpartisan activities include voter registration and "get-out-the-vote" campaigns. To be nonpartisan voter registration and "get-out-the-vote" campaigns must not be specifically identified by the organization with any candidate or political party.

(c) *Character of items included in gross income*—(1) *General rule.* The items of income included in the gross income of an organization under paragraph (a) of this section retain their character as ordinary income or capital gain.

(2) *Special rule in determining character of item.* If the amount included in gross income is determined under paragraph (a)(2)(ii) of this section, the character of the items of income is determined by multiplying the total amount included in gross income under such paragraph by a fraction, the numerator of which is the portion of the organization's net investment income that is gain from the sale or exchange of a capital asset, and the denominator of which is the organization's net investment income. For example, if $5,000 is included in the gross income of an organization under paragraph (a)(2) of this section, and the organization had $100,000 of net investment income of which $10,000 is long term capital gain, then $500 would be treated as long term capital gain:

Capital gain net investment income	X	Amount expended on an exempt function	=	Portion of income subject to tax under section 1201
$\frac{\$\ 10,000}{\$100,000}$	X	$5,000	=	$500

(d) *Modifications.* The modifications described in section 527(c)(2) apply in computing the tax under paragraph (a)(2) of this section. Thus, no net operating loss is allowed under section 172 nor is any deduction allowed under part VIII of subchapter B. However, there is allowed a specific deduction of $100.

(e) *Transfer not treated as exempt function expenditures.* Provided the provisions of this paragraph (e) are met, a transfer of political contributions or dues collected by a section 501(c) organization to a separate segregated fund as defined in paragraph (f) of this section is not treated as an expenditure for an exempt function (within the meaning of § 1.527–2(c)). Such transfers must be made promptly after the receipt of such amounts by the section 501(c) organization, and must be made directly to the separate segregated fund. A transfer is considered promptly and directly made if:

(1) The procedures followed by the section 501(c) organization satisfy the requirements of applicable Federal or State campaign law and regulations;

(2) The section 501(c) organization maintains adequate records to demonstrate that amounts transferred in fact consist of political contributions or dues, rather than investment income; and

(3) The political contributions or dues transferred were not used to earn investment income for the section 501(c) organization.

(f) *Separate segregated fund.* An organization or fund described in section 527(f)(3) is a separate segregated fund. To avoid the application of paragraph (a) of this section, an organization described in section 501(c) that is exempt from taxation under section 501(a) may, if it is consistent with its exempt status, establish and maintain such a separate segregated fund to receive contributions and make expenditures in a political campaign. If such a fund meets the requirements of § 1.527–2(a) (relating to the definition of a political organization), it shall be treated as a political organization subject to the provisions of section 527. A segregated fund established under the Federal Election Campaign Act will continue to be treated as a segregated fund when it engages in exempt function activities as defined in § 1.527–2(c), relating to State campaigns.

(g) *Effect of expenditures on exempt status.* Section 527(f) and this section do not sanction the intervention in any political campaign by an organization described in section 501(c) if such activity is inconsistent with its exempt status under section 501(c). For example, an organization described in section 501(c)(3) is precluded from engaging in any political campaign activities. The fact that section 527 imposes a tax on the exempt function (as defined in § 1.527–2(c)) expenditures of section 501(c) organizations and permits such organizations to establish separate segregated funds to engage in campaign activities does not sanction the participation in these activities by section 501(c)(3) organizations.

§ 1.527–7 Newsletter funds.

(a) *In general.* For purposes of this section, a fund established and maintained by an individual who holds, has been elected to, or is a candidate (within the meaning of section 41(c)(2)) for nomination or election to, any Federal, State, or local elective public office for the use by such individual exclusively for an exempt function, as defined in paragraph (c) of this section, shall be a newsletter fund. If assets of a newsletter fund are used for any purpose other than the exempt function of the newsletter fund as defined in paragraph (c) of this section, such amount shall be treated as expended for the personal use of the individual who established and maintained such fund. In addition, future contributions to such fund are treated as income to the individual who established and maintained the fund. In such a case, the facts and circumstances may indicate that the fund was never established and maintained exclusively for an exempt function as defined in paragraph (c) of this section.

(b) *Determination of taxable income.* A newsletter fund shall be treated as if it were a political organization for purposes of determining its taxable income. However, the specific $100 deduction provided by section 527(c)(2)(A) shall not be allowed.

(c) *Exempt function.* For purposes of this section, the exempt function of a newsletter fund consists solely of the preparation and circulation of the newsletter. Among the expenditures treated as preparation and circulation expenditures of the newsletter are—

(1) Secretarial services,

(2) Printing,

(3) Addressing, and

(4) Mailing.

(d) *Nonexempt function purposes.* Newsletter fund assets may not be used for campaign activities. Therefore, an exempt function of a newsletter fund does not include—

(1) Expenditures for an exempt function as defined in § 1.527–2(c) or

(2) Transfers of unexpended amounts to a political organization described in section 527(e)(1).

(e) *Excess funds.* Excess funds held by a newsletter fund which has ceased to engage in the preparation and circulation of the newsletter are treated as expended for the personal use of the individual who established and maintained such fund. However, to the extent such excess funds are within a reasonable period of time—

(1) Contributed to or for the use of any organization described in paragraph (1) or (2) of section 509(a) which is exempt from taxation under section 501(a),

(2) Deposited in the general fund of the U.S. Treasury or in the general fund of any State or local government (including the District of Columbia), or

(3) Contributed to any other newsletter fund as described in paragraph (a) of this section,

the excess funds are not treated as expended for the personal use of such individual. In such a case the individual is not allowed a deduction under the Internal Revenue Code of 1954 for such contribution or deposit.

§ 1.527–8 Effective date; filing requirements; and miscellaneous provisions.

(a) *Assessment and collections.* Since the taxes imposed by section 527 are taxes imposed by subtitle A of the Code, all provisions of law and of the regulations applicable to the taxes imposed by subtitle A are applicable to the assessment and collection of the taxes imposed by section 527. Organizations subject to the tax imposed by section 527 are subject to the same provisions, including penalties, as are provided for corporations, in general, except that the requirements of section 6154 concerning the payment of estimated tax do not apply. See, generally, sections 6151, et. seq., and the regulations prescribed thereunder, for provisions relating to payment of tax.

(b) *Returns.* For requirements of filing annual returns with respect to political organization taxable income, see section 6012 (a) (6) and the applicable regulations.

(c) *Taxable years, method of accounting, etc.* The taxable year (fiscal year or calendar year, as the case may be) of a political organization is determined without regard to the fact that such organization may have been exempt from tax during any prior period. See sections 441 and 446, and the regulations thereunder in this part, and section 7701 and the regulations in Part 301 of this chapter (Regulations on Procedure and Administration). Similarly, in computing political organization taxable income, the determination of the taxable year for which an item of income or expense is

taken into account is made under the provisions of sections 441, 446, 451, 461, and the regulations thereunder, whether or not the item arose during a taxable year beginning before, on, or after the effective date of the provisions imposing a tax upon political organization taxable income. If a method for treating bad debts was selected in a return of income (other than an information return) for a previous taxable year, the taxpayer must follow such method in its returns under section 527, unless such method is changed in accordance with the provisions of § 1.166–1. A taxpayer who has not previously selected a method for treating bad debts may, in its first return under section 6012 (a) (6), exercise the option granted in § 1.166–1.

(d) *Effective date.* Except as provided in paragraph (b) (2) of § 1.527–6, the regulations under section 527 apply to taxable years beginning after December 31, 1974.

This Treasury decision is issued under the authority contained in section 7805 of the Internal Revenue Code of 1954.

(68A Stat. 917; 26 U.S.C. 7805).

William E. Williams,

Acting Commissioner of Internal Revenue.

Approved: December 15, 1980.

Donald C. Lubick,

Assistant Secretary of the Treasury.

[FR Doc. 80–40500 Filed 12–29–80; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to Cotton Dust

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of respirator-use enforcement policy concerning the period of use of respirators as required by the cotton dust standard.

SUMMARY: This notice enunciates a respirator use enforcement policy for the provisions of the OSHA cotton dust standard, 29 CFR 1910.1043 with respect to the period of use of respirators. The administrative stay of paragraphs 1910.1043(f)(1) (i) and (iii), published at 45 FR 64872 has now expired. Enforcement of these provisions will commence in accordance with this enforcement policy, which requires that respirators are to be worn to the extent necessary to assure that each employee's 8-hour time weighted average exposure is maintained at less than the permissible exposure limit. The employee's exposure is computed by assuming that while respirators are worn, ambient cotton dust levels are reduced by the assigned class protection factor of the respirator being worn.

DATES: Effective January 19, 1981, 29 CFR 1910.1043(f)(1) (i) and (iii) will be enforced in accordance with this policy.

FOR FURTHER INFORMATION CONTACT: Dr. Bailus Walker, Occupational Safety and Health Administration, Room N3718, U.S. Department of Labor, Washington, D.C. 20210. Telephone (202) 523–7076, or Mr. Frank Tipton, Occupational Safety and Health Administration, Room N3718, U.S. Department of Labor, Washington, D.C. 20210. Telephone (202) 523–7174.

SUPPLEMENTARY INFORMATION: OSHA issued a final occupational safety and health standard for occupational exposure to cotton dust on June 19, 1978 (codified at 29 CFR 1910.1043); published at 43 FR 27350–399, June 23, 1978. The standard applied to textile manufacturing and non-textile industries. Petitions for review of the standard were consolidated in the U.S. Court of Appeals for the District of Columbia Circuit and a stay of the standard pending judicial review was issued on October 20, 1978. Petitions filed by representatives of the cotton waste processing industries and purchasers and users of cotton batting were severed from the main action on November 1, 1978. No decision respecting these industries has been issued as of this time. On Ocotober 24, 1979, the D.C. Circuit affirmed the standard in the main action except as applied to cotton seed oil mills. It subsequently denied petitions for rehearing, suggestions for rehearing en banc, and motions to continue the stay (except for cottonseed oil mills), and the standard became effective and enforceable on March 27, 1980. See 45 FR 12416, February 26, 1980. Thereafter, the Department suspended enforcement of the standard in the classing and warehousing industries for further consideration in light of the Supreme Court's ruling in Industrial Union Department, AFL–CIO v. American Petroleum Institute. (Nos. 78–911 and 78–1036). See 45 FR 50328, July 29, 1980. Petitions for certiorari to review the Court of Appeal's decision in the main action were granted by the U.S. Supreme Court.

Under the timetable for implementation of the requirements of the standard, employers were required to complete initial monitoring of covered facilities by September 27, 1980. Accordingly, on that date, the provisions of the standard for respirator usage would have become effective as to all employers covered by the standard. These respirator provisions (29 CFR 1910.1043(f)) require, among other things, respirator use (i) during the time period necessary to install or implement feasible engineering controls and work practice controls and (ii) in work situations where feasible engineering controls are not yet sufficient to reduce exposure to or below the permissible exposure limit. However, it became apparent that there was widespread misunderstanding throughout the textile industry and among employees about how an effective respirator program should be implemented, which resulted in an unsuccessful implementation of the respirator provisions. Therefore, on September 30, 1980, at 45 FR 64872, OSHA published a notice of an administrative stay of 75 days ending December 15, 1980, of 29 CFR 1910.1043(f)(1) (i) and (iii). That notice included a commitment to develop guidelines for implementing effective respirator programs in the textile industry and in doing so to "meet with representatives of the cotton textile industry, workers and their unions and the National Institute for Occupational Safety and Health." These meetings were held and OSHA received many useful comments.

In addition to the parties mentioned above, these meetings also included state plan representatives, respirator manufacturers and independent organizations. All of the comments and criticisms have been carefully evaluated in developing this enforcement policy.

By this notice, OSHA announces this enforcement policy with respect to the use of respirators under the cotton dust standard, 29 CFR 1910.1043, and sets forth in detail the meaning and application of the enforcement policy. It must be noted that this interpretation is based on the unique circumstances involved in the cotton dust standard and therefore is limited to that standard. This enforcement policy will be incorporated into the compliance directive now being prepared for the cotton dust standard. The policy concerns the period of required use of respirators and allows the partial shift wearing of respirators on the condition that each employee's 8-hour time weighted average exposure is kept below the permissible exposure limit (PEL). In computing the exposure of an employee who is wearing a respirator, the respirator is assumed to reduce the ambient concentration of cotton dust by a factor equal to the assigned class protection factor of the respirator. Respirators need be worn only as long

as necessary to ensure compliance with the PEL. Some adjustment of the nominally required wearing times is made to allow for occasional lapses in protection due to brief respirator removal and to arrange an easily administered program.

Partial shift use is clearly implied in the cotton dust standard in paragraph (k)(1)(ii)(b) which requires a record of the "type of protective devices worn, if any, and length of time worn." Partial shift use of respirators is also incorporated in the lead standard (section 1910.1025).

The partial shift use of respirators as enunciated in this notice does not affect the requirement for using respirators during so-called "blow down" cleaning using compressed air, nor any other respirator provision of the standard not subject to the administrative stay of September 30, 1980. The requirement for respirators contained in paragraph (g)(1) is in addition to the routine use of respirators needed to comply with the PEL's.

In the interest of facilitating implementation of the partial shift use and of fostering understanding of the partial shift policy, industry suggested that OSHA include in its notice a table which would set forth a single set of specific times for donning and removing respirators that would constitute compliance with the standard in the presence of various increments of cotton dust concentration. Although this may appear reasonable, OSHA has concluded that such an approach would unnecessarily limit employers' flexibility and unnecessarily interfere with employers normal routines, both of which are often-mentioned industry concerns. By contrast the tables which have been provided below are a compilation, for the simplest case, of cotton dust levels and respirator use durations that satisfy the enforcement policy states herein.

The enforcement policy being enunciated by this notice clarifies what is the minimum actual respirator requirements of the cotton dust standard. OSHA recognizes that this may be somewhat less than the procedures being used in some existing respirator use schedules. However, OSHA continues to endorse and recommend that all employees on their own initiative wear respirators as much as possible when they are likely to be over exposed to toxic materials, whether cotton dust or other materials.

The concentration dependent time of use concept for respirators in no way makes a respiratory protection program inexpensive and does not by itself assure that a respiratory protection program is effective. Although OSHA has as a matter of necessity accepted the use of respirators under some circumstances, this does not mean that respirators are as effective, reliable, or safe as primary control of a hazardous contaminant at the source by engineering controls.

Partial Use Enforcement Policy

When respirators are required to comply with the permissible exposure limit (PEL) the required time of use of the respirators depends on the levels of cotton dust in the air and the type of respirator that is worn. The respirators must be worn a sufficient amount of time to assure that no employee is subjected to an 8-hour average concentration in excess of the PEL as explained below. While the employee is wearing a respirator the actual exposure that employee sustains may be assumed to be reduced by the assigned class protection factor for the respirator. The overall exposure is then computed using the formula found in appendix A to the standard and in § 1910.1000(d)(1)(i). An employee's 8-hour time weighted average exposure is constructed by multiplying each dust concentration by the time the employee is exposed to it, adding these quantities, and then dividing by eight. Hence, if the employee works in two different concentrations of cotton dust and wears a respirator part of the time in each environment then the employee has four different exposure times and levels. Thus

(eqn 1) $TWA=(C_1T_1+C_2T_2+C_3T_3+\ldots+C_nT_n)/8$

where TWA = 8 hour time weighted average (in micrograms).
C = constant concentation for a time period (in micrograms).
T = time in hours that concentration exists. The sum of all time periods equals 8 hours.

If time period two is the time of wearing a respirator in the environment with concentration C_1, then $C_2=C_1$ divided by the protection factor (PF) of the respirator. If we assume a similar relationship for time periods 3 and 4 and that the same respirator is worn both times, then the formula becomes

(eqn 2) $TWA=(C_1T_1+(C_1/PF)T_2+C_3T_3+(C_3/PF)T_4)/8$

Again, $T_1+T_2+T_3+T_4=8$

For example, if a half mask respirator is worn in a yarn manufacturing process; the dust level in the first period of 3 hours is 1400 micrograms per cubic meter and the respirator is worn for 2 hours; and the dust level in the second period, of 5 hours, is 1200 micrograms, equation 2 can be used to find the nominal minimum time of use of the respirator required to comply with the PEL.

$1000=[1400(1)+(1400/10)(2)+1200(T_3)+(1200/10)(T_4)]/8$

Combining, and substituting from $T_3+T_4=5$,

$1000=[1680+1200(5-T_4)+120T_4]/8-1080T_4=320$

which indicates clearly that T_4 is a negative value. This indicates that the use of respirators is not required for the second period. In fact equation 2 indicates a TWA of 960 micrograms per cubic meter without respirator use in the second period. The above calculation also demonstrates the advisability of using respirators first in the areas of highest concentration, a practice OSHA strongly endorses.

Alternatively, if an employee works in a single cotton dust concentration all day and wears a respirator part of the time the expression comparable to equation 2 is

(eqn 3) $TWA=(C_1T_1+(C_1/PF)T_2)/8$

Since $T_1+T_2=8$ hours, equation 3 can be rearranged to solve explicitly for the nominal minimum time of use of the respirator required to comply with the PEL, if the value of the PEL is substituted for the TWA, as

$T=(C-PEL)/C(1-1/PF)/8$

With a half mask respirator used in a slashing and weaving operation, this expression becomes

$T=(C-750)/.9C/8$

or

$T=(C-750)/.112C$

The employer has the responsibility to ensure that respirators are worn a sufficient amount of time to reduce each employee's actual exposure below the PEL's. Respirator wear for time in excess of that necessary to keep the actual exposure below the PEL is not required by the standard unless an employee requests the extra use (see para (f)(1)(v)).

All contributions to an employee's exposure to cotton dust must be included in the above computation. That is, the cotton dust exposure in *any* place in an employer's plant must be measured and included. This applies to service areas, break areas, etc. in addition to assigned work stations. If these other areas are not monitored, then the work station dust levels shall be applied. For work shifts longer than eight hours, the maximum allowable average cotton dust concentrations shall be proportionately reduced. For example, for a ten hour shift, an 8-hour

PEL of 500 $\mu g/m^3$ becomes 400 $\mu g/m^3$ instead.

One can expect that there may be, under most circumstances, brief occasions that employees will remove respirators for such purposes as personal hygiene, drinking, readjusting the respirator, or vital communications. Consequently it is inappropriate to assume constant wear of a respirator when using equation (1). To properly apply this equation, all periods, even short ones, that an employee is not wearing a respiratory must be accounted for because the exposure contribution without a respirator is so much larger than with a respirator. Since doing this accurately for each employee would be quite time consuming and burdensome, OSHA will accept a simpler procedure of lengthening by 10% the nominal wearing periods otherwise indicated by equation (1). It is OSHA's judgement that a 10% adjustment makes adequate allowance for these expected interruptions in periods normally considered to be periods of respirator wear. Such adjustment is more reasonable and feasible than the technically correct method of calculating exposure for each time interval when the respirator is removed. Alternatively and equivalently, when using the 10% adjustment and using equation 1 to calculate the resulting TWA, the assigned time of wear of the respirator shall be reduced by 9% (recall that 9% of 110 equals 10) and that difference interval shall be added to the unprotected exposure time.

The wearing period for respirators has a practical upper bound that is less than a full work shift regardless of cotton dust concentration. Lunch periods and other breaks that can be expected to involve substantial interference with wearing a respirator may not be included in the scheduled wearing periods for respirators.

Reasonable program administration and supervision, as well as OSHA enforcement, requires that a certain degree of uniformity and regularity be applied to the respirator wearing schedules. To this end, and as neccessary to prevent an unwieldy complexity of schedules, all required periods of respirator wearing shall be rounded up to the next quarter hour so that all schedules will begin and end on a quarter hour.

The assigned class protection factors to be used in equation 1 are those in table 1 of the standard, namely, 5 for a single use or quarter mask; 10 for a half mask; 100 for a full facepiece; and 1000 for positive pressure devices.

Rationale

The basis for the standard, which is designed to reduce worker exposure to cotton duct, and the basis for the supporting health risk analysis is the cumulative effects of an average daily dose and not the immediate or acute effects of an instantaneous exposure level. The standard does not contain requirements for a maximum instantaneous ceiling on cotton dust exposure levels. Instead an averaged exposure is relied upon for protection. Hence partial shift wearing of a respirator is consistent with the basis of the standard.

Reference to exposure periods without respirators as uncontrolled may be misleading in the context of employee exposure. These periods may be uncontrolled by engineering means but they should result in known and controlled exposures of employees. As described above, the employer is required to accurately quantify the exposure contribution from all aspects of an employee's work. Therefore a high exposure during one period must be offset by correspondingly lower exposures at other times. In addition, the dust generating processes must be continuous or repetitive, resulting in predictable dust levels, for any exposure calculations to be meaningful.

Because paragraph (d) of the standard requires complete exposure determination, the exposure contribution of any period during a work shift will be known without regard to the use of respirators. Each employer was required to monitor by September 27, 1980 any area, including break areas, etc. that he had any reason to believe contained cotton dust.

No new uncertainties or inaccuracies in exposure determinations or in employee protection are introduced by using respirators on a schedule that is dependent on the cotton dust concentrations. At the same time these schedules do not reduce any of the uncertainties with respect to adequate protection that have always been a part of reliance on respiratory protection to protect employee health.

One policy alternative suggested to OSHA was that employees should be allowed to remove respirators only at assigned break times or in assigned break areas including rest rooms, and that exposure during these periods be ignored. So limiting the removal of respirators could be overly restrictive (depending on cotton dust levels). Such a policy could easily become unreasonable by ignoring the real and legitimate causes for brief removals of a respirator. These periods of exposure should be not ignored and shall not be ignored.

Direct comparison with the practice of other industries is not possible because unlike in those other industries the workplaces with cotton dust do not have clean areas conveniently accessible to which an employee can go to remove a respirator to clean it or his face, get a drink, etc. Since the cotton dust contaminated areas are not immediately dangerous to life and health (IDLH) and have no sensory warning properties, it is even more likely that these brief removals of the respirators will occur in the significantly contaminated areas. There has been no showing that cotton dust levels in break areas are negligible, especially in view of the fact that many employees take their breaks and lunch right at their assigned work stations. Without monitoring, or some other specific demonstrable reason, the dust levels in other areas cannot be assumed to be negligible. This includes rest rooms since they are normally under negative pressure from the odor control exhaust ventilation.

Tables

Tables I, II, III show the maximum allowable 8-hour time weighted average cotton dust concentrations for the various PEL's as a function of assigned time of use of the respirators. The inclusion of these tables was requested at the informal meetings and address the simplest yet most common situation. The tables incorporate the short cut approach of using the 10% time adjustment and apply only to the case where an employee is exposed to a single cotton dust concentration in which the respirator is used part of the time. The assumption is also made that all time spent without a respirator is time exposed to cotton dust, which has repeatedly been affirmed to OSHA as the normal situation. The maximum time of assigned respirator use is seven and one quarter hours to allow for lunchs and normal breaks. The table values were computed from a rearrangement of equation 3, $C = 8\ PEL/(8-KT)$ where $K = 1-1/PF$.

The values in these tables clearly demonstrate that a major influence in increasing the average actual employee exposure is the removal of a respirator. Because of this it will be observed that the highest values in the table fall far short of the PEL times the PF of the respirator even at seven and one quarter hours of assigned wear. This is not surprising since each minute without a respirator contributes 5, 10 or 100 times (depending on respirator) the dose to the employee as each minute wearing a respirator.

ALLOWABLE COTTON DUST LEVELS*

[Respirator PF=5]

Assigned time (hours)	PEL (μg/m³)			
	200	500	750	1,000
.25	205	512	767	1,023
.5	210	524	786	1,048
.75	215	537	805	1,073
1.0	220	550	825	1,100
1.25	226	564	846	1,128
1.50	232	579	869	1,158
1.75	238	595	892	1,189
2.0	244	611	917	1,222
2.25	251	629	943	1,257
2.5	259	647	971	1,294
2.75	267	667	1,000	1,334
3.0	275	688	1,032	1,376
3.25	284	710	1,065	1,420
3.5	293	734	1,101	1,467
3.75	304	759	1,139	1,518
4.0	314	786	1,179	1,572
4.25	326	815	1,223	1,631
4.5	339	847	1,270	1,693
4.75	352	881	1,321	1,761
5.0	367	917	1,376	1,835
5.25	383	957	1,436	1,915
5.5	400	1,001	1,502	2,002
5.75	420	1,049	1,573	2,098
6.0	441	1,101	1,652	2,203
6.25	464	1,159	1,739	2,319
6.5	490	1,224	1,836	2,448
6.75	518	1,296	1,944	2,592
7.0	551	1,377	2,066	2,755
7.25	588	1,470	2,204	2,939

*Table values (in μg/m³) are maximum allowable 8-hour time weighted averages for a single cotton dust environment (see eqn 3). Assigned time is of respirator use; all other time is assumed to be at full exposure. Standard 10 percent adjustment has been included.

ALLOWABLE COTTON DUST LEVELS*

[Respirator PF=10]

Assigned time (hours)	PEL (μg/m³)			
	200	500	750	1,000
.25	205	513	770	1,026
.5	211	527	790	1,054
.75	217	542	812	1,083
1.0	223	557	836	1,114
1.25	229	573	860	1,147
1.50	236	591	886	1,181
1.75	244	609	914	1,218
2.0	251	629	943	1,257
2.25	260	650	974	1,300
2.5	269	672	1,008	1,344
2.75	278	696	1,044	1,392
3.0	289	722	1,082	1,443
3.25	300	749	1,124	1,499
3.5	312	779	1,169	1,558
3.75	325	812	1,217	1,623
4.0	339	847	1,270	1,693
4.25	354	885	1,328	1,770
4.5	371	927	1,391	1,854
4.75	389	973	1,460	1,946
5.0	410	1,024	1,536	2,049
5.25	432	1,081	1,622	2,162
5.5	458	1,144	1,716	2,289
5.75	486	1,216	1,823	2,431
6.0	518	1,296	1,944	2,592
6.25	555	1,388	2,082	2,777
6.5	598	1,494	2,242	2,989
6.75	647	1,618	2,427	3,237
7.0	706	1,764	2,647	3,529
7.25	776	1,940	2,909	3,879

*Table values (in μ/m³) are maximum allowable 8-hour time weighted averages for a single cotton dust environment (see eqn 3). Assigned time is of respirator use; all other time is assumed to be at full exposure. Standard 10 percent adjustment has been included.

ALLOWABLE COTTON DUST LEVELS*

[Respirator PF=100]

Assigned time (hours)	PEL (μg/m³)			
	200	500	750	1,000
.25	206	514	772	1,029
.5	212	530	795	1,060

ALLOWABLE COTTON DUST LEVELS*—Continued

[Respirator PF=100]

Assigned time (hours)	PEL (μg/m³)			
	200	500	750	1,000
.75	218	546	819	1,092
1.0	225	563	845	1,127
1.25	233	582	873	1,164
1.5	241	602	902	1,203
1.75	249	623	934	1,245
2.0	258	645	968	1,290
2.25	268	669	1,004	1,339
2.5	278	696	1,043	1,391
2.75	290	724	1,086	1,448
3.0	302	755	1,132	1,509
3.25	315	788	1,182	1,576
3.5	330	825	1,237	1,649
3.75	346	865	1,297	1,730
4.0	364	909	1,364	1,818
4.25	383	958	1,437	1,916
4.5	405	1,013	1,519	2,025
4.75	430	1,074	1,611	2,148
5.0	457	1,143	1,714	2,286
5.25	489	1,221	1,832	2,443
5.5	525	1,311	1,967	2,623
5.75	566	1,416	2,124	2,832
6.0	615	1,538	2,308	3,077
6.25	674	1,684	2,526	3,368
6.5	744	1,860	2,791	3,721
6.75	831	2,078	3,117	4,156
7.0	941	2,353	3,529	4,706
7.25	1,085	2,712	4,068	5,424

*Table values (in μg/m³) are maximum allowable 8-hour time weighted averages for a single cotton dust environment (see eqn 3). Assigned time is of respirator use; all other time is assumed to be at full exposure. Standard 10 percent adjustment has been included.

This notice was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, Frances Perkins Labor Department Building, 3rd Street and Constitution Avenue, N.W., Washington, D.C. 20210.

(Secs. 6, 8, 84 Stat. 1593–96, 1599, [29 U.S.C. 655, 657]; Secretary of Labor's Order 8–76 [41 FR 25059]; [29 CFR Part 1911])

Signed at Washington, D.C., this 22nd day of December, 1980.

Eula Bingham,

Assistant Secretary of Labor.

[FR Doc. 80–40444 Filed 12–23–80; 11:56 am]

BILLING CODE 4510–26–M

29 CFR Part 1952

Certification of Completion of Developmental Steps for Wyoming State Plan

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: Wyoming, on July 31, 1980, submitted documentation attesting to the completion of all structural, developmental aspects of its approved State plan. After extensive review and opportunity for State correction, all developmental plan supplements have now been approved. This notice certifies this completion and the beginning of the final evaluation phase of State plan development. This certification attests only to the fact that Wyoming now has in place those structural components necessary for an effective program. It does not render judgment, either positively or negatively, on the adequacy of the State's actual performance. In addition, although original State plan commitments on staffing and resources have been met, these initial commitments may not be interpreted as meeting the ultimate requirements of the Occupational Safety and Health Act of 1970 for "sufficient staff" as redefined by the U.S. Court of Appeals decision in "AFL–CIO v. Marshall", 570 F. 2d 030 (D.C. Cir. 1978).

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: Charles Y. Boyd, Project Officer, Office of State Programs, Occupational Safety and Health Administration, 200 Constitution Avenue, N.W., Rm N3613, Washington, D.C. 20210—(202) 523–8081.

SUPPLEMENTARY INFORMATION:

Background

Section 18 of the Occupational Safety and Health Act of 1970 (the "Act," 29 U.S.C. 667) provides that States which desire to assume responsibility for the development and enforcement of occupational safety and health standards shall submit for Federal approval a State plan for such development and enforcement. Part 1902 of Title 29, Code of Federal Regulations, sets forth procedures under which the Assistant Secretary of Labor for Occupational Safety and Health ("Assistant Secretary") shall approve such plans. Under the Act and regulations, plan approval is essentially a two-step procedure. A State must first submit its plan for an initial determination under section 18(b) of the Act. If the Assistant Secretary, after reviewing the State's submission, determines that the plan satisfies or will satisfy the criteria set forth in section 18(c) of the Act, a decision of "initial approval" is issued and the State may begin enforcement of its safety and health standards in accordance with the plan and with concurrent enforcement by the Occupational Safety and Health Administration (OSHA).

A State plan may receive initial approval even though at the time of submission not all essential components of the plan are in place. As provided at 29 CFR 1902.2(b) the Assistant Secretary may intially approve the submission as a "developmental plan," and a schedule within which the State must complete specified "Developmental steps" is issued as part of the initial approval decision.

When the Assistant Secretary finds that the State has completed all developmental steps specified in the initial approval decision, a notice of such completion is published in the **Federal Register** (see 29 CFR 1902.34 and 35). Certification of completion of developmental steps initiates a thorough evaluation of the State plan by the Assistant Secretary to determine, on the basis of actual operations, whether the plan adequately protects safety and health of the State's workers. Certification does not render judgment as to the adequacy of State performance.

Final approval of the plan under section 18(e) of the Act and 29 CFR Part 1902 may not be granted until at least three years after initial approval and until at least one year after completion of developmental steps. Thereafter, when the Assistant Secretary determines on the basis of actual performance under the plan that the Act's criteria are being applied, a decision of final approval may be granted.

On May 3, 1974, a notice was published in the **Federal Register** (39 FR 15394) of initial approval of the developmental Wyoming plan and the adoption of Subpart BB of Part 1952 containing the decision, a description of the plan and the developmental schedule.

On July 31, 1980, Donald Owsley, Administrator of the Wyoming Occupational Health and Safety Department, submitted documentation attesting to the completion of each State developmental commitment for review and approval as provided in 29 CFR Part 1953. Following Departmental review, opportunity for public comment and subsequent modification of the State's submissions, as deemed appropriate, the Assistant Secretary has approved the completion of all individual Wyoming developmental steps.

Completion of Developmental Steps

All developmental steps specified in the May 3, 1974 notice of initial approval have been completed as follows:

a. The State adopted Federal standards covering all the issues contained in 29 CFR Part 1910, Subparts D through S, and Part 1926 (the State will not cover Parts, 1915, 1916, 1917, and 1918). (40 FR 8948, March 4, 1975; 41 FR 26767, June 29, 1976.)

b. Wyoming's Occupational Health and Safety posters for private and local government employees were approved by the Assistant Secretary on July 14, 1976. (41 FR 30329, July 23, 1976.)

c. Wyoming has developed and implemented a Management Information System approved by the Assistant Secretary on July 2, 1976. (41 FR 28789, July 13, 1976.)

d. The State plan has been amended to include an Affirmative Action Plan outlining the State's policy of equal employment opportunity. (42 FR 45907, September 13, 1977.)

e. Guidelines and Procedures for implementing the State's health and safety program for public employees were approved by the Assistant Secretary on June 1, 1978. (41 FR 51011, Nov. 19, 1976.) (43 FR 4510–26, June 13, 1978.)

f. Administrative regulations for recordkeeping and reporting, variances, posting requirements, employee complaint procedures, inspections under the Act, employee exposure to toxic materials, providing information to employees on their exposure to hazards, personal protective equipment, medical examinations, and monitoring, safeguarding trade secrets, administrative review of citations, proposed penalties, and abatement periods were approved by the Assistant Secretary on December 19, 1980. (45 FR 83485.)

g. Legislation revising the enabling law to provide for civil enforcement of safety and health violations and revised regulations establishing procedures for review of enforcement actions was approved by the Assistant Secretary on December 19, 1980. (45 FR 83483.)

h. The State has met its plan commitment for hiring enforcement staff under an approved merit system for administration of its health and safety program pursuant to a July 3, 1980 memo from Don Owsley, Administrator of the Wyoming Occupational Health and Safety Department.

i. As required by 29 CFR 1902.34(b)(3), the personnel operations of the Wyoming Occupational Health and Safety Department have been found to be in substantial conformity with the "Standards for a Merit System of Personnel Administration" by the Office of Personnel Management in a letter dated October 17, 1980.

This certification covers all occupational safety and health issues covered under the Federal program except for longshoring and maritime standards found in 29 CFR Parts 1915, 1916, 1917 and 1918 (longshoring, ship repairing, ship building, and ship breaking), which are excluded from coverage under the plan. This certification also covers the State's program covering State and local government employees.

Location of the Plan and Its Supplements for Inspection and Copy

Copies of the supplements, along with the approved plan, may be inspected and copied during normal business hours at the following locations:

Office of the Director of Federal and State Programs, Occupational Safety and Health Administration, Room N–3613, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Office of the Regional Administrator, Occupational Safety and Health Administration, Region VIII, Federal Building, Room 1554, 1961 Stout Street, Denver, Colorado 80294.

Office of the Administrator, Occupational Health and Safety Department, 200 East Eighth Avenue, Cheyenne, Wyoming 82002.

Effect of Certification

The Wyoming plan is certified effective December 30, 1980 as having completed all developmental steps on or before April 25, 1977. This certification attests to structural completion, but does not render judgment on adequacy of performance.

The Wyoming occupational health and safety program will be monitored and evaluated for a period of not less than one year after publication of this certification to determine whether the State program in operation provides for an effective program of enforcement. The Assistant Secretary will then determine whether Federal authority should be withdrawn with respect to issues covered by the plan pursuant to Section 18(e) of the Act.

Level of Federal Enforcement

In accordance with 29 CFR 1902.35, Federal enforcement authority under sections 5(a)(2), 8, 9, 10, 13 and 17 of the Act (29 U.S.C. 654 (a)(2), 657, 658, 659, 662 and 666) and Federal standards authority under section 6 of the Act (29 U.S.C. 655) will not be relinquished during the evaluation period. However, OSHA's concurrent Federal enforcement authority will be exercised on a limited basis.

In accordance with this certification, 29 CFR 1952.344 is hereby amended to reflect successful completion of the developmental period by changing the title of the section and by adding paragraph (j) as follows:

§ 1952.344 Completion of developmental steps and certification.

* * * * *

(j) In accordance with § 1902.34 of this chaper, the Wyoming occupational safety and health plan was certified, effective December 30, 1980, as having

completed all developmental steps specified in the plan as approved on April 25, 1974, on or before April 25, 1977. This certification attests to structural completion, but does not render judgment on adequacy of performance.

(Sec. 18, Pub. L. 91-596, 84 Stat. 1608 (29 U.S.C. 667))

Signed at Washington, D.C. this 18th day of December 1980.

Eula Bingham,

Assistant Secretary of Labor.

[FR Doc. 80-40220 Filed 12-29-80; 8:45 am]

BILLING CODE 4510-26-M

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 7

Glacier Bay National Monument; Protection of Humpback Whales

AGENCY: National Park Service, Interior.

ACTION: Final rule.

SUMMARY: The regulations set forth below are designed to protect declining populations of the humpback whale (*Megaptera Novaeangliae*) within Glacier Bay National Monument. To minimize the effects of vessel-whale interactions, these regulations establish numerical limitations upon small vessels within the monument. These regulations also prohibit the commercial harvesting of the major organisms upon which the humpback whales feed. Both these regulations and the final regulations published on May 15, 1980 (45 FR 32234 and 32228), the latter of which addressed: (1) Operating restrictions on all vessels within the monument and (2) numerical limitations on entries by large vessels (vessels at or in excess of 100 tons gross), will be in effect through May 15, 1983, subject to ongoing review and modification by the National Park Service where warranted.

EFFECTIVE DATE: January 29, 1981.

FOR FURTHER INFORMATION CONTACT: Superintendent, Glacier Bay National Monument, P.O. Box 1089, Juneau, Alaska 99802; Telephone: (907) 586-7137.

SUPPLEMENTARY INFORMATION:

The Humpback Whale

As a result of commercial whaling during the first half of this century, the number of humpback whales in the North Pacific was seriously reduced from former levels. Populations have declined from an estimated 15,000 in 1905 to a present estimate of 1,000. In 1966, the International Whaling Commission placed a prohibition on the commercial taking of humpback whales. In 1970, the humpback whale was designated an endangered species under the Endangered Species Conservation Act of 1969. Additionally, humpback whales are protected by the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), The Marine Mammal Protection Act of 1972, as amended (16 U.S.C. *et seq*), and the Convention of International Trade in Endangered Species of Wild Fauna and Flora, March 3, 1973 (T.I.A.S. No. 8249).

It is estimated that between 70 and 100 humpback whales spend the summer months in the waters of Southeastern Alaska. They have been known to frequent these inland waters since before 1900. When humpback whales historically began occupying Glacier Bay is unknown. Their presence in Glacier Bay has been documented by National Park Service personnel since the area was staffed on-site in the 1950's.

Glacier Bay National Monument

Glacier Bay National Monument was established by Presidential Proclamation on February 26, 1925 (43 Stat. 1988), and expanded by subsequent proclamations on April 18, 1939 (53 Stat. 2534), and December 1, 1978 (43 FR 57053).

The primary purpose of the monument's establishment and enlargements is the protection and preservation of a wide array of geological, ecological and biological resources to be preserved in their natural condition.

The boundaries of Glacier Bay National Monument include approximately 973 square miles of marine waters. The Pacific Ocean marine life of the monument is one of the major attractions of the 120,000 visitors using the area annually. Of this marine life, the humpback whale is a high point in a visitor's experience.

Records indicate that in the years 1967 through 1977, an annual average of 20–25 individual whales were observed to use the Bay for summer feeding, entering in two stages (June and July) following the neap tides, and remaining into early fall. This period of occupancy is commonly referred to as the whale season. Seven years of scientific research and improved photo identification techniques indicate that certain individual whales repeatedly return to feed in Glacier Bay. In 1978, during the first entry stage, the whales entered the mouth of the Bay and several whales successfully moved up Bay into feeding areas. However, the whales of the second entry stage did not stay, but left, accompanied by all but three animals of the first entry phase.

In 1979, only a few humpbacks entered Glacier Bay, and again, only three or four remained in up Bay feeding areas.

Research Investigations and Findings

Research into the behavioral responses of humpback whales to vessels has been conducted under contract in Glacier Bay since 1976. Preliminary results of this research indicate adverse impacts on humpback behavior from interaction with increasing numbers of vessels using the Bay. Although there is disagreement over the severity of impact caused by each vessel class and method of operation, it is clear that vessels can create stress in whale behavior.

Prior to the 1979 visitor season, vessel operating guidelines were publicized and discussed with boaters. Some of these were similar to the regulations now in effect. Basically, all motorized vessels were asked to remain ¼ mile from any humpback whale, and cruise ships were asked to proceed through designated waters at 10 knots or less. These requests were complied with in most respects, but the number of whales entering the Bay and remaining through their historic use period continued to decline.

On August 6, 1979, when these procedures appeared to have no beneficial effect on the use of Glacier Bay by humpback whales, the National Park Service requested a formal consultation with the National Marine Fisheries Services (NMFS) in accordance with the provisions of the Endangered Species Act. In their formal response to the consultation process, the National Marine Fisheries Service concluded "* * * that uncontrolled increase of vessel traffic, particularly of erratically traveling charter/pleasure craft, probably has altered the behavior of humpback whales in Glacier Bay * * *, "and" * * * that continued increased in the amount of vessel traffic * * * is likely to jeopardize the continued existence of the humpback whale population frequenting Southeast Alaska."

NMFS recomended "* * * that total vessel use of the Bay be restricted to 1976 levels, at the very least, * * * "and further, that "* * * regulations should address vessel routing and vessel maneuvering * * *." and "* * * the system should be flexible enough to accommodate changes of areas of concentrated feeding activity." In a letter to the Superintendent of Glacier Bay dated October 15, 1980, the NMFS Director, Alaska Region unequivocably

reconfirmed NMFS' vessel use restriction recommendations.

The National Park Service and professional marine biologists recognize that a full understanding of marine mammal behavior and habitat processes is a complex problem, and that worldwide research to date has not provided final answers to many issues. However, until such time as additional research yields a more complete picture, the Service must exercise its responsibility to the total environment of the monument it manages. In addition, the Service must comply with the mandate of the Endangered Species Act to take appropriate steps to protect an endangered species and to mitigate any possible adverse impacts resulting from the actions of man.

The Service will re-evaluate the regulations promulgated today in approximately two and one-half years in order to consider any new or relevant information. The designation of a two and one-half year period does not eliminate the flexibility to take more stringent or relaxed measures if necessary or warranted.

Legal Authorities

On February 26, 1925, pursuant to his authority under the Antiquities Act, 16 U.S.C. 431 *et seq.* (1976), President Coolidge established Glacier Bay National Monument and directed the National Park Service to administer it in accordance with the Act of August 25, 1916, 16 U.S.C. 1 *et seq.* (hereinafter "the National Park Service Organic Act"). Proclamation No. 1733 (February 26, 1925) 43 Stat. 1988. Under the same authority, Presidents Roosevelt and Carter subsequently enlarged the monument in 1939 and 1978, respectively. Proclamation No. 2330 (April 18, 1939), 53 Stat. 2534; Proclamation No. 4618 (December 1, 1978), 43 FR 57053. The boundaries of Glacier Bay National Monument encompass approximately 973 square miles of marine waters.

The National Park Service Organic Act directs the National Park Service to "promote and regulate the use of the Federal areas known as 'national monuments,' including Glacier Bay National Monument" by such means and measures as conform to the "fundamental purpose of the said * * * monuments * * * which purpose is to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations." 16 U.S.C. 1 (1976).

Furthermore, the Organic Act authorizes the Secretary of the Interior to "make such rules and regulations as he may deem necessary or proper for the use and management of the monuments * * * under the jurisdiction of the National Park System". Id. S 1(a)–2(h) (1976).

In addition to the National Park Service Organic Act, both the Endangered Species Act of 1973, as amended, and the Marine Mammal Protection Act of 1972, as amended, provide authority for the regulations proposed today to protect humpback whales. 16 U.S.C. 1531 *et seq.;* 16 U.S.C. 1361 *et seq.* With respect to the Endangered Species Act, the humpback whale is listed as an endangered species of whale under the Act. 50 CFR 17.11; see also, Convention on International Trade in Endangered Species of Wild Fauna and Flora, March 3, 1973 (T.I.A.S. No. 8249). The Endangered Species Act directs the Secretary of the Interior to utilize all the programs which he administers in furtherance of the purposes of this Act. It also directs all Federal agencies to "utilize their authorities in furtherance of the purposes of the Act by carrying out programs for the conservation of endangered species * * *" 16 U.S.C. 1536(a); 1531(c). By its terms, the Act's purposes "are to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved, to provide a program for the conservation of each endangered species and threatened species, and to take such steps as may be appropriate to achieve the purposes of the (listed) treaties and conventions * * *" Id. S 1531(b).

The Endangered Species Act defines "conservation" broadly to mean "all methods and procedures which are necessary to bring any endangered species to the point at which the measures provided pursuant to this Act are no longer necessary." Id. S 1532(2). The Endangered Species Act also makes it unlawful for any person "to take any such (endangered) species within the United States * * * Id. S 1538(a)(1)(B). The Act defines "take" broadly to include, inter alia, "harass, harm, pursue." Id. S 1532(14); see 50 CFR 17.3.

The Marine Mammal Protection Act also protects humpback whales. 16 U.S.C 1361 *et seq.* The Act prohibits, except as specifically permitted, the taking of marine mammals including, by definition, humpback whales. Id. 1372(a); 1362(5). Again, taking is defined broadly to include harassing or attempting to harass. Id. S 1362(13). As stated in the Act's legislative history:

"The act of taking need not be intentional. The operation of motorized vessels in waters in which these animals are found in a manner prohibited by the proposed rule can clearly constitute harassment." H.R. Rep. No. 707, 92d Cong., 1st Sess. 23.

The Marine Mammal Protection Act recognizes that "there is inadequate knowledge of the ecology and population dynamics of * * * marine mammals." 16 U.S.C. 1361(3). Nevertheless, the Act directs each Federal agency to protect significant habitat for marine mammals from the "adverse effect of man's actions." Id. S S 1361(2); 1382 (a), (b). The above proclamations and acts provide the legal authority for the regulations which the National Park Service is promulgating today. These regulations are also based on the opinion of the National Marine Fisheries Service quoted above. Both the Endangered Species Act and the Marine Mammal Protection Act confer major responsibility for management of the endangered humpback whales on the National Oceanic and Atmospheric Administration. *See* Reorganization Plan No. 4 of 1970, 35 FR 15627; 16 U.S.C. 1532(10), 1533(a)(2); 50 CFR 17.2, see, also, 16 U.S.C. 1362 *et seq.*, and 16 U.S.C. 916 *et seq.*

Public Participation on the Interim Rules

The National Park Service has published two sets of regulations designed to protect the summer habitat of the humpback whale within Glacier Bay. The Service published final rules limiting large vessel entries and governing methods of operation for all vessels on May 5, 1980 (45 FR 32228). On the same date, interim rules governing small vessel entries and commercial fishing activities were published (45 FR 32234) as well as a request for public comments regarding those interim rules. The period for public comment on the interim rules closed July 14, 1980.

The National Park Service received eleven timely comments on its interim regulations. Of these, seven comments were from private individuals, three were from organizations, and one was from the State of Alaska.

The Service has carefully considered each of these comments and has adopted numerous suggestions made by the commenters. The comments received and the Service's reasons for accepting or rejecting the comments are as follows:

Commenters on Small Vessel Entries

1. Eight comments indicated general support for limiting the number of small vessel entries during the whale season. One individual suggested prohibiting all

pleasure craft entries while three others recommended further reducing the number of small vessel entries. The National Park Service appreciates the support it has received for its response to a difficult but important problem. That response involves a literal application of the NMFS recommendation to return all vessel entries to 1976 levels. This includes small vessel entries for which the very best available historic use data has been applied. That historic data base has been re-evaluated since these regulations were published in proposed form on May 15, 1980.

For small vessels other than charter vessels, the Bartlett Cove vessel observation sheets have been carefully examined and show total use during the 1976 whale season of 339. Since a conservative approach toward establishing a 1976 use level is warranted and no reasonable method of estimating uncounted vessels has been developed, a total entry limit of 339 private small vessels during the whale season is applied.

For charter vessels, which include the Park concessioner as well as special use permit operators the historic data base indicates the following: Concession entries in 1976 totaled 368. Since these entries are already controlled through a concessions contract they will not be subject to the small vessel permit system. Instead, the 1976 concessioner use level will be maintained through contract provisions. Likewise, charter vessel operators are controlled via special use permits. Rather than impose a second permit system on these individuals, the special use permit itself will limit charter vessel use to 1976 levels (an estimated 78 entries) or less.

The Service is confident that these levels reflect 1976 vessel use of Glacier Bay.

2. Several commenters asked specific questions regarding the permit system being implemented. These included five comments regarding entries allocated to the concession operation at Bartlett Cove, one request to limit the period of stay for any small vessel in Glacier Bay to three days, and one recommendation that unused daily entry allocations not be accumulated for later use without a firm ceiling on the maximum number of vessels permitted in the Bay. The permit system for small vessels set forth in these regulations responds affirmatively to these comments. Essentially, three limited use levels will be in effect. All are based upon 1976 use records. First, total entries for small vessels for the whale season will be at 1976 levels. Second, the maximum number of entries per day will be based upon the average number of entries per day in 1976. And third, the maximum number of vessels permitted in Glacier Bay at any one time shall not be allowed to exceed the maximum number reported in the Bay in 1976.

As discussed above, while the concessionaire has increased the number of vessels he operates since 1976 he will not be permitted more vessel entries than those recorded for 1976.

All other charter vessels will similarly be restricted to 1976 levels.

3. One commenter alleged that the National Park Service has failed to provide sufficient funds for the enforcement of these regulations. As with any other Law Enforcement Programs, voluntary compliance is critical to success. Voluntary compliance is gained through public understanding of the need for the regulations, publicizing widely the nature of the regulations, facilitating compliance, and visible enforcement and the apprehension of violators. During the 1980 whale season the Service addressed all four areas through public education programs, public announcements, a clear and simple permit system, and an active enforcement program which resulted in several warnings and violation citations. Few, if any, enforcement programs are completely effective. However, the current level of compliance with previous regulations is remarkably high. Still, the Service maintains the flexibility to reallocate resources in response to significant enforcement problems and will do so at Glacier Bay if necessary.

Comments on Commercial Fishing

1. The State of Alaska, Department of Fish and Game, made three specific recommendations regarding commercial fishing of whale feed species. These recommendations included (1) applying the prohibition against fishing for certain species year around (2) applying them only within Glacier Bay proper, and (3) prohibiting the retention of those species as opposed to the incidental capture. Each of these recommendations has been adopted.

2. One comment questioned the exemption of commercial fishing vessels from entry limits. The data clearly indicates a significant reduction in commercial fishing vessel entries since 1976 making regulated limits unnecessary.

Drafting Information

The following persons participated in the writing of these regulations: John Chapman, Superintendent; Donald D. Chase, Chief of Operations, Glacier Bay National Monument; William F. Paleck, Alaska Regional Office; Deborah L. Williams, Solicitor's Office, Anchorage.

Impact Analysis

The National Park Service has made a determination that the regulations contained in this rulemaking are not significant, as that term is defined under Executive Order No. 12044 as amended, and 43 CFR Part 14, nor do they require the preparation of a regulatory analysis pursuant to the provisions of these authorities. In addition, the Service has determined that these regulations do not represent a major Federal action significantly affecting the quality of the human environment which would require preparation of an Environmental Impact Statement. An Environmental Assessment and Finding of No Significant Impact have been prepared and are available at the address listed at the beginning of this rulemaking.

Authority: Presidential Proclamations No. 1733 (43 Stat. 1988), 2330 (53 Stat. 2534), and 4618 (43 FR 57053); Act of August 25, 1916 (39 Stat. 535, as amended, 16 U.S.C. 1 *et seq.*); 245 DM 1 (44 FR 23384); National Park Service Order 77 (38 FR 7478), as amended.

John F. Chapman,

Superintendent.

In consideration of the foregoing, § 7.23 of Title 36 of the Code of Federal Regulations is amended by the addition of paragraphs (e) and (f) as follows:

§ 7.23 Glacier Bay National Monument, Alaska.

* * * * *

(e) *Small Vessel Entry Restrictions.* (1) Entries into Glacier Bay during the whale season by all small vessels, except charter vessels and commercial fishing vessels, will be limited to a total of 339. (2) Entries into Glacier Bay during the whale season by charter vessels will be at 1976 levels. (3) No small vessel operator shall enter or remain in Glacier Bay National Monument without a valid permit issued by the Superintendent, or in the case of charter vessel operators without special use permit or concession contract. (4) Upon entering and leaving Glacier Bay, each small boat operator shall notify the designated Park Service official. (5) The Superintendent shall develop, announce, and implement a permit system which details (i) how permits can be obtained, (ii) who the operator must contact when entering and leaving Glacier Bay (iii) the average number of small vessel entries to be allowed each day during the whale season (iv) the maximum number of small vessels to be allowed in Glacier Bay at any one time during the whale season and (v) the allocation of entry

permits among concessionaire, charter and all other types of small vessels.

(f) *Commercial Fishing.* (1) No commercial or charter fishing operator will actively fish for, or retain if incidentally caught, capeline *(Mallotus)*, sandlance *(Ammodytes)*, euphausids *(Thalassia)*, or shrimp *(Pandalidae)* within Glacier Bay. (2) These restrictions on fishing shall apply throughout the year but shall only apply to the waters inside the mouth of Glacier Bay.

[FR Doc. 80-40345 Filed 12-29-80; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-10-FRL 1710-8]

Alaska; Approval and Promulgation of Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The purpose of this notice is to indicate final action on the transportation control plan portion of the Alaska State Implementation Plan (SIP) dealing with Part D (Plan Requirements for Nonattainment Areas) of the Clean Air Act (hereafter referred to as Act) as amended in 1977 (42 U.S.C. 1857 et seq.). EPA is conditionally approving the transportation control plan (TCP) portions of the Anchorage and Fairbanks carbon monoxide (CO) attainment strategies and is taking no action on the portions of the SIP addressing Part D New Source Review, Section 110 Preconstruction Review, Section 111 Standards for a New Source Performance and Part C Prevention of Significant Deterioration. Action on these other than Part D nonattainment SIP's will be taken at a later date and will incorporate the new EPA requirements promulgated August 7, 1980 as a result of *Alabama Power* v. *Costle*. In accordance with conditional approvals, the State of Alaska is required to submit to EPA additional materials to satisfy the conditions no later than 120 days after publication of this final rulemaking.

EFFECTIVE DATE: December 30, 1980.

ADDRESSES: Copies of the related material for this revision may be examined during normal business hours at the following locations:

The Office of the Federal Register, 1100 L Street, NW., Room 8401, Washington, D.C. 20408

Central Docket Section (10A-79-6), West Tower Lobby, Gallery I, Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460

Air Programs Branch, Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Seattle, Washington 98101

FOR FURTHER INFORMATION CONTACT: Richard R. Thiel, P.E., Chief, Air Programs Branch, U.S. Environmental Protection Agency, Region 10, 1200 Sixth Avenue, Seattle, Washington 98101; Telephone No. (206) 442-1226; FTS 399-1226.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA finds that good cause exists for making the action taken in this notice immediately effective for the following reasons: (1) Implementation plan revisions are already in effect under State law and EPA approval poses no additional regulatory burden, and (2) EPA has a responsibility under the Clean Air Act to take final action on the portion of the SIP which addresses Part D regulations by July 1, 1979 or as soon thereafter as possible.

On September 16, 1980 the Environmental Protection Agency published in the **Federal Register** a notice of proposed rulemaking (45 FR 61319) which described the nature of the SIP revision, discussed certain provisions which, in the opinion of EPA, did not comply with the Act, and requested public comment.

As discussed in greater detail below, EPA has reviewed public comments received on the September 16, 1980 **Federal Register** proposal and is taking the following action:

1. Conditional Approval

(a) Anchorage CO nonattainment area TCP.

(b) Fairbanks CO nonattainment area TCP.

2. No Final Action

(a) Title 18 Alaska Annotated Code Chapter 50 (18 AAC 50)—provisions for New Source Review (NSR) in nonattainment areas, preconstruction review, Prevention of Significant Deterioration (PSD) and standards for new source performance.

In this notice the problems interfering with SIP approval are discussed, comments from the State and the public are presented, and EPA's responses to comments on its proposal are presented. In addition, the notice describes final action with regard to conditional approval of the Alaska SIP. It should be noted that only the requirements pertaining to Part D of the Act are discussed.

Following this introduction, the information in this notice is divided into three sections entitled, "Background," "Plan Review" and "SIP Requirements for Conditional Approval." The first section outlines the background leading to the development of the Alaska SIP in relation to the Clean Air Act Amendments of 1977. The "Plan Review" portion is divided into three major sub-sections. The first, "General Regulations," discusses regulatory portions of the plan applicable to more than one nonattainment area; e.g., New Source Review. The second sub-section, "Nonattainment Area Plans," provides a description of each Part D nonattainment plan element for (CO). Deficiencies, together with appropriate corrective actions, which were proposed earlier, are summarized at the end of each topical discussion section.

Further public comments pertaining to those deficiencies, proposed corrective actions and other concerns regarding the SIP are then summarized along with EPA's responses. Following the public comment section, final EPA action is then described for each deficiency noted as well as EPA final action regarding other major elements of the SIP.

The third sub-section contains a discussion of other pertinent comments of a general nature, which apply to this action but were not in response to identified deficiencies.

II. Background

On March 3, 1978 (43 FR 8962), and September 11, 1978 (43 FR 40435), pursuant to the requirements of Section 107 of the Act, EPA designated certain areas of the State of Alaska as not attaining certain National Ambient Air Quality Standards (NAAQS). Part D of the Act requires States to revise their State Implementation Plans (SIP) for all areas that have not attained the NAAQS. The Alaska SIP revisions were developed and submitted to EPA to satisfy the requirements of the Act and are intended to update the present EPA approved SIP. The basic criteria for an approvable Part D SIP are summarized in a General Preamble published in the April 4, 1979, **Federal Register** (44 FR

20372) as supplemented in the **Federal Register** on July 2, 1979 (44 FR 38583), August 28, 1979 (44 FR 50371), September 17, 1979 (44 FR 53761), and November 23, 1979 (44 FR 67182). These criteria are incorporated by reference and will not be restated here. Additional guidance was published in the " EPA/DOT Transportation Planning guidelines" and the "Transportation SIP Checklist" and general requirements for all SIPs are found in EPA regulations in 40 CFR Part 51.

In accordance with Section 174 of the Act, primary responsibility for preparing carbon monoxide (CO) control plans was delegated by the Governor of Alaska to organizations of local elected officials. These designated organizations are the Municipality of Anchorage (MOA) for the Anchorage CO nonattainment area and the Fairbanks North Star Borough (FNSB) for the Fairbanks CO nonattainment area. As a result of these designations, a description of the responsibilities between the various State and local agencies involved in the planning process was developed. Designated lead agencies were responsible for transportation control plan development, while the State, in general, retained responsibility for stationary source control efforts.

The CO control strategies for Anchorage and Fairbanks were developed in early 1979. Public hearings were held on March 22, and April 5, 1979, in Fairbanks and Anchorage, respectively. These plans were then submitted to the Alaska Department of Environmental Conservation (ADEC). Additional public hearings were then held on the entire State SIP in Anchorage and Fairbanks on May 15 and 16, 1979, respectively. Just before these hearings, a draft SIP was submitted informally to EPA for comment. After the public hearings, this version of the SIP was finalized and submitted to EPA by the Governor on June 28, 1979.

On July 18, 1979 EPA submitted comments to the State covering all aspects of the SIP. The State revised the SIP and submitted a second version for comments on January 20, 1980. EPA's review comments were then discussed in-depth with the State on May 7 and 8, 1980. Agreement was reached on all the changes that were required to make the SIP approvable.

On September 16, 1980 EPA proposed action on the revised Alaska Part D TCPs for Anchorage and Fairbanks CO nonattainment areas.

III. Plan Review

As stated above, this section is divided into three major sub-sections. The first, "General Regulations," briefly describes the regulatory portions of the plan applicable to more than one nonattainment area; e.g., New Source Review, and discusses the deficiencies and specifically states which category of action EPA is proposing to take. The second sub-section, "Nonattainment Area Plans" discusses each area-pollutant-specific plan in terms of plan development, emission reduction required, control strategy proposed, deficiencies identified and corrective actions required, State response, public comments, and EPA's final action. The third "General Comments," contains a discussion of other pertinent comments on subjects not specifically defined as deficiencies in this action.

A. New Source Review (NSR)

Title 18 Alaska Annotated Code Chapter 50 (18 AAC 50) does not include provisions to satisfy the requirements of Section 172(b)(6) and 173 of the Act for major sources of CO in the Anchorage and Fairbanks nonattainment areas. Provisions must be added to ensure that (1) reasonable further progress (RFP) is achieved in attainment and maintenance of CO NAAQS; (2) no permit is granted to a source unless other sources in the State owned by the same company are in compliance with the Act; and (3) that lowest achievable emission rate (LAER) is required for emission control.

The State has prepared revisions to the regulation to correct this deficiency. The revised regulation was subject to public hearing on September 9 and 10, 1980 and is currently being revised based on comments received. Therefore, EPA is not taking action on Part D New Source Review at this time.

Until EPA takes final action to approve or conditionally approve the Part D CO attainment plans for the Anchorage and Fairbanks areas, which include new source review procedures submitted by the State, the ban on construction of new and modified major stationary sources of CO required by Section 110(a)(2)(I) of the Act, will remain in effect. These restrictions apply only in the designated nonattainment areas and only to new or modified major stationary sources. The restriction does not affect existing sources (unless they are being modified) or sources which applied for permits to construct before July 1, 1979.

Other deficiencies in 18 AAC 50 which affect the New Source Review (NSR) process are outlined below:

1. Deficiencies:

a. *Source Applicability:* 18 AAC 50.300(a) excludes many sources with potential emissions equal to or greater than 100 tons per year. This must be changed to require NSR in accordance with Section 302(j) of the Act, which defines major source as one which has the potential to emit 100 tons or more per year of any air pollutant.

b. *Potential emissions* or *potential to emit:* 18 AAC 50 contains no definition for either of these terms. This terminology must be defined in order to ensure that NSR provisions apply to all required sources.

c. *Emission standard* or *emission limitation:* 18 AAC 50 contains no definition for either of these terms. This terminology must be defined to ensure proper understanding of the underlying permit review criteria.

2. State Response: The State is correcting these deficiencies and others as a result of EPA regulations promulgated after the final court decision on *Alabama Power vs. Costle.* and will resubmit the regulations at a later date.

3. Public Comment: None.

4. EPA Action: *No Action.* As explained earlier, EPA will take final action on the NSR program at a later date when the Alaska regulations have been revised.

B. Nonattainment Area Plans

Alaska's two nonattainment areas, located in Achorage and Fairbanks, are both designated for carbon monoxide (CO). They will be discussed in terms of a brief description of the area, extensions requested, control measures proposed, any problems that would interfere with SIP approval, State actions to correct the problems, public comment and EPA's final action.

1. *Extension Requests:* Under Section 172(a)(2) of the Act, the State has described a need for an extension of the attainment date for CO for both the Anchorage and Fairbanks areas. This requires that the plans demonstrate the application of all reasonably available control measures (RACM), establish a program for determining costs and benefits of proposed facilities, and commit to expand public transportation. Attainment of the standard by 1987 in both areas will be defined upon completion of the alternatives analysis.

EPA approves extensions for the Anchorage and Fairbanks areas thus requiring an enforceable transportation control plan by July 1, 1982. EPA approves the CO SIP's conditioned upon the inclusion of provisions in each control strategy for cost benefit analyses as required by Section 172(b)(11)(A) of the Act. Further, EPA finds that the SIP's

contain adequate demonstrations of the application of RACM's and that commitments to expand public transportation are evident in the SIP and other planning documents. It should be noted that even though EPA's 200,000 population criterion exempts both cities from the inspection maintenance requirement. Anchorage and Fairbanks are each considering it as one of the alternatives for the 1982 SIP.

2. *Carbon Monoxide:*

a. *Anchorage:* i. *Background:* The Anchorage area consists of a large portion of the urbanized area which was defined based on air monitoring conducted in 1977 and 1978. The area is bounded by Elmendorf Air Force Base to the North, Muldoon Road and Lake Otis Parkway to the East, O'Malley Road to the South and Cook Inlet to the West.

The designated lead agency is the Municipality of Anchorage (MOA). The MOA worked with the Anchorage Air Pollution Control Program, the Alaska Department of Transportation (ADOT), the Federal Highway Administration (FHWA) and the Alaska Department of Environmental Conservation (ADEC) in developing the plan. Public participation was realized largely through the Citizens Delphi Panel and the Air Quality Citizens Advisory Committee. Public hearings on the Plan were held April 5 and May 15, 1979.

ii. *Emission Reduction Required:* For CO the maximum hotspot emission reduction required to achieve standards is 52 percent. At this time an attainment date for NAAQS will fall beween 1983 and 1987. It is apparent, though, that the Federal Motor Vehicle Emission Control Program (FMVECP) will only produce a 17 percent reduction by 1982 and a 35 percent reduction by 1987. Reductions attributable to other alternative measures are currently being determined using the latest mobile source emission factors. There is also an effort underway by EPA to determine the effectiveness of an inspection and maintenance program (I/M) as an alternative measure in cold weather climates.

iii. *Control Strategy:* Carbon monoxide is primarily a transportation-related pollutant. In Anchorage transportation sources contribute about 85 percent of the emissions with commercial, residential and industrial stationary sources of fuel generation contributing the remaining 15 percent.

In light of the dominant motor vehicle contribution to the CO nonattainment problem, the control strategy focuses on transportation measures. Typical reasonably available control measures are listed in Section 108(f)(1)(A) of the Act. It should be noted that measures designed to reduce vehicle emissions operate in one of three basic ways: (a) by reducing trips and miles traveled; i.e., improved mass transit, carpooling, etc., or (b) improving traffic speeds; i.e., improved traffic signalization, traffic flow improvements, parking restrictions, etc., or (c) by reducing the emissions from individual vehicles; i.e., an inspection and maintenance program and the FMVECP.

The overall strategy will be based on the results of the comprehensive analysis of the alternative transportation control measures outlined below:

(1) Selected Restrictions of Commercial and Other Vehicles [a]
(2) Pedestrian Facilities [b]
(3) Inspection and Maintenance Program [c]
(4) Vehicle Idling Controls [a]
(5) Fleet Vehicle Controls [b]
(6) Cold Start Strategies [b]
(7) Public Transit Improvements [a]
(8) Paratransit Improvements [a]
(9) Parking Management [a]
(10) Flex-Time and Staggered Work Hour Schedules [a]
(11) Indirect Source Review [b]
(12) Traffic-Improvement—Capital Intensive [a]
(13) Traffic Improvements—Non-Capital Intensive [a]

[a] Currently implemented measure which will be expanded in scope.
[b] New measure.
[c] Voluntary measure which may become mandatory.

This analysis was due to be completed in April 1980, but has been delayed until December 1980 due to the revisions to the EPA mobile source emission factors. The 1982 strategy will contain sufficient measures from the above list to show attainment no later than December 31, 1987.

iv. *Deficiencies/Comments/EPA Action:* (1) *Deficiencies:* The CO TCP for the Anchorage area addresses all the requirements contained in Part D of the Act and in the EPA–DOT Transportation-Air Quality Guidelines Checklist except as described below. Accordingly, EPA approves the Anchorage TCP with the following conditions:

(a) The emissions inventory must be updated to include area sources and emissions associated with parking and idling activities.

(b) The population growth rates used to project CO emissions for 1982 and 1987 must be included in the SIP and shown to be consistent with Bureau of Economic Affairs (BEA) population projections or other more localized projections such as those used in water quality planning under Sections 201 and 208 of the Federal Clean Water Act.

(c) Provisions must be included for cost-benefit analysis as required by Section 172(b)(11)(A) of the Act.

(2) *State Response:* The State has agreed to adopt and submit the required changes.

(3) *Public Comment:* The Muncipality of Anchorage commented that information to correct the deficiencies was being developed.

(4) *EPA Action: Conditional Approval.* The action proposed by the State will correct the deficiencies.

b. *Fairbanks:* i. *Background:* The Fairbanks area consists of the major portion of the urbanized areas of Fairbanks and North Pole and Fort Wainwright military post.

The designated lead agency is the Fairbanks North Star Borough (FNSB). The FNSB worked with the Fairbanks/North Pole Metropolitan Air Quality Planning Organization and a technical advisory committee, which included representation from the City of Fairbanks, ADEC, ADOT, EPA Arctic Research Laboratory to develop the plan. Public participation was realized largely through a series of six public meetings and three public hearings prior to the June 29, 1979 submission of the SIP. A speakers bureau and a voluntary inspection and maintenance program were other means of informing the public and obtaining public input regarding the efforts underway to control CO emissions.

ii. *Emission Reduction Required:* The CO hotspot emission reduction required to achieve standards is 66 percent. At this time, an attainment date for NAAQS will fall between 1983 and 1987. It is apparent, though, that the reduction from the FMVECP will be offset in 1982 because of expected population growth. The FMVECP reduction expected for 1987 is 40 percent. Reductions attributable to alternate measures are currently being revised using the latest mobile source emission factors. In addition, there is an effort underway by EPA to determine the effectiveness of an inspection and maintenance program (I/M) as an alternative measure in cold weather climates.

iii. *Control Strategy:* In Fairbanks CO is primarily a transportation-related pollutant. CO from transportation sources contributes about 85 percent of the emissions with commercial, residential and industrial stationary sources of fuel generation contributing the remaining 15 percent.

In light of the dominant motor vehicle contribution to the CO nonattainment problem, the control strategy focuses on transportation measures. Typical

reasonably available control measures are listed in Section 108(f)(1)(A) of the Act. It should be noted that measures designed to reduce vehicle emissions operate in one of three basic ways: (a) by reducing trips and miles traveled; i.e., improved mass transit, carpooling, etc., or (b) improving traffic speeds; i.e., improved traffic signalization, traffic flow improvements, parking restrictions, etc., or (c) by reducing the emissions from individual vehicles; i.e., an inspection and maintenance program and the FMVECP.

A preliminary analysis of all reasonably available control measures resulted in the selection of the measures outlined below:

(1) Implementation of a Transportation System Management Plan[b]
(2) Implementation of a Transit Plan[b]
(3) Implementation of a Parking Management Plan[a]
(4) Plug-in Regulations[a]
(5) Provision for Plug-ins in Parking Lots[a]
(6) Carpooling Program[a]
(7) Inspection and Maintenance Program[c]
(8) Auto-start Retrofit[b]
(9) Low Temperature Automobile Standard[b]
(10) Idling Controls[a]
(11) Gasohol[b]
(12) Restricted Delivery Hours.[b]

[a]Currently implemented measure which will be expanded in scope.
[b]New measure.
[c]Voluntary measure which may become mandatory.

A comprehensive analysis was due to be completed in January 1980, but was delayed until July 1980. A preliminary package is currently being reviewed by EPA.

The remaining measures listed below were excluded due to the extremely limited reduction attributable to each due to the magnitude of the CO problem in a small urban area (60,000 population) with cold temperature climate. These measures will be reconsidered if the analysis currently in progress does not show attainment by the end of 1987.

(1) Vehicle Free Zones
(2) Land Use Controls
(3) Gasoline Tax Changes
(4) Indirect Source Review
(5) Preferential High Occupancy Vehicle Lanes
(6) Changes in Work Schedules (Flex-Time)
(7) Ski Trails and Facilities
(8) Long Range Transit Improvements

iv. *Deficiencies/Comments/EPA Action:* The TCP portion of the CO SIP for the Fairbanks area addresses all the requirements contained in Part D of the Act and in the EPA–DOT Transportation-Air Quality Guidelines Checklist except as described below. Accordingly, EPA approves the Fairbanks TCP with the following conditions:

(1) Deficiencies: (a) The emissions inventory must be updated to include area sources and emissions associated with parking and idling activities.

(b) The population growth rates used to project CO emissions for 1982 and 1987 must be included in the SIP and shown to be consistent with Bureau of Economic Affairs (BEA) population projections or other more localized projections such as those used in water quality planning under Sections 201 and 208 of the Federal Clean Water Act.

(c) Procedures for carrying out an air quality consistency analysis program in order to retain eligibility for DOT and other Federal grants for highway improvement must be included in the SIP.

(d) Provisions must be added for a cost-benefit analysis as required by Section 172(b)(11)(A) of the Act.

(2) *State Response:* The State has agreed to adopt and submit the required changes.

(3) *Public Comment:* Comment was received from the Alaska office of the FHWA in regard to their purported agreement with Fairbanks to conduct air quality consistency analyses as required under Section 176(c) of the Act. According to the commenter, there is no agreement. However, the commenter felt that since Fairbanks has no Metropolitan Planning Organization (as designated by DOT) which would perform that required function in an officially recognized capacity, the procedure to conduct the analysis should be described in the SIP. EPA agreed and conditioned the approval accordingly.

(4) *EPA Action:* Conditional Approval: The agreement by the State to include in the SIP a procedure to describe the air quality consistency analysis will satisfy the condition.

C. National Comments

One commenter submitted extensive comments which were requested to be considered part of the record for each State plan. Although most of the issues raised are not relevant to provisions in Alaska's submission, EPA has placed its response to those comments in the Regional Office docket and in the Public Information Reference Unit in Washington, D.C., in relation to this action, the commenter questioned EPA's requirement for a demonstration that application of all reasonably available control measures (RACM) would not result in attainment any faster than application of less than all RACM. In EPA's view, the statutory deadline is that date by which attainment can be achieved as expediously as practicable. If application of all RACM results in attainment more expeditiously than application of less than all RACM, the statutory deadline is the earlier date. While there is no requirement to apply more RACM than is necessary for attainment, there is a requirement to apply controls which will ensure attainment as soon as possible. Consequently, the State must select the mix of control measures that will achieve the standards most expeditiously, as well as assure reasonable further progress.

The commenter also suggested that all RACM may not be "practicable." By definition, RACM are only those measures which are reasonable. If a measure is impracticable, it would not constitute a reasonable available control measure.

IV. Additional SIP Requirements

EPA is taking final action to conditionally approve certain elements of Alaska's plan. A discussion of conditional approval and its practical effect appears in a supplement to the General Preamble, 44 FR 38583 (July 2, 1979). 44 FR 50371 (August 28, 1979), 44 FR 53716 (September 17, 1979), and 44 FR 67182 (November 23, 1979). As proposed, the conditional approval requires the State to submit additional materials within 120 days of the effective date of this action. There will be no extensions of conditional approval deadlines which are being promulgated today. EPA will follow the procedures described below when determining whether the State has satisfied the conditions.

1. If the State submits the required additional documentation according to schedule, EPA will publish a notice in the **Federal Register** announcing receipt of the material. The notice of receipt will also announce that the conditional approval is continued pending EPA's final action on the submission.

2. EPA will evaluate the State's submission to determine if the conditions are fully satisfied. After review is complete, a **Federal Register** notice will be published either approving or disapproving the State's action. If the action is disapproved, the funding limitations under Sections 176 and 316 of the Act may be imposed. Growth limitations under Section 110(a)(2)(I) will remain in effect until both stationary and mobile source portions of the plan are approved.

3. If the State fails to timely submit the required materials needed to meet a condition, EPA will publish a **Federal Register** notice shortly after the expiration of the time limit for submission. The notice will announce that the conditional approval is withdrawn, the SIP is disapproved and funding limitations under Section 176 and 316 may be imposed. Section 110(a)(2)(I) restrictions on growth will continue to be in effect.

If funding limitations are necessary, procedures for applying them would be consistent with those published in the **Federal Register** on April 10, 1980 (45 FR 24692). These procedures will not be discussed in detail here.

Section 316 of the Act also allows the Administrator of the EPA of withhold, condition or restrict grants for the construction of sewage treatment works in nonattainment areas where the State is not making reasonable further progress towards attainment of all NAAQS.

Under Executive Order 12044, EPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the Order or whether it may follow other specialized development procedures. I have reviewed this regulation and determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044.

Under Section 307(b)(1) of the Clean Air Act, judicial review of EPA's final action conditionally approving the transportation control plan portions of the Anchorage and Fairbanks CO nonattainment strategies is available *only* by the filing of a petition for review in the United States Court of Appeals for the appropriate circuit within 60 days of today. Under Section 307(b)(2) of the Clean Air Act, the requirements which are the subject of today's notice may *not* be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

(Secs. 110(a) and 172 of the Clean Air Act as amended (42 U.S.C. 7410(a) and 7502))

Dated: December 18, 1980.

Douglas M. Costle,

Administrator.

Note.—Incorporation by reference of the State Implementation Plan for the State of Alaska was approved by the Director of the Federal Register on July 1, 1980.

Part 52 of Chapter I, Title 40, Code of Federal Regulations is amended as follows.

Subpart C—Alaska

1. In § 52.70, paragraphs (c)(7) and (8) are added as follows:

§ 52.70 Identification of plan.

* * * * *

(c) * * *

(7) Revisions to the SIP including Part D nonattainment plans and modifications to Title 18 Chapter 50 Alaska Annotated Code to provide for Part C Prevention of Significant Deterioration (PSD) Section 111 New Source Performance Standards (NSPS) and Section 110(a)(2)(D) (Preconstruction Review) were submitted June 29, 1979.

(8) Revisions to the June 29, 1979 submission to further modify 18AAC 50 and to include Part D New Source Review (NSR).

2. Section 52.71 is amended by changing the hearing "photochemical oxidants (hydrocarbons)" to "ozone." Also, in the Table the listing for Cook Inlet Intrastate carbon monoxide, "III" is changed to "I."

§ 52.71 [Amended]

3. In § 52.76 paragraph (a) is removed and new paragraphs (a) and (b) are added as follows:

§ 52.76 Control strategy: Carbon monoxide.

(a) The transportation control plan portion of the Anchorage carbon monoxide attainment plan required under Part D of the Clean Air Act is approved conditioned upon receipt within 120 days of the effective date of this action of information to satisfy the following conditions:

(1) Update emission inventory to including parking and idling emissions.

(2) Show that population projections are consistent with Bureau of Economic Affairs (BEA) population projections or other more localized projections, such as those used in water quality planning under Sections 201 and 208 of the Federal Clean Water Act.

(3) Add provisions for a cost-benefit analysis required by Section 172(b)(11)(A) of the Act.

(b) The transportation control plan portion of the Fairbanks carbon monoxide attainment plan required under Part D of the Clean Air Act is approved conditioned upon the receipt within 120 days of the effective date of this action of information to satisfy the following conditions:

(1) Update the emission inventory to include parking and idling emissions.

(2) Show that population projections are consistent with Bureau of Economic Affairs (BEA) population projections or other more localized projections such as those used for water quality planning under Sections 201 and 208 of the Federal Clean Water Act.

(3) Add procedures for carrying out an air quality consistency analysis for transportation projects in the nonattainment area.

(4) Add provisions for a cost-benefit analysis required by Section 172(b)(11)(A) of the Act.

Until EPA takes final action to approve the Part D carbon monoxide attainment plan for the Anchorage and Fairbanks areas which includes the new source review procedures submitted by the State, the ban on construction of new and modified major stationary sources required by Section 110(a)(2)(I) of the Clean Air Act as amended, will remain in effect.

§ 52.71 Classification of regions [Amended]

4. Section 52.71 is amended by changing the Table for Cook Inlet Intrastate carbon monoxide form the letter "d" to "e" and by replacing the date "May 31, 1977" for the Northern Alaska Intrastate with the letter "e". The following footnote is then added; "e. December 31, 1987." Also, the heading is changed on the Table from "Photochemical Oxidants (hydrocarbons)" to "Ozone."

§ 52.81 Attainment dates for national standards [Amended]

5. In Section 52.81, paragraph (c) is added as follows:

§ 52.81 Extensions

* * * * *

(b) * * *

(c) The Administrator hereby extends the attainment date for carbon monoxide in the Anchorage and Fairbanks nonattainment areas to December 31, 1987.

[FR Doc. 80-40222 Filed 12-29-80; 8:45 am]

BILLING CODE 6560-01-M

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40 CFR Part 52

[A-3-FRL 1714-1]

Virginia State Implementation Plan; Correction

AGENCY: Environmental Protection Agency.

ACTION: Correction of final rulemaking.

SUMMARY: This Notice corrects several errors in the codification of several revisions to the Virginia State Implementation Plan. On August 19, 1980 (45 FR 55180) and October 8, 1980 (45 FR 66789 and 66792), EPA published final approval and disapproval actions regarding changes to the Virginia SIP. Since that time, we have become aware of several errors in the CFR codification.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT:
Ms. Eileen M. Glen, 3AH11, Air Programs Branch, U.S. Environmental Protection Agency, Region III, 6th & Walnut Streets, Curtis Building, 10th Floor, Philadelphia, Pennsylvania 19106, (215) 597-8187.

SUPPLEMENTARY INFORMATION:
Amendments to § 52.2420 (Identification of Plan) of 40 CFR, Subpart VV (Virginia) which appeared in the **Federal Register** on August 19, 1980, 45 FR 55180, omitted two amendments because they were inadvertently listed under 40 CFR 52.2423 (Approval Status). Because of this omission, subsequent publications on October 8, 1980 (45 FR 66789 and 66792) erroneously listed amendments under paragraphs (c) (29) thru (36) of § 52.2420. Therefore, to avoid any confusion we are now reprinting § 52.2420 (c) (27) thru (37) as it should now appear. Paragraphs (c)(1) thru (c)(26) of 40 CFR 52.2420 remain unchanged.

In addition, amendments to 40 CFR 52.2423 (Approval Status) published on August 19, 1980 at 45 FR 55180 were inadvertently listed under § 52.2423 (d) and (f) rather than under § 52.2420(c) (28) and (29).

An amendment to 40 CFR 52.2436 was also incorrect in that it was listed here as (b) rather than in 40 CFR 52.2423(e).

Because of the above errors, 40 CFR 52.2423 (Approval Status) must also be renumbered.

On August 19, 1980, an amendment to 40 CFR 52.2431 (Control Strategy: Carbon Monoxide and Ozone) was published and inadvertently listed the revision under § 52.2431 (d) rather than (e).

This Notice serves to correct all of the above errors and since it does not alter previously approved revisions, only the codification of said revisions, EPA finds that a notice and comment period are unnecessary. See 5 U.S.C. 552(b)(A)(B). Under Executive Order 12044, EPA is required to judge whether a regulation is "significant" and, therefore, subject to the procedural requirements of the Order or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized." I have reviewed this regulation and have determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044.

(42 U.S.C. 7401–7642)

Dated: December 11, 1980.

Jack J. Schramm,
Regional Administrator.

Part 52 of Title 40, Code of Federal Regulations, is corrected to read as follows:

Subpart VV—Virginia

1. In § 52.2420, the previous additions to paragraph (c) are correctly renumbered as (c) (27) through (37) and republished as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

(27) On January 11, 1979, the Governor submitted the nonattainment area plans for Virginia with respect to ozone and carbon monoxide.

(28) The following portions of Virginia's September 6, September 21, and December 17, 1979, submittals are approved:

(1) September 6, 1979, submittal: Section 2.33(g)(1)(vi) of the regulation.

(2) September 21, 1979, submittal, the following Sections of Virginia's regulations: Section 4.57(b)(2)(ii); 4.55(f)(4)(i); 4.56(e); 4.52(a); 2.03(a)(1); 2.33(f)(3); Part I of the regulations, the definitions of "Delayed Compliance Order" and "Nonattainment Area;" Sections 4.02(f)(1) through 4.02(f)(5); Appendix N; and those portions of Sections 4.54, 4.55 and 4.56 where the phrase "will be considered acceptable compliance by the Board" has been modified.

(3) December 17, 1979, submittal: Chapter 3, Control Strategy Demonstration, design value for Northern Virginia.

(29) The following portions of Virginia's August 14, 1975, August 31, 1977, and January 11, 1979, submittals as they relate to Section 2.33 are approved:

(1) August 14, 1975, submittal: Section 2.33 (b) and (i).

(2) August 31, 1977, submittal: Section 2.33(h).

(3) January 11, 1979, submittal: Section 2.33 (a), (c), (d), (e), (f), (g) and (k).

(30) Amendments of Part I (Definitions), §1.02; Part II (General Provisions). Sections 2.02 (a), (c), and (e) (former §2.11 (a), (b), and (d)), § 2.05(b), § 2.11; and Part IV (Regulations for Existing sources), §§ 4.10, 4.11, and 4.13 deletion of the following regulations from Part IV: Former §§ 4.03.02, 4.05.03, 4.05.04, 4.05.05(b), 4.10.03, 4.705.04, and 4.705.05 submitted on August 14, 1975 by the Secretary of Commerce and Resources.

(31) Amendments on Part I (Definitions), § 1.02; Part III (Ambient Air Quality Standards), § 3.02(c); Part IV (Special Provisions), § 4.02(a), (a)(1), (a)(2), (b), (c), and (d) (Formerly § 2.04) and § 4.03; and Part VII (Air Pollution Episode), §§ 7.04 (a), (b), (d), and (e) submitted on October 20, 1976 by the Secretary of Commerce and Resources.

(32) Amendments of Part II, (General Provisions), § 2.02(b) submitted on March 11, 1977, by the Secretary of Commerce and Resources.

(33) Amendments on Part II, (General Provisions), § 2.02(d) submitted on September 20, 1978, by the Secretary of Commerce and Resources.

(34) Amendments to Part II (General Provisions), § 2.06 (b) and (c); and Part VII (Air Pollution Episode), § 7.03(d); and deletion of Part IV (Existing Sources), Rule EX–7, § 4.07.05 submitted on August 14, 1975, by the Secretary of Commerce and Resources.

(35) Amendments to Part I (Definitions), § 1.02; Part II (General Provisions), § 2.06 (a) and (d); Part III (Ambient Air Quality Standards), § 3.02 (a) and (b); Part IV (Existing Sources), §§ 4.20, 4.21, 4.23 (formerly § 4.41), 4.25, 4.26, 4.27, and 4.51(a); Part VII (Air Pollution Episode), former § 4.51 (b) through (g) are changed to § 4.51 (c) through (h). Section 7.01(b) and 7.02 (a), (b), and (d); and Appendix A; and, deletion of former §§ 4.20, 4.21, and 4.22 submitted on September 20, 1978 by the Secretary of Commerce and Resources.

(36) Amendments to Part VII (Air Pollution Episode), §§ 7.03 (c) and (e) and 7.04(c); and deletion of Part II (General Provisions), § 2.04(a)(2) as submitted on March 11, 1977 by the Secretary of Commerce and Resources.

(37) Amendments to Part I (Definitions), § 1.02; Part IV (Existing Sources), Rule EX–2, § 4.22; and Part VII (Air Pollution Episode), § 7.03 (a) and (b) as submitted on September 21, 1979 by the Secretary of Commerce and Resources.

2. Section 52.2423 is corrected by revising paragraphs (c) through (f) to read as follows:

§ 52.2423 Approval status.

* * * * *

(c) With the exceptions set forth in this subpart, the Administrator approves Virginia's plan for the attainment and maintenance of national standards under Section 110 of the Clean Air Act. Furthermore, the Administrator finds that the plan satisfies all requirements of Part D, Title I, of the Clean Air Act as amended in 1977, except as noted below in § 52.2431. In addition, continued satisfaction of the requirements of Part D for the ozone portion of the SIP depends on the adoption and submittal, by each subsequent January following January 1980, of additional RACT

requirements for sources covered by CTGs issued by the previous January.

(d) The portion of the January 11, 1979 SIP submittal pertaining to Smyth County is not approved, pending a possible redesignation of the area to attainment status.

(e) The requirements of § 51.22 are not met with respect to § 4.55(b) of the Virginia regulations, because the regulation is not adequately enforceable. Therefore, § 4.55(b) is disapproved.

(f) Section 4.02(a)(3) of Part IV of the Virginia Regulations for the Control and Abatement of Air Pollution is not considered part of the Applicable plan because it contradicts a previously approved section of the SIP.

3. Section 52.2431 is corrected by adding paragraph (e) to read as set forth below. At 45 FR 55196, August 19, 1980, this addition was erroneously codified as (d).

§ 52.2431 Control strategy: Carbon monoxide and ozone.

* * * * *

(e) The nonattainment plan for Carbon Monoxide and Ozone is approved provided that the following conditions are satisfied:

(1) *Margin for Growth.* A system for tracking emissions growth must be submitted.

(2) RACT as expeditiously as practicable. The following regulations contain RACT deficiencies that must be remedied:

(i) The emission limitation on automobile and light duty truck coating in § 4.55(e)(2).

(ii) The exemption from Stage I vapor controls for gasoline service stations with a throughput of less than 20,000 gallons per month, contained in § 4.56(d)(3)(ii) (for Richmond only).

(iii) The general exemption for sources of VOC emissions contained in § 4.54(a)(4)(i), as it applies to § 4.54(c) dealing with Solvent Metal Cleaning (For Richmond and Northern Virginia only).

(iv) The regulations covering cutback asphalt paving in § 4.57(b) must be remedied to correct two deficiencies: first, the maximum allowable solvent content of emulsified asphalt of 15% is not RACT; second, allowing the use of cutback asphalt as a tack coat is not allowed under RACT.

(3) *Inspection and Maintenance (I/M).* Adequate I/M legislation must be submitted. The SIP must include, as a minimum, a schedule for implementation of the I/M program and a clear commitment to implement and enforce the program and to reduce emissions by 25% by 1987. Specifically, the SIP should include a commitment to require retesting of vehicles initially failing the annual emissions test, along with a commitment to prohibit registration or provide some equally effective mechanism to prevent vehicles not complying with applicable emission requirements from operating on public roads.

(4) *Enforceability.* (i) Acceptable test methods and procedures for determining compliance with §§ 4.54, 4.55, 4.56 and 4.57 must be submitted.

(ii) An acceptable definition of "reasonable further progress" must be submitted.

(5) *Conformity and requirement.* Commitments must be adopted by each lead agency and Metropolitan Planning Organization (MPO) in the Northern Virginia, Richmond, Peninsula, and Southeastern Virginia areas that no project, program, or plan will be approved that does not conform with the SIP. These commitments must be adpoted by the designated lead agencies and MPOs, be endorsed by the State, and be submitted to EPA.

(6) *Carbon monoxide.* A "hot spot" analysis for Carbon Monoxide, as well as a line of reasonable further progress, must be submitted for the Carbon Monoxide nonattainment areas.

[FR Doc. 80-40343 Filed 12-24-80; 8:45 am]
BILLING CODE 6560-38-M

DEPARTMENT OF LABOR

Office of Federal Contract Compliance Programs

41 CFR Part 60-4

Construction Contractors, Affirmative Action Requirements

AGENCY: Office of Federal Contract Compliance Programs, Labor.

ACTION: Effective date of reporting requirements stayed and goals for female utilization extended.

SUMMARY: Final regulations were published in the **Federal Register** of October 3, 1980 (45 FR 65976), clarifying the requirement in 41 CFR 60-4.1 that a non-exempt construction contractor's total construction workforce is covered under 41 CFR Part 60-4 even though some of the contractor's employees perform work on non-Federal or nonfederally assisted construction contracts or subcontracts, and even though such nonfederally related work may occur in geographical areas where the contractor does not currently have work on Federal or federally assisted construction projects. While those regulations took effect on November 3, 1980 (45 FR 65976), increased reporting requirements (beyond those required prior to November 3, 1980) are stayed pending clearance by the Office of Management and Budget (OMB) under the Federal Reports Act and until further **Federal Register** notice.

In addition, pursuant to 41 CFR Part 60-4.6, the goal for female utilization by Federal and federally assisted construction contractors, which is now 6.9%, is extended until further notice.

EFFECTIVE DATE: Both the stay of the reporting requirements and the extension of the goals for female utilization is effective December 30, 1980 and until further notice.

FOR FURTHER INFORMATION CONTACT: James Cisco, Acting Director, Division of Program Policy, Office of Federal Contract Compliance Programs, room C-3324, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Telephone (202) 523-9426.

SUPPLEMENTARY INFORMATION:

(1) Reporting Requirements

On October 3, 1980, the Office of Federal Contract Compliance Programs (OFCCP) published in the **Federal Register** a final rule clarifying the requirement in 41 CFR Part 60-4.1 that a non-exempt construction contractor's total construction workforce is covered under 41 CFR Part 60-4 even though some of the contractor's employees perform work on non-Federal or nonfederally assisted construction contracts or subcontracts, and even though such nonfederally related job work may occur in geographical areas where the contractor does not currently have work on Federal or federally assisted construction projects (45 FR 65976). Published on the same date was a final Notice pursuant to 41 CFR Part 60-4.6 establishing goals under Executive Order 11246, as amended, for minorities working on construction projects located in certain areas (45 FR 65979). Both the final rule and the minority goals are scheduled to become effective on November 3, 1980 (45 FR 65976, 65984).

It has come to the attention of the OFCCP that the final rule (45 FR 65976) and new minority goals (45 FR 65979) may involve the imposition of new reporting requirements which are subject to clearance by the Office of Management and Budget (OMB) pursuant to its authority under the Federal Reports Act.

Specifically, contractors will be required to submit Monthly Employment Utilization Reports (Form CC-257) showing minority utilization (a) on Federal and nonfederal construction work performed in geographic areas

which have heretofore not been subject to minority utilization goals, and (b) on nonfederal construction work performed in geographic areas which have heretofore been subject to minority utilization goals but in which the contractor performs no Federal or federally assisted construction work. Under existing OFCCP practice, construction contractors have generally been submitting Forms CC–257 showing minority utilization only for construction work performed in geographic areas in which they hold Federal or federally assisted construction contracts and in which there has been a minority goal applicable.

In addition, contractors will be required to submit Forms CC–257 showing female utilization on construction work performed in geographic areas in which the contractor performs no Federal or federally assisted construction work. Since the female utilization goals took effect in May 1978, it has been OFCCP's intent that such reporting occur. However, OFCCP's experience has shown that there is confusion in this area. Therefore, for present purposes, OFCCP will treat this as a potential new reporting requirement.

Accordingly, the potential increased reporting burdens, as outlined above, are stayed pending clearance by OMB and further notice to be published in the **Federal Register.** However, all other requirements published on October 3, 1980 (i.e., the applicability of 41 CFR Part 60–4 to a nonexempt construction contractor's total workforce, and goals for minorities working on construction projects in certain areas) shall, as scheduled, take effect on November 3, 1980.

(2) Goals for Women

OFCCP regulations at 41 CFR 60–4.6 provide, *inter alia,* as follows:

> The director, from time to time, shall issue goals and timetables for minority and female utilization * * * which shall cover construction projects, or construction contracts performed in specific geographical areas. The goals * * * shall be published as notices in the **Federal Register** * * *.

Goals for the utilization of women by Federal and federally assisted construction contractors were last published on April 7, 1978 (43 FR 14888, 14900). The April 7, 1978, publication included a 6.9% goal for the period from April 1, 1980, until March 31, 1981. Pursuant to 41 CFR 60–4.6, the 6.9% goal for female utilization is extended until further notice.

Date: December 19, 1980.

Ray Marshall,

Secretary of Labor.

Donald Elisburg,

Assistant Secretary, Employment Standards Administration.

Weldon J. Rougeau,

Director, Office of Federal Contract Compliance Programs.

[FR Doc. 80–40219 Filed 12–29–80; 8:45 am]

BILLING CODE 4510–27–M

GENERAL SERVICES ADMINISTRATION

Transportation and Public Utilities Services

41 CFR Part 101–40

[FPMR Amendment G–49]

Transportation and Traffic Management Policies and Procedures

AGENCY: Transportation and Public Utilities Service, General Services Administration.

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is changing its policies and procedures in the area of transportation and traffic management. This rule establishes traffic management regulations pertaining to shipments of household goods and personal effects and defines disqualification measures which may be imposed upon carriers which fail to meet the transportation needs and requirements of executive agencies. Further, in exercise of its mandate as traffic manager of executive agencies, GSA prescribes parameters by which agencies are required to obtain rate and/or routing information from specified GSA regional Transportation and Travel Management Divisions. Part 101–40 is amended to achieve a more efficient traffic management program in meeting the transportation needs and requirements of executive agencies.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: Joseph M. Napoli, Traffic Programs Branch, Transportation and Public Utilities Service, General Services Administration (TTMP), Washington, DC 20406 (202–275–0654).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 15, 1979 (44 FR 59247), GSA proposed to amend Part 101–40 by revising existing policies and procedures relative to transportation and traffic management and by adding new procedures providing for temporary exclusion of carriers participating in passenger or freight transportation for the account of Federal executive agencies.

GSA received comments on the proposal from 18 sources—12 Federal agencies (Department of Agriculture, Department of Energy, Department of Health and Human Services, Department of Housing and Urban Development, Department of Justice, Department of Transportation, Department of the Treasury, Environmental Protection Agency, Federal Emergency Management Agency, National Aeronautics and Space Administration, U.S. General Accounting Office, and Veterans Administration); 3 carrier associations (Association of American Railroads; American Trucking Associations, Inc.; and Air Transport Association of America); 2 railroad companies (Boston and Maine Corporation, and St. Louis-San Francisco Railway Company); and 1 motor carrier (American Freight System, Inc.).

The following is a summary of the major comments received and the response GSA has made in addressing them:

1. Five agencies suggested that exemption from the requirements of § 101–40.301(a) be given for exigencies arising from national disasters, national defense, critical aerospace activity, firefighting emergencies, and isolated areas involved in shipping or receiving household goods.

GSA finds these exigencies appropriate for relief, and exceptions have been stated in this rule.

2. Carriers, in general, took issue with the routing factor "most fuel efficient carrier or mode." These opinions seemed weighted by the subjective interest of the particular carrier or mode. The energy crisis obligates GSA to weight fuel efficiency in proper balance with service, cost and socioeconomic factors. Reliance is placed upon the traffic manager to become sufficiently knowledgeable of a carrier's operating practices and thus enable the manager to identify the most fuel efficient carrier or mode.

3. The carrier industry requested clarification of the conditions which would justify the use of Government-owned equipment.

In deleting the phrase "and when their use will result in substantial economies," GSA accentuates the use of commercial carriers except in cases when suitable common carriage does not exist to meet the Government's service needs or where the use of Government-owned equipment provides the most economical and efficient complement to commercial carriage.

4. The Department of Agriculture suggested that GSA develop courses in managerial aspects of transportation in addition to operational-type training.

GSA will give this suggestion future consideration.

5. In establishing criteria for temporary nonuse, disqualification and suspension of carriers, GSA affected appropriate revisions affording carriers due process.

The addition of Subpart 101–40.2 supersedes FPMR Temporary Regulation A–12, dated January 26, 1978 (43 FR 5436, February 8, 1978) and its Supplement 2 (44 FR 37929, June 29, 1979), which are deleted and removed from the appendix at the end of Subchapter G in 41 CFR Chapter 101. The temporary regulation established procedures for a centralized household goods traffic management program by which GSA provides executive agencies with carrier selections and routings for domestic moves based on cost comparisons.

Sections 101–40.4906–1, 101–40.4906–2, 101–40.4906–3, 101–40.4906–4, are revised to illustrate the current editions of GSA Form 420 (Rev. 9–76), Optional Form 280 (3–80), Standard Form 361 (Rev. 11–79) and the Guidelines for Preparation of Standard Form 361, respectively. Sections 101–40.4906–8 and 101–40.4906–9 are added to illustrate GSA Form 2485 (Rev. 8–80) and GSA Form 3080 (Rev. 8–80), respectively.

The General Services Administration has determined that this regulation will not impose unnecessary burdens on the economy or an individuals and, therefore, is not significant for the purposes of Executive Order 12044.

Accordingly, Part 101–40 is amended as follows:

1. The table of contents for Part 101–40 is amended by revising, adding, reserving, or deleting the following entries:

PART 101–40—TRANSPORTATION AND TRAFFIC MANAGEMENT

Subpart 101–40.1—General Provisions

Sec.

Subpart 101–40.2—Centralized Household Goods Traffic Management

Subpart 101–40.3—Rates, Routes, and Services

Subpart 101–40.4—Temporary Nonuse, Disqualification and Suspension of Carriers

Subparts 101–40.5—101–40.6—[Reserved]

Subpart 101–40.49 Forms, Formats, and Agreements

2. Section 101–40.000 is revised to read as follows:

§ 101–40.000 Scope of part.

This part prescribes regulations that apply to the freight and passenger transportation and traffic management activities of executive agencies except the Department of Defense. It also covers arrangements for transportation and related services by bill of lading type commitments. These regulations are designed to ensure that all transportation and traffic management activities will be carried out on the basis most advantageous to the Government in terms of economy, efficiency, and service.

3. Subpart 101–40.1 is revised to read as follows:

Subpart 101–40.1—General Provisions

§ 101–40.101 Transporation Assistance.

§ 101–40.101–1 Freight and passenger transportation management assistance.

(a) Executive agencies of the United States shall request assistance from the Department of State on shipments of household goods moving to, from and between foreign countries. The administrative support provided by the Department of State will include carrier cost comparison, carrier selections and quality control assistance.

(b) Executive agencies of the United States without transportation officers or those in need of assistance concerning freight (except shipments of household goods moving to, from and between foreign countries) and passenger transportation management matters shall request assistance from the Transportation and Public Utilities Service (TPUS), General Services Administration, Regional offices having jurisdiction over shipments originating in the following areas:

Region 1, General Services Administration (1TT), J. W. McCormack, P.O. and Court House (Room 820), Boston, MA 02019, FTS 223–2735; COML 617–223–2735; Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.

Region 2, General Services Administration (2TT), 26 Federal Plaza, New York, NY

10007, FTS 264–1286, COML 212–264–1286; New Jersey, New York, Puerto Rico, Virgin Islands.

Region 3, General Services Administration (3TT), 9th & Market Streets, Philadelphia, PA 19107, FTS 597–1247, COML 215–597–1247, Delaware, Maryland (except Prince Georges and Montgomery counties), Pennsylvania, Virginia (except Prince William, Loudoun, Fairfax, and Arlington counties).

Region 4, General Services Administration (4TT), 75 Spring Street, SW., Atlanta, GA 30303, FTS 242–5121, COML 404–221–5121; Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee.

Region 5, General Services Administration (5TT), 230 S. Dearborn Street, Chicago, IL 60604, FTS 353–0818, COML 312–353–0818; Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin.

Region 6, General Services Administration (6TT), 1500 E. Bannister Road, Kansas City, MO 64131, FTS 258–3841, COML 816–258–3841; Iowa, Kansas, Missouri, Nebraska.

Region 7, General Services Administration (7TT), 819 Taylor Street, Fort Worth, TX 76102, FTS 334–2733, COML 817–334–2733; Arkansas, Louisiana, New Mexico, Oklahoma, Texas.

Region 8, General Services Administration (8TT), Building 41, Denver Federal Center, Denver, CO 80225, FTS 234–2626, COML 303–234–2626; Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming.

Region 9, General Services Administration (9TT), 525 Market Street (MS 42), San Francisco, CA 94105, FTS 556–3271, COML 415–556–3271; Arizona, California, Hawaii, Nevada.

Region 10, General Services Administration (10TT), GSA Center, Auburn, WA 98002, FTS 396–5411, COML 206–833–6500; Alaska, Idaho, Oregon, Washington.

National Capital Region, General Services Administration (WTT), 7th and D Streets SW., Washington, DC 20407, FTS 472–2003, COML 202–472–2003; Washington, DC, Maryland, (Prince Georges and Montgomery counties), Virginia (Prince William, Loudoun, Fairfax, and Arlington counties).

§ 101–40.101–2 GSA Transportation and traffic management liaison.

GSA will maintain a continuing transportation and traffic management liaison program with the executive agencies to assist in the establishment, improvement, and maintenance of effective freight and passenger transportation and traffic management policies, practices, and procedures to meet executive agency program requirements.

§ 101–40.102 Representation before regulatory bodies.

GSA, in behalf of executive agencies, will, as it considers appropriate, institute formal or informal action before Federal or State regulatory bodies with respect to carriers' tariffs, rates, and operating authority matters. (See also § 101–40.305–1.) Agencies shall submit their requests and recommendations for these actions to the appropriate GSA office specified in § 101–40.101–1.

§ 101–40.103 Selection of carriers.

§ 101–40.103–1 Domestic transportation.

Preferential treatment, normally, shall not be accorded to any commercial mode of transportation (motor, rail, air, or water) or to any particular commercial carrier when arranging for domestic transportation services. However, where for valid reasons, a particular mode of transportation or a particular carrier within that mode must be used to meet specific program requirements and/or limitations, only that mode or carrier shall be considered. Examples of valid reasons for considering only a particular mode or carrier are (a) where only a certain mode of transportation or individual carrier is able to provide the needed service or is able to meet the required delivery date; and (b) where the consignee's installation and related facilities preclude or are not conducive to service by all modes of transportation. (See also § 101.40.303–1.)

§ 101–40.103–2 International transportation.

(See § 1–1.323 of this title and 4 CFR 52.2 for a certificate required for nonuse of U.S.-flag vessels or U.S.-flag certificated air carriers.)

(a) *U.S.-flag ocean carriers.* Arrangements for international ocean transportation services shall be made in accordance with the provisions of section 901(b) of the Merchant Marine Act of 1936, as amended (46 U.S.C. 1241 (b)), concerning the use of privately owned U.S.-flag vessels. (See also § 5A–19.108 of this title for implementing policies and procedures followed by the General Services Administration.)

(b) *U.S.-flag certificated air carriers.* Arrangements for international air transportation services shall be made in accordance with the provisions of section 5 of the International Air Transportation Fair Competitive Practices Act of 1974, dated January 3, 1975 (49 U.S.C. 1517), which requires the use of U.S.-flag certificated air carriers for international travel of persons or property to the extent that service by these carriers is available.

§ 101–40.104 Insurance against transportation hazards.

The policy of the Government with respect to insurance of its property while in the possession of commercial carriers is set forth in § 1–19.107 of this title.

§ 101–40.105 Use of Government-owned transportation equipment.

Generally, the preferred method of transporting property for the Government is through use of the facilities and services of commercial carriers. However, under certain circumstances, Government vehicles may be used when they are available. They may be used for such purposes as local transfer of property, pickup or delivery services which are not performed by the commercial carriers in connection with the line-haul transportation, transportation of property to meet emergencies, and accomplishment of program objectives which cannot be attained through use of commercial carriers.

§ 101–40.106 Reports.

Each executive agency shall submit reports concerning its transportation procedures, practices, and operations to the Transportation and Public Utilities Service, General Services Administration (TT), Washington, DC 20406, whenever so requested or as prescribed in the individual sections of this subpart or as provided in each specific request.

§ 101–40.107 Surveys.

As necessary and after adequate advance notice to the agencies affected, or upon request of agencies, GSA will make onsite surveys of transportation activities and will make recommendations, when necessary, for changes in agencies' policies, standards, practices, and procedures to improve transportation concepts and operations at all levels.

§ 101–40.108 Transportation seminars and workshops.

GSA will, from time to time, conduct transportation seminars and workshops for the benefit of executive agency personnel assigned functions relating to the movement of persons or materials. The objective of this training is to broaden traffic management knowledge and experience within the agency and to economy of operations. Agencies desiring assistance should direct their request to the Assistant Commissioner, Office of Transportation and Travel Management (TT), Transportation and Public Utilities Service, General Services Administration, Washington, DC 20406.

§ 101–40.109 Availability of transportation-related contracts and agreements.

§ 101–40.109–1 Miscellaneous transportation-related contracts and agreements.

(a) The Transportation and Public Utilities Service, General Services Administration, will, as considered necessary, enter into agreements or contracts for transportation and related services, including but not limited to stevedoring, passenger charters, storage, drayage, packing, marking, ocean freight forwarding, accessorial services, demurrage, and weighing. (See § 101–41.304–2 for the use of commercial forms and procedures instead of Government bills of lading.) These contracts and agreements will be made for and in behalf of all executive agencies.

(b) The availability of these contracts and agreements will be announced through GSA bulletins which will outline the specific contractual services and the terms of the agreements. After distribution of these bulletins, GSA will furnish copies of the contracts and agreements to agencies upon request.

§ 101–40.109–2 Office relocation contracts.

(a) In accordance with the provisions of Part 101–17, Assignment and Utilization of Space, prior approval is required from the Public Buildings Service, GSA, for agencies desiring to relocate office space which has been assigned by GSA.

(b) The Transportation and Public Utilities Service, GSA, offices specified in § 101–40.101–1 will enter into term contracts for office relocations, estimated to cost $5,000 or less, in cities where it is determined that these contracts are warranted. On single office moves exceeding $5,000, GSA will arrange to contract for the required moving services under competitive bidding procedures. The availability of term contracts for office relocations will be announced through GSA bulletins as indicated in § 101–40.109(b).

(c) In cities where term contracts are not available and where an executive agency anticipates an office relocation estimated to cost $1,500 or more, GSA will enter into, in behalf of the agency, a specific relocation contract or other appropriate relocation arrangement. As soon as possible before the move, preferably 90 calendar days, the appropriate GSA office specified in § 101–40.101–1 shall be contacted and furnished with pertinent information concerning the proposed relocation, such as the origin, destination, moving date, property to be moved, and the agency relocation coordinator.

Note.—Arrangements for office relocations expected to cost less than $1,500 may be handled by the agency requiring the services.

(d) Whether an office relocation is made under a GSA term moving contract or under a specific contract entered into by GSA in behalf of an individual agency, the agency being relocated shall make operational arrangements directly with the moving contractor. These arrangements shall include: (1) Issuing the purchase order or placing the work order; (2) arranging for direct billing; (3) supervising the actual move; (4) processing loss and damage claims, if any; (5) providing certification on the contractor's invoices; and (6) processing the invoice for direct payment to the contractor. The GSA contracting office shall be notified upon completion of the relocation and is prepared to provide technical assistance as necessary.

§ 101–40.109–3 Mandatory use of transportation-related contracts and agreements.

(a) When a contract or agreement for transportation-related services, including office relocations, is awarded in response to an agency's specific request, the use of the contract or agreement is mandatory for that requesting agency.

(b) When term contracts or agreements for transportation-related services, including office relocations, are entered into and awarded by GSA for use "as required," the term contract or agreement is mandatory upon all executive agencies; however, exceptions to the mandatory use of term contracts or agreements may be granted by the appropriate GSA office cited in § 101–40.101–1.

§ 101–40.110 Assistance to economically disadvantaged transportation businesses.

§ 101–40.110–1 Small business enterprises.

Consistent with the policies of the Government with respect to small business as set forth in Subpart 1–1.7 of this title, executive agencies shall place with small business concerns a fair proportion of the total purchases and contracts for intrastate and interstate transportation and related services, such as packing and crating, loading and unloading, and local drayage.

§ 101–40.110–2 Minority business enterprises.

Consistent with the policies of the Government stated in Subpart 1–1.13 of this title, minority business enterprises shall have the maximum practicable opportunity to participate in the performance of Government purchases and contracts. Agencies shall encourage transportation-related minority enterprises regardless of the mode of transportation to identify themselves and provide services that will support the agencies' transportation requirements. The GSA offices cited in § 101–40.101–1 may be contacted for assistance, if needed.

§ 101–40.111 Maintenance of tariff files.

(a) The Transportation and Public Utilities Services, National Capital Region, General Services Administration (WTT), Washington, DC 20407, shall maintain a master file of carrier tariffs covering all modes and methods of transportation commonly used by executive agencies. Each of the 10 other Transportation and Public Utilities Service, GSA, regional offices will maintain a tariff file sufficient to meet the normal requirements of the executive agencies located within the area of responsibility of the GSA regional office.

(b) Executive agencies may maintain only those tariffs necessary to meet their routine operational requirements. Agencies may use GSA tariff files to meet unusual or abnormal transportation needs; or, alternatively, may request GSA to furnish rates, freight or passenger routings, or other tariff information. (See § 101–40.301 for use of GSA-furnished rates and routes.)

§ 101–40.112 Transportation factors in the location of Government facilities.

(a) Transportation rates, charges, and commercial carrier transportation services shall be considered and evaluated before selecting new site locations and during the planning and construction phases in the establishment of leased or relocated Government installations or facilities.

(b) If changes in the location, relocation or deactivation of Government installations or facilities are contemplated and will result in significant changes in the movement of property, executive agencies shall use the traffic management services of GSA to ensure that consideration is given to the various transportation factors that may be involved in this relocation or deactivation.

§ 101–40.113 Employee travel and relocation allowances.

The General Services Administration has the responsibility to prescribe and promulgate regulations governing employee travel and relocation allowances. These allowances are published in the Federal Travel Regulations and the Commuted Rate Schedule for Transportation of

Household Goods. These regulations are incorporated by reference into Part 101–7. Amendments are made to these regulations from time to time as conditions warrant. Suggestions or questions concerning regulations governing employee travel and relocation allowances may be addressed to the Director, Federal Travel Management Division, Transportation and Public Utilities Service, General Services Administration (TTT), Washington, DC 20406.

4. Subpart 101–40.2 is added to read as follows:

Subpart 101–40.2—Centralized Household Goods Traffic Management

§ 101–40.200 Scope of subpart.

This subpart prescribes regulations concerning the movement of household goods and personal effects of Government employees (and their families) who are eligible for relocation in connection with their employment. Under the centralized household goods traffic management program, GSA will provide agencies with cost comparisons, the names of carriers eligible to handle specific shipments, and requested administrative support related to the Government employees' household goods movements.

§ 101–40.201 Applicability.

(a) This subpart applies to executive agencies. In addition to the Department of Defense, uniformed personnel of the U.S. Coast Guard are exempt from this subpart.

(b) Cost comparisons between the commuted rate system and the actual expense method, as required in § 101–40.203–4, apply only to movements within the conterminous United States.

§ 101–40.202 The General Services Administration Household Goods Tender of Service (TOS) agreement.

As part of the centralized household goods traffic management program, GSA has developed a master household goods tender of service (TOS) agreement. This agreement establishes carrier service and performance standards which participating carriers agree to provide. Commercial carriers who desire to participate in this program must enter into an individual TOS agreement with GSA, acting in behalf of executive agencies. Carriers that desire to enter into a TOS agreement or agencies desiring additional information should contact the Office of the Assistant Commissioner for Transportation and Travel Management, General Services Administration (TTMS), Washington, DC 20406.

§ 101–40.203 Household goods movement evaluation procedures.

§ 101–40.203–1 Household goods rate tenders.

GSA will accept or reject household goods carriers' rate tenders (see § 101–40.306) on behalf of executive agencies.

(a) *Interstate shipments.* Household goods carriers' TOS agreements and individual carrier rate tenders covering interstate shipments shall be submitted to the Office of the Assistant Commissioner for Transportation and Travel Management, General Services Administration (TTMS), Washington, DC 20406.

(b) *Intrastate shipments.* Household goods carriers' TOS agreements and individual carrier rate tenders covering intrastate shipments shall be submitted to the appropriate GSA office specified in § 101–40.101–1 which has responsibility over the State specified in the rate tender.

§ 101–40.203–2 The actual expense method.

(a) For the purpose of the centralized household goods traffic management program described in this Subpart 101–40.2, authorized shipments of Government employees' household goods moving under a Government bill of lading (GBL) are classified as "actual expense method" shipments. Under this method the appropriate GSA office specified in § 101–40.101–1 that processes the shipment (1) furnishes the cost comparison (see § 101–40.230–4), (2) specifies the name(s) of carrier(s) eligible to handle the shipment, and (3) will assist in an advisory capacity in filing loss and damage claims, if requested. Under this method, the Government, not the employee, is considered as the shipper, and the Government reimburses the carrier for the applicable transportation charges. The actual cost of transportation, including related accessorial carrier services, falling within the employee's authorized weight allowance (11,000 pounds for employees with immediate families; 7,500 pounds for employees without immediate families) shall be allowed at the Government's expense. Under the actual expense method, the shipment is made using a GBL. Agencies are responsible for preparing the GBL, booking the shipment and filing loss and damage claims.

(b) When an agency makes the final determination that the actual expense method will be used, the Government's financial obligation for the shipment of the employee's household goods is established. Once the actual expense method is authorized as the most economical means of shipment and the employee chooses to move all or part of the household goods by some other means, reimbursement will be limited to the cost that would have been incurred by the Government if the shipment had been made in one lot from one origin to one destination by the available low cost carrier on a Government bill of lading.

(c) When an employee chooses, for personal reasons, to use a higher cost carrier than the carrier selected by the Government, excess costs will be paid by the Government directly to the carrier and then collected from the employee. Agencies are cautioned to counsel employees as to their responsibilities under this alternative.

(d) When an employee chooses to use a rental truck, trailer or private conveyance, reimbursement will be limited to the actual costs incurred (e.g., truck rental, material handling equipment, packaging materials, gasoline, toll charges, etc.) not to exceed the maximum amount authorized in paragraph (b) above.

§ 101–40.203–3 The commuted rate schedule.

The commuted rate schedule is published in GSA Bulletin FPMR A–2 and contains allowances for reimbursement of Government employees who are authorized to transport their household goods at Government expense. In addition to transportation allowances, the commuted rate schedule includes allowances for various related accessorial expenses, including packing and crating, storage-in-transit, carrier labor charges, appliance servicing, and piano/organ handling. Under the commuted rate schedule the employee is responsible for making all arrangements with the carrier; filing loss and damage claims, if any, with the carrier; and making payment to the carrier after the shipment has been completed. Under the commuted rate schedule, the shipment is moved using a commercial bill of lading (CBL). The use of household goods rate tenders (see § 101–40.203–1) is not authorized when household goods are shipped under the commuted rate schedule.

§ 101–40.203–4 Cost comparisons.

(a) As stated in paragraph 2–8.3c(4)(a) of the Federal Travel Regulations (FPMR Part 101–7), the commuted rate system shall be used for individual employee transfers without consideration being given to the actual expense method, except that the actual expense method may be used if the actual costs to be incurred by the Government for packing

and other accessorial services are predetermined (at least as to price per 100 pounds) and if that method is expected to result in a real savings to the Government of $100 or more. Under the centralized household goods traffic management program, agencies shall obtain cost comparisons from the appropriate GSA, TPUS, office specified in § 101–40.101–1.

(b) Requests for cost comparisons shall be made as far in advance of the moving date as possible (preferably 30 calendar days) and shall contain the following information:

(1) Name of employee to be moved;

(2) Origin city, county, and State;

(3) Destination city, county, and State;

(4) Anticipated or actual date household goods are to be picked up;

(5) Estimated weight of shipments;

(6) Number of days storage-in-transit is required (if applicable); and

(7) Other pertinent data.

(c) Agencies should use GSA Form 2485, Cost Comparison for Shipping Household Goods (Commuted Rate System vs. Actual Expense Methods) for this purpose. (See § 101–40.4906–8.) In case of an emergency or an imminent moving date (less than 10 workdays), these details may be transmitted to GSA by phone. If information is received by phone, the response will be made by phone when requested. Regardless, all cost comparisons and carrier selection information will be confirmed in writing by GSA. Agencies will make the final determination as to the method of shipment (actual expense method or commuted rate system), based on the results of the cost comparison furnished by GSA.

§ 101–40.204 Carrier selection and distribution of shipments.

Results of the cost comparison will be furnished to the requesting agency together with the names and points of contract for at least three qualified carriers eligible to handle the shipment. If the rates of these carriers differ, the carrier offering the lowest rate should be used by the requesting agency. Carriers offering higher rates or charges should be used only if the less costly carrier cannot accept the shipment.

§ 101–40.205 Quality control.

(a) When the GSA, TPUS, Office specified in § 101–40.101–1 furnishes a cost comparison indicating that the actual expense method is less costly, a GSA Form 3080, Household Goods Shipment Report (See § 101–4906–9) shall be provided together with GSA Form 2485 to the requesting agency. GSA Form 3080 is a mailable form that contains a self-addressed portion, which shall be completed by the moving employee. The agency's employee should be instructed to complete the GSA Form 3080, indicating the quality of performance of the household goods carrier upon completion of the household goods move, and to mail it to the GSA office which provided the cost comparison. Information compiled from completed reports will be used by GSA to monitor carrier performance and to determine whether suspension or disqualification actions should be considered as provided in § 101–40.208.

(b) Agencies may submit other documented instances of inadequate carrier service or performance to GSA, TPUS, offices specified in § 101–40.101–1. Sufficient details must be furnished to identify specific shipments.

§ 101–40.206 Household goods carriers' liability.

(a) Ordinarily, it is the policy of the Government to assume its own risks of loss. (See also § 1–19.107 of this title.) This policy also applies to personal property during transportation. Therefore, when a Government employee's household goods are shipped under the commuted rate system using a CBL or under the actual expense method using a GBL, they are based on a limited carrier liability of 60 cents per pound per article.

(b) In the event of loss or damage, the employee's recovery from the carrier is restricted to this limited carrier liability. Carriers have tariff provisions that provide increased liability at a valuation of $1.25 times the weight of the shipment in pounds or a higher lump sum according to the employee's value of the shipment. These higher valuations are generally available at 50 cents per $100 of valuation. However, the added cost for the increased carrier liability is not reimbursable by the Government but must be borne by the employee. Under the actual expense method, if the employee requests a higher valuation and agrees in writing, the excess cost will be paid by the Government and then collected from the employee. This information applies to interstate shipments. Carrier liability and increased valuation charges may differ on intrastate shipments. For these shipments, the appropriate GSA office should be contacted.

§ 101–40.207 Household goods loss and damage claims.

Claims for loss or damage to household goods will normally be filed and processed with the destination or delivering carrier as part of the bill of lading contract between the carrier and the shipper. When shipments are made under the commuted rate system using a CBL, the employee, as the shipper, is responsible for filing claims. When shipments are made under the actual expense method using a GBL, the issuing agency, as the shipper, will assist the employee in filing claims. Under the Military and Civilian Employees' Claims Act of 1964, as amended (31 U.S.C. 241), employees may file claims against the United States for not more than $15,000 for damage to or loss of personal property incident to the employee's service; this applies to commuted rate moves as well as actual expense moves. If the carrier's liability stated in § 101–40.206 is less than the loss or damage sustained by the employee, executive agencies may use the provisions of this act to more fully compensate the employee. Agencies should advise their employees regarding the use of this act for reimbursement of loss and damage to household goods shipments using a CBL or GBL. Additional information concerning processing loss and damage claims may be obtained from the appropriate GSA, TPUS, office specified in § 101–40.101–1.

§ 101–40.208 Disqualification or suspension of household goods carriers.

Based on information obtained from completed GSA Forms 3080 or documented instances of other service complaints or deficiencies, GSA, TPUS offices or executive agencies may disqualify or suspend household goods carriers in accordance with the procedures specified in § 101–40.4.

5. Subpart 101–40.3, with a new caption, is revised to read as follows:

Subpart 101–40.3—Rates, Routes, and Services

§ 101–40.300 Scope of subpart.

This subpart prescribes regulations governing the determination and use of rates and related data in the transportation of persons and property for the Government; selection of the mode of transportation and the carrier or carriers within the mode; and negotiations of classification ratings, rates, and services.

§ 101–40.301 GSA rate and routing services.

(a) Except as otherwise provided in this subpart, executive agencies shall obtain rate and/or routing information from the appropriate GSA transportation office specified in § 101–40.101–1 when they have a planned group of 25 or more individuals traveling at one time from the same origin to the same destination or when they have freight shipments that fall within the following categories:

Shipment category	Shipment weight
Surface shipments (other than uncrated used household goods) (See 101-40.305-3(a) for exemption).	10,000 pounds and over or shipments that occupy the full visible capacity (see note) of a railcar or intercity motor vehicle regardless of weight.
Air shipments	1,000 pounds and over.
Uncrated used household goods shipments.	All shipments, regardless of weight (except will not apply on shipments moving in foreign commerce). (See Subpart 101-40.2 for shipments moving within the conterminous U.S.)

Note.—Full visible capacity generally means that quantity of freight which in the manner loaded so fills a vehicle that no additional article in the shipping form tendered identical in size to the largest article in the shipment can be loaded in or on the vehicle. Consult governing tariffs for precise definition and application.

(1) Exemption to the provisions of § 101–40.301(a) is granted to the Federal Emergency Management Agency (FEMA), Department of Energy (DOE), National Aeronautics and Space Administration (NASA) and United States Department of Agriculture (USDA) to the following extent:

FEMA Initial positioning of mobile homes shipped in response to disasters.
DOE Priority energy and classified defense and nuclear waste management shipments.
NASA Shipments of key, critical items necessary to the success of space and aerospace research, development, acquisition, flight or launch activities.
USDA Emergency shipments of forest fire fighting materials and equipment. Household goods shipments to and from isolated areas.

(2) To meet other transportation exigencies of a critical and recurring nature, executive agencies including those agencies exempted to the extent noted in paragraph (1) of this section may request the GSA transportation office having jurisdiction (See § 101–40.101–1) to grant relief from the routing requirements of this section. In a local emergency, which precludes the requesting of routing instructions in accordance with the requirements of this section, routing by any mode may be made without prior approval. Requests for exemption shall be in writing, and the GSA transportation office will accept or deny the request by written instructions to the requesting agency. Exemptions will apply for a duration of time not to exceed one year, however, on written request an exemption may be renewed or extended.

(b) Agencies shall submit requests for rate and route information to the appropriate regional office, Transportation and Public Utilities Service, General Services Administration, listed in § 101–40.101–1. Agencies may telephone urgent requests to GSA. Replies will be made by telephone and confirmed upon request by the use of GSA Form 420 or GSA 2485, as appropriate.

(1) On shipments that are rated or routed by GSA, agencies will furnish the necessary details concerning the shipment as far in advance of the proposed shipping date as possible. For freight shipments, GSA Form 420, Freight Rate and Route Request/Response (see § 101–40.4906–1) may be used for this purpose. The procedures in Subpart 101–40.2 shall be followed when requesting household goods rate and route information on shipments moving within the conterminous United States.

(2) To eliminate the need for repetitive routing instructions, the GSA transportation offices listed in § 101–40.101–1 may issue standing route orders to cover normal repetitive movements (two or more shipments per month) of specifiec items between specified points by any mode of transportation. Ordinarily, a standing route order will be issued when the origin, destination, commodity(ies) and frequency of shipments constitute a repetitive traffic pattern. The GSA transportation office will maintain a standing route order file and review routings at 60 day intervals from the date of their issuance to assure current application of rates, ratings, routes and classification. When required by changed conditions, GSA shall provide the requesting agency with revised routing instructions.

(c) Agencies are encouraged, but not required, to request GSA-furnished rate or routing information for their freight shipments that are less than the shipment weights specified in paragraph (a) of this section.

(d) Executive agency shippers will comply with all state and local, as well as Federal, laws and regulations relating to vehicular size and weight limitations.

§ 101–40.302 Standard routing principle.

Shipments shall be routed using the mode of transportation, or individual carrier or carriers within the mode, that can provide the required service at the lowest overall delivered cost to the Government.

§ 101–40.303 Application of the standard routing principle.

In the application of the standard routing principle, the major factors to be considered are, in the order of their importance, satisfactory carrier service, overall cost considerations, most fuel efficient carrier/mode, and equitable distribution of traffic among carriers.

§ 101–40.303–1 Service requirements.

The following factors shall be considered in determining whether a carrier or mode of transportation can meet an agency's transportation service requirements for each individual shipment:

(a) Availability and suitability of carrier equipment;

(b) Shipping and receiving facilities at origin and destination;

(c) Pickup and/or delivery service (including inside pickup or delivery), if required;

(d) Availability of required accessorial and special services, if needed;

(e) Estimated time in transit;

(f) Record of past performance of the carrier; and

(g) Transit privileges when available.

§ 101–40.303–2 Cost considerations.

When developing cost comparisons to determine the most economical routing of shipments consistent with service requirements, consideration shall be given to costs of packing, loading and unloading, bracing, blocking, extra handling, drayage, pickup and delivery, and other accessorial services, as well as the line-haul rate.

§ 101–40.303–3 Most fuel efficient carrier/mode.

When more than one mode, or more than one carrier within a mode, can satisfy the service requirements of a specific shipment at the same lowest aggregate delivered cost, the carrier/mode determined to be the most fuel efficient shall be selected. In determining the most fuel efficient carrier/mode, consideration shall be given to such factors as use of the carrier's equipment in "turn around" service, proximity of carrier equipment to the shipping activity, and ability of carriers to provide the most direct service to the destination points.

§ 101–40.303–4 Equitable distribution of traffic among carriers.

When more than one mode of transportation, or more than one carrier within a mode, can provide equally satisfactory service at the same overall cost and all modes are equally fuel efficient, the traffic shall be distributed as equally as practicable among the modes and among the carriers within the modes.

§ 101–40.304 Description of property for shipment.

(a) Each shipment shall be described on the bill of lading or other shipping document as specified by the governing freight classification, carrier's tariff, or rate tender. Shipments shall be described as specifically as possible. Trade names such as "Foamite" or "Formica" or general terms such as "vehicles," "furniture," or "Government

supplies," shall not be used as bill of lading descriptions.

(b) A shipment containing hazardous materials, such as explosives, flammable liquids, flammable solids, oxidizers, or poison A or poison B, shall be prepared for shipment and described on bills of lading or other shipping documents in accordance with the Department of Transportation Hazardous Materials Regulations, 49 CFR Parts 170 thru 177.

(c) Agency requests for specific freight descriptions shall be submitted to the appropriate Transportation and Public Utilities Service office as listed in § 101–40.101–1.

§ 101-40.305 Transportation negotiations.

§ 101-40.305-1 Negotiations by GSA.

Except as provided in § 101–40.305–3, GSA will conduct all transportation negotiations for executive agencies to establish or modify rates, fares, charges, ratings, services, and the rules or regulations pertaining thereto.

§ 101-40.305-2 Cost analysis required on substantial movements.

Except as provided in § 101–40.305–3, executive agencies shall submit to the appropriate GSA regional Transportation and Public Utilities Service office, as listed in § 101–40.101–1, complete information concerning planned transportation so that a cost analysis may be made to determine whether negotiation is appropriate. This information should be submitted as far in advance of the planned transportation as possible. The information supplied shall be detailed and shall include but not be limited to the number of individuals traveling as a group, property characteristics (those requiring shipment in bags, boxes or bulk; hazardous properties; weight; dimension; density; value; and susceptibility to damage), origin, destination, number of shipments, weight per shipment, planned shipping schedule, and planned required delivery date. The provisions of this subsection shall apply to all transportation payable by the Government.

§ 101-40.305-3 Negotiations by other executive agencies.

Except for the transportation of an employee's personal household goods and the relocation of offices, the executive agencies are authorized to initiate and conduct negotiations on their own behalf under the following conditions:

(a) When the total planned quantity of property to be shipped does not exceed 100,000 pounds per shipment or when the known aggregate of several shipments will not exceed 100,000 pounds.

Note.—Agencies making surface shipments under agency-negotiated rates are exempt from obtaining GSA rate and routing information as required in § 101–40.101–1.(1).

(b) Except as otherwise provided in the Federal Property Management Regulations A–15, or as it may be amended, when planned group travel, under Standard Form 1169, U.S. Government Transportation Request, consists of fewer than 25 individuals traveling at one time from the same origin to the same destination.

(c) When the planned shipment is less than that which would require the assessment of carload or truckload rates.

(d) When approval to negotiate is granted by the General Services Administration (TT), Washington, DC 20406, or the appropriate GSA regional Transportation and Public Utilities office.

Note.—§ 101–40.305–3 does not prohibit executive agencies from seeking GSA assistance in negotiations.

§ 101-40.306 Rate tenders to the Government.

Under the provisions of section 10721 (formerly section 22) of the Interstate Commerce Act (49 U.S.C. 10721), common carriers are permitted to submit tenders to the Government which contain rates lower than published tariff rates available to the general public. In addition, rate tenders may be applied to shipments other than those made by the Government provided the total benefits accrue to the Government; that is, provided the Government pays the charges or directly and completely reimburses the party that initially bears the freight charges (Interpretation of Government Rate Tariff for Eastern Central Motor Carriers Association, Inc., 332 I.C.C. 161 (1968)).

§ 101-40.306-1 Recommended rate tender format.

(a) Only those rate tenders which have been submitted by the carriers in writing and which apply to shipments of the U.S. Government shall be considered for use by executive agencies. Carriers should be encouraged to use Optional Form 280, Uniform Tender of Rates and/or Charges for Transportation Services, illustrated in § 101–40.4906–2, when preparing and submitting rate tenders to the Government. Rate tenders that are ambiguous in meaning shall be resolved in favor of the Government; therefore, explicit terms and conditions are necessary to preclude misunderstandings by the parties to the rate tender.

(b) Carriers may purchase Optional Form 280 from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or print it commercially. When ordering this form from the Superintendent of Documents, specify national stock number 7540–01–092–8057. When printing this form commercially, carriers shall ensure that the form conforms to the same size, wording, and arrangement of the approved optional form and, while no minimum grade or paper is set, carriers shall provide a reasonable grade of paper stock.

§ 101-40.306-2 Required shipping documents and annotations.

(a) To qualify for transportation under section 10721 rates, property must be shipped by or for the Government on:

(1) Government bills of lading;

(2) Commercial bills of lading endorsed to show that these bills of lading are to be converted to Government bills of lading after delivery to the consignee; or

(3) Commercial bills of lading showing that the Government is either the consignor or the consignee and endorsed with the following statement: "Transportation hereunder is for the (name the specific agency, such as the General Services Administration) and the actual total transportation charges paid to the carrier(s) by the consignor or consignee are assignable to, and are to be reimbursed by, the Government."

(b) When a rate tender is used for transportation furnished under a cost-reimbursable contract, the following endorsement shall be used on covering commercial bills of lading:

"Transportation hereunder is for the (name the specific agency, such as the General Services Administration), and the actual total transportation charges paid to the carrier(s) by the consignor or consignee are to be reimbursed by the Government, pursuant to cost reimbursable contract number ( ). This may be confirmed by contacting the agency representative at (name and telephone number)." (See 332 ICC 161.)

(c) To ensure proper application of a Government rate tender on all shipments qualifying for their use, the issuing officer shall show on the bills of lading covering these shipments the applicable rate tender number and carrier identification, such as, "ABC Transportation Company, Tender ICC No. 374." In addition, if commercial bills of lading are used, they shall be endorsed as specified in paragraphs (a) or (b) of this section, as necessary.

§ 101-40.306-3 Distribution.

Each agency receiving rate tenders shall promptly submit one signed copy

to the Transportation and Public Utilities Service, General Services Administration WTT, Washington, DC 20407. Also, two copies (including at least one signed copy) shall be promptly submitted to the General Services Administration (TAD), Chester A. Arthur Building, Washington, DC 20406.

§ 101-40.306-4 Bill of lading endorsements.

To ensure application of Government rate tenders to all shipments qualifying for their use, bills of lading covering the shipments shall be endorsed with the applicable tender or quotation number and carrier identification; e.g., "Section 10721 quotation ABC Transportation Company I.C.C. No. 143." In addition, where commercial bills of lading are used rather than Government bills of lading, the commercial bills of lading shall be endorsed in conformance with the provisions set forth in § 101–40.306–2(a). (For specific regulations covering transportation generated under cost-reimbursement type contracts, see § 1–19.109 of this title.)

6. Subpart 101–40.4 is added to read as follows:

Subpart 101-40.4—Temporary Nonuse, Disqualification, and Suspension of Carriers

§ 101-40.400 Scope of subpart.

This subpart prescribes policies and procedures governing the temporary nonuse, disqualification, and suspension of carriers transporting freight, household goods, or passengers for the account of executive agencies.

§ 101-40.401 General.

Temporary nonuse, disqualification, and suspension are measures taken to exclude carriers from participating in GSA routed or unrouted movements of persons or freight under tariffs, tenders of service, commercial or Government bills of lading, and similar arrangements. To ensure that the Government derives the benefits of full and free competition of interested carriers, temporary nonuse, disqualification, and suspension shall not apply for any period of time longer than necessary to protect the interests of the Government.

§ 101-40.402 Temporary nonuse of carriers.

GSA, TPUS regional offices or other executive agencies may place carriers that serve the agency in a temporary nonuse status for a maximum period of 30 calendar days when the carriers do not show a willingness or ability to meet the transportation service requirements of the agency. (Consecutive 30 calendar day nonuse periods shall require advance approval of the Director, Transportation Management Division, TPUS, General Services Administration (TTM), Washington, DC 20406, *and shall not be used to avoid the procedures and requirements of § 101–40.403 or § 101–40.404.*) No component of an executive agency shall apply temporary nonuse actions against a carrier for a violation made by that same carrier in serving a different component of the same or another agency. Compliance with applicable laws and regulations that preclude arbitrary or capricious actions, among other things, rests upon the agency placing a carrier in this status.

§ 101-40.402-1 Agency responsibility.

(a) Agencies placing a particular carrier in a temporary nonuse status shall fully document that action with specific instances of carrier nonperformance, which may include but are not limited to the causes and conditions set forth in § 101–40.403–1. The documentation shall also include information showing that the carrier was provided with prior notices of service deficiencies and was afforded a reasonable opportunity to correct or explain these deficiencies.

(b) The carrier shall, by certified mail, with return receipt requested, be notified by the agency concerning the proposed 30 calendar day temporary nonuse status. This notice shall include:

(1) The proposed period of nonuse;

(2) The reasons for placing the carrier in a temporary nonuse status;

(3) The corrective actions that may be taken by the carrier for reinstatement;

(4) The time period of 7 calendar days afforded the carrier to present information refuting the proposed temporary nonuse status (information from the carrier must be *received* by the agency within 7 calendar days from the date notice is received by the carrier. If the carrier presents information within the allotted time, the agency must determine within 7 calendar days of receiving the carrier's data whether to place the carrier in temporary nonuse status).

(5) The date on which temporary nonuse status commences in the event that information from the carrier is not received by the agency within the 7 calendar day period provided in paragraph (4) of this section.

(c) The agency shall review the carrier's reply, and shall prepare a response according to the facts presented. The agency's decision is administratively final.

(d) Copies of the notification to the carrier of the proposed temporary nonuse status and supporting documentation shall be forwarded immediately to: Director, Transportation Management Division, Transportation and Public Utilities Service, General Services Administration (TTM), Washington, DC 20406.

(e) The agency shall also furnish the Director, Transportation Management Division, Transportation and Public Utilities Service, General Services Administration (TTM), Washington, DC 20406, a recommendation for disqualification or suspension, if considered necessary. If further action is warranted, appropriate measures in accordance with the provisions of this Subpart 101–40.4 will be initiated.

§ 101-40.403 Administrative disqualification of a carrier.

GSA may, in the public interest, disqualify a carrier from participation in traffic for any of the causes and under any of the conditions set forth in § 101–40.403–1.

§ 101-40.403-1 Causes and conditions for disqualification.

The causes and conditions for which a carrier may be disqualified by GSA are set forth in paragraphs (a) through (h) of this § 101–40.403–1.

(a) Willful violations of the terms of the tariffs, tenders of service, commercial or Government bills of lading, or similar arrangements determining the relationship of the parties.

(b) A record of failure to perform or of unsatisfactory performance in accordance with the terms of tariffs, tenders of service, commercial or Government bills of lading, or similar arrangements determining the relationship of the parties. Failure to perform or unsatisfactory performance includes but is not limited to the following:

(1) Failure to meet requested packing/pickup dates;

(2) Deliveries exceeding time-in-transit standards when established by the Government; e.g., the General Services Administration household goods tender of service and transit times established for shipments from Federal Supply Service distribution facilities;

(3) Failure to meet required delivery dates on Government or commercial bills of lading;

(4) Failure to furnish and use clean and safe equipment;

(5) Violation of Department of Transportation (DOT) hazardous materials regulations;

(6) Mishandling of freight; e.g., damaged or missing transportation seals or improper loading, blocking, packing, or bracing;

(7) Excessive loss or damage;
(8) Improper routing;
(9) Failure to pay just debts so as to subject Government shipments to possible frustration, unlawful seizure, or detention;
(10) Failure to maintain insurance coverage;
(11) Expiration of carrier exemption, permit, or authority;
(12) Failure to settle claims in accordance with applicable Government regulations; and
(13) Repeated failure to comply with the regulations of DOT, the Interstate Commerce Commission, or State and local governments; or repeated failure to comply with any other applicable Government regulations.

(c) A conviction for commission of a criminal offense as an incident to obtaining or attempting to obtain a public or private contract, or subcontract, thereunder, or as an incident to performing the contract or subcontract;

(d) A conviction under the Organized Crime Control Act of 1970 or a conviction of embezzlement, theft, forgery, bribery, falsification or destruction of records, receiving stolen property, or any other offense indicating a lack of business integrity or business honesty which seriously and directly affects the question of present responsibility as a carrier of Government property.

(e) A conviction under the Federal antitrust statutes arising out of the submission of bids or proposals.

(f) Inclusion in a list issued by the Comptroller General (as provided in part 5, section 56(b) of the regulations issued by the Secretary of Labor under the authority of Reorganization Plan 14 of 1950) as found by the Secretary of Labor to be in aggravated or willful violation of the prevailing wage or overtime pay provisions of applicable regulations or statutes;

(g) A finding by the Director, Office of Federal Contract Compliance, Department of Labor, of noncompliance with the provisions of the Equal Employment Opportunity Clause; and

(h) Any other cause or condition of a serious or compelling nature affecting the present responsibility as a carrier of Government property.

§ 101-40.403-2 Disqualification procedures.

(a) *Disqualification for periods of 90 calendar days or less*—(1) *Determining official.* A determination to disqualify a carrier for 90 calendar days or less will be made by the following GSA offical: Director, Transportation Management Division, Office of Transportation and Travel Management, Transportation and Public Utilities Service, General Services Administration (TTM), Washington, DC 20406. Notwithstanding the provisions of § 101-40.403-2, the Director, if he determines such action to be in the best interest of the United States, may deny awards of Government traffic to a carrier during the period commencing with the notice of proposed disqualification and continuing during the pending disqualification determination. In such event, the carrier shall be advised of the action and the basis therefor.

(2) *Notice of proposed disqualification.* GSA will, by certified mail, with return receipt requested, forward to the carrier and, if appropriate, to the carrier's known affiliates, a notice of proposed disqualification which will state:

(i) That disqualification is being considered;

(ii) The reasons that disqualification is being considered;

(iii) The proposed period of disqualification;

(iv) The time period of 10 calendar days afforded the carrier to present information refuting the proposed disqualification (information from the carrier must be *received* by GSA within 10 calendar days from the date the carrier receives the notice. The carrier may within that 10 calendar day period request the Director, Transportation Management Division (TTM), to grant an additional 5 days for presenting refuting information).

(3) *Carrier presentation of information.* The carrier may present information refuting the proposed disqualification in writing, in person, or through representation, to the Director, Transportation Management Division.

(4) *Disqualification determination.* (i) If within the time limit specified in paragraph (a)(2)(iv) of this section GSA receives the carrier's data refuting the proposed disqualification, GSA's determination to disqualify the carrier must be made within 20 calendar days after receipt of those data.

(ii) If, within the time period specified in paragraph (a)(2)(iv) of this section, the carrier neither refutes the notice of proposed disqualification nor requests additional time to present refuting information, GSA shall disqualify the carrier for the period specified in the notice of proposed disqualification.

(5) *Carrier notification of disqualification determination.* When a carrier's refuting information is duly filed and received, GSA will notify the carrier by certified mail, with return receipt requested, whether the disqualification will apply. If the disqualification applies, the notice will specify the reasons for the disqualification as well as the period during which disqualification will be in effect.

(6) *Period of disqualification.* A period of disqualification for 90 calendar days or less shall begin on the first day following the date on which the carrier is notified of the determination to disqualify. If the carrier neither refutes the notice of proposed disqualification nor requests additional time to present refuting information as provided in paragraph (b)(2)(iv) of this section, the period of disqualification will commence on the first day following the expiration of the appeal period.

(7) *Request for review of determination.* A carrier may request that a review of a determination to disqualify for 90 calendar days or less be made by the Assistant Commissioner for Transportation and Travel Management, Transportation and Public Utilities Service, GSA. The request for review shall be forwarded to the General Services Administration (TT), Washington, DC 20406, within 10 calendar days after receipt of the disqualification notice. The Assistant Commissioner will issue a determination within 10 calendar days after receipt of the carrier's request. The carrier will be notified of this determination by certified mail with return receipt requested. The determination of the Assistant Commissioner shall be administratively final.

(b) *Disqualification for periods of more that 90 calendar days*—(1) *Determining official.* A determination to disqualify a carrier for more than 90 calendar days will be made by the following GSA official: Assistant Commissioner for Transportation and Travel Management, Transportation and Public Utilities Service, General Services Administration (TT), Washington, DC 20406. Nothwithstanding the provisions of § 101-40.403-2, the Assistant Commissioner, if he determines such action to be in the best interest of the United States, may deny awards of Government traffic to a carrier during the period commencing with the notice of proposed disqualification and continuing during the pending disqualification determination. In such event, the carrier shall be advised of the action and the basis therefor.

(2) *Notice of proposed disqualification.* GSA will, by certified mail, with return receipt requested, forward to the carrier and, if appropriate, to the carrier's known

affiliates, a notice of proposed disqualification which states:

(i) The disqualification is being considered;

(ii) The reasons that disqualification is being considered;

(iii) The proposed period of disqualification; and

(iv) The time period of 20 calendar days afforded the carrier to present information refuting the proposed disqualification (information from the carrier must be *received* by GSA within 20 calendar days from the date carrier receives the notice. The carrier may within that 20 calendar day period request the Assistant Commissioner for Transportation and Travel Management, to grant an additional 5 days for presenting refuting information).

(3) *Carrier presentation of information.* The carrier may present information refuting the proposed disqualification in writing, in person, or through representation, to the Assistant Commissioner.

(4) *Disqualification determination.* (i) If within the time limit specified in paragraph (b)(2)(iv) of this section, GSA receives the carrier's data refuting the proposed disqualification, GSA's determination whether to suspend the carrier will be made within 30 calendar days after receipt of those data.

(ii) If within the time limit specified in paragraph (b)(2)(iv) of this section the carrier neither refutes the notice of proposed disqualification nor requests additional time to present refuting information, GSA shall disqualify the carrier for the period of time specified in the notice of proposed disqualification.

(5) *Carrier notification of disqualification determination.* When a carrier's refuting information is duly filed and considered, GSA will notify the carrier by certified mail, with return receipt requested, whether disqualification will apply. If disqualification applies, the notice will specify the reasons for the disqualification as well as the period during which disqualification will be in effect.

(6) *Period of disqualification.* (i) A period of disqualification for more than 90 calendar days shall begin on the first day following the date on which the carrier is notified of the determination to disqualify. If the carrier neither refutes the notice of proposed disqualification nor requests additional time to present refuting information as provided in paragraph (b)(2)(iv) of this section, the period of disqualification will commence on the first day following the expiration of the appeal period.

(ii) A disqualification under this § 101–40.403–2(b) for causes other than failure to comply with the provisions of the Equal Employment Opportunity clause will be for a reasonable, specified period of time commensurate with the seriousness of the offense or the failure or inadequacy of performance. As a general rule, a period of disqualification will not exceed 3 years. If it is determined necessary to extend a period of disqualification, GSA will forward a new notice of proposed disqualification in accordance with § 101–40.403–(b)(2) on or about the expiration date of the disqualification period. Notifications of extended periods of disqualifications will be handled in the same manner as initial periods of disqualifications.

(iii) A disqualification under this § 101–40.403–2(b) for failure to comply with the provisions of the Equal Employment Opportunity clause will generally continue until removed by the Director, Office of Federal Contract Compliance, Department of Labor.

(7) *Request for review of determination.* A carrier may request that a review of a determination to disqualify for more than 90 calendar days be made by the Commissioner, Transportation and Public Utilities Service (TPUS), GSA. The request for review shall be forwarded to the General Services Administration (T), Washinton, DC 20406, within 10 calendar days after receipt of the disqualification notice. The Commissioner will issue a determination within 30 calendar days after receipt of the carrier's request. The carrier will be notified of this determination by certified mail. The determination of the Commissioner shall be administratively final.

(8) *Application for relief from disqualification.* Except as precluded by statute, GSA may terminate or reduce the period of time of a disqualification on the basis of appropriate evidence that the causes and conditions for which the disqualification was imposed have been eliminated or corrected. A carrier may apply to the Assistant Commissioner for Transportation and Travel Management for the granting of relief from a disqualification at any time after receipt of the notice of disqualification. The application shall fully document the reasons for the requested relief, which may include but are not limited to the discovery of new material evidence, the reversal of a conviction, or the bona fide change of ownership or management. The Assistant Commissioner for Transportation and Travel Management will review the application and supporting documentation and notify the carrier of a determination by certified mail with return receipt requested.

§ 101–40.404 Suspension of carrier.

Suspension is an action that GSA may take against a carrier which is suspected, on the basis of adequate evidence, of engaging in criminal, fraudulent, or seriously improper conduct. In determining whether the evidence merits invoking a suspension, GSA will consider the creditability of the evidence available, the existence or absence of corroboration as to important allegations, and the inferences which may be drawn from the existence or absence of affirmative facts. This assessment will include an examination of basic documents, such as contracts, inspection reports, and correspondence. A suspension may be modified whenever GSA determines that it is in the best interest of the Government to do so.

§ 101–40.404–1 Causes and conditions for suspension.

GSA may, in the interest of the Government, suspend a carrier from participation in traffic for the causes and under the conditions set forth in this § 101–40.404–1:

(a) Suspicion, based upon adequate evidence, of the following:

(1) Commission of fraud or a criminal offense either as an incident to obtaining or attempting to obtain a public contract or in the performance of a public contract;

(2) Violation of the Federal antitrust statutes arising out of the submission of bids or proposals; or

(3) Commission of an act in violation of the Organized Crime Control Act of 1970 or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, receiving stolen property, or any other offense indicating a lack of business integrity or business honesty which seriously and directly affects the question of present responsibility as a carrier of Government property.

(b) Any cause of a serious and compelling nature affecting the responsibility of a carrier which, in the determination of GSA, warrants suspension. However, suspensions relating to matters involving the Equal Opportunity clause shall be handled in accordance with regulations prescribed by the Secretary of Labor.

§ 101–40.404–2 Period of suspension.

Suspension is for a temporary period pending the completion of an investigation and any subsequent legal proceedings. If prosecution has not been initiated by the Department of Justice

(DOJ) within 12 months from the issue date of a notice of suspension (see § 101–40.404–4), GSA will terminate the suspension unless DOJ requests continuance of the suspension. (GSA will notify DOJ of a proposed suspension termination 30 calendar days before expiration of the 12-month period.) If a continuation is requested, the suspension may remain in effect for an additional 6 months. However, no suspension shall continue beyond 18 months unless prosecution has been initiated within that period. If prosecution has been initiated, a suspension may continue until the legal proceedings are completed.

§ 101–40.404–3 Restrictions during period of suspension.

A suspended carrier will not be permitted to transport freight or passengers for the Government during the period of suspension, unless otherwise determined by GSA to be in the best interest of the Government.

§ 101–40.404–4 Notice of suspension.

A carrier that has been suspended by GSA will, by certified mail, with return receipt requested, be furnished with a notice of suspension issued by the following GSA official: Assistant Commissioner for Transportation and Travel Management, Transportation and Public Utilities Service, General Services Administration (TT), Washington, DC 20406. The notice of suspension shall state that:

(a) The suspension is based on (1) an outstanding indictment or (2) adequate evidence that the carrier has committed irregularities which seriously reflect on the propriety of further dealings of the carrier with the Government. (The notice will identify the indictment or describe the nature of the irregularities in general terms, without disclosing the Government's evidence.);

(b) The suspension is for a temporary period pending the completion of an investigation and any subsequent legal proceedings; and

(c) The carrier will be excluded from participating in the movement of freight and passengers for the Government, unless otherwise determined by the Assistant Commissioner for Transportation and Travel Management to be in the best interest of the Government.

§ 101–40.404–5 Review of suspension.

(a) *Carrier request for review.* A carrier suspended by GSA may request that a review of the suspension action be made by the Commissioner, Transportation and Public Utilities Service (TPUS), GSA, and that the carrier be provided an opportunity to present information refuting the suspension to the Commissioner, in person, in writing, or through representation. The request for review shall be forwarded to the General Services Administration (T), Washington, DC 20406.

(b) *Coordination with other executive agencies.* Upon receipt of a request for a review, GSA will seek the advice of other interested executive agencies as set forth below.

(1) *Coordination with Department of Justice (DOJ).* In all instances, GSA will solicit the formal advice of DOJ concerning the possible impact that the release of evidence could have on possible civil or criminal action against the carrier.

(2) *Coordination with the Department of Labor (DOL).* If the suspension is based upon violations of labor standards subject to legal proceedings before administrative law judges of DOL, GSA will solicit the formal advice of DOL concerning the possible proceedings against the carrier.

(c) *Response to carrier request for review.* GSA's decision on whether to grant the requested review will be based on the advice received from DOJ or DOL as to the possible effects of the release or disclosure of Government evidence. The Commissioner, TPUS, GSA, will notify the carrier of this decision by certified mail with return receipt requested. If a review is granted, GSA will, as necessary, determine the extent of the review and the conditions under which the review will be conducted and the carrier will be so notified. If a review is denied, the carrier will be notified that the release or disclosure of evidence which would occur as the result of a review would be prejudicial to the interest of the Government but that the carrier may, nevertheless, present any information refuting the suspension action to the Commissioner, TPUS, GSA.

(d) *GSA determination and carrier notification.* GSA will determine whether to continue or terminate the suspension following a review of the suspension action and/or consideration of information presented by the carrier to refute the suspension. The Commissioner, TPUS, GSA shall notify the carrier of this determination by certified mail with return receipt requested.

7. Subparts 101–40.5 and 101–40.6 are reserved.

Subparts 101–40.5—101–40.6—[Reserved]

8. Section 101–40.49 is revised to read as follows:

Subparts 101–40.49—Forms, Formats, and Agreements

§ 101–40.4906–1 GSA Form 420, Freight Rate and Route Request/Response.

Note.—The form illustrated in § 101–40.4906–1 is filed as part of the original document and does not appear in this volume.

§ 101–40.4906–2 Optional Form 280, Uniform Tender of Rates and/or Charges for Transportation Services.

Note.—The form illustrated in § 101–40.4906–2 is filed as part of the original document and does not appear in this volume.

§ 101–40.4906–3 Standard Form 361, Discrepancy in Shipment Report.

Note.—The form illustrated in § 101–40.4906–3 is filed as part of the original document and does not appear in this volume.

§ 101–40.4906–4 Guidelines for Preparation of Standard Form 361, Discrepancy in Shipment Report (Short Title "DISREP") (Rev. 11–79)

(a) Page 1 of Guidelines for Preparation of Standard Form 361.

Section A

General

a. The November 1979 edition of Standard Form 361, Discrepancy in Shipment Report (DISREP) requires the use of codes for certain information. A stub attached to the top of the form provides instructions concerning where to locate these codes for civilian agencies and the Department of Defense. The codes furnished in this section are uniform codes for civilian agencies to use in preparing the DISREP.

b. The DISREP is a two page form, but, when used by civilian agencies, the back requires completion only when the spaces in items 12 and 13 do not provide adequate space to fully describe the discrepancies being reported. Items 19 and 20 are primarily for use by the Department of Defense.

Item Details. The following are detailed instructions of the data required in completing the DISREP:

Item Number, Title and Data Entry

1. *Date.*—Date on which report is prepared in the sequence of: year, month and day; e.g., November 6, 1979, would be entered as 79 Nov. 6.
2. *File Reference.*—Activity address code (if assigned) of reporting activity and a 4-digit number (0001–

9999) for each DISREP issued within the calendar year.

3. *To.*—Name, address, activity address code (if assigned) and ZIP code of activity which is to receive the original of the report.
4. *Reporting Activity.*—Name, address, activity code (if assigned) and ZIP code of reporting activity.
5. *Consignor.*—Name, address, activity address code (if assigned) and ZIP code of activity making or directing the shipment. When shipper is a contractor or vendor always enter name and activity address code (if assigned) of the Government office responsible for documenting or arranging for shipment.
6. *Consignee.*—Name, address, activity address code (if assigned) and ZIP code of activity scheduled to receive the shipment. If same as item 4, enter "same as item 4".
7. *Shipper (if other than consignor).*—Name, address, activity address code (if assigned) and ZIP code of the activity physically making shipment for the account of the consignor shown in item 5. When a container shipment, enter name of activity stuffing the container in item 13.
8. *Point of origin (city and state).*—Enter city and state where carrier accepted shipment.
9. *Identification (conveyance/voyage number) and carrier routing.*—Enter identification number of railcar, truck, trailer, or name of vessel, as appropriate and routing shown on covering transportation document. Enter MILVAN, SEAVAN or CONEX type code in parentheses and trailer/container number and SEAVAN carrier. Enter TCN number of SEAVAN, MILVAN or CONEX or other consolidation container, and, when known, the voyage number.
10. *Destination (city and state).*—Enter city and state of destination as shown on covering transportation document.
11. Documentation Data:
    a. *Carrier's pro/freight bill number.*—Enter number appearing on carrier's delivery receipt (waybill, pro, freight bill, lading, warrant or similar document).
    b. *Bill of lading number.*—Enter document number under appropriate heading. Enter port of exit with an ocean bill of lading number.
    c. *Exception noted on carrier's delivery receipt.*—Check "yes" or "no" as appropriate.
    d. *Type of shipment code.*—Enter alpha or numeric code as listed in section B to designate whether rail, carload; motor, truckload, etc., as appropriate.
    e. *Documents attached.*—Check applicable block(s).
    f. *Date carrier signed for shipment.*—Enter actual date carrier signed for shipment.
    g. *Date consignee received shipment.*—Enter actual date consignee received shipment.
    h. *Date discrepancy discovered.*—Enter actual date discrepancy was discovered.
    i. *Date carrier notified.*—Enter date carrier was first notified of discrepancy i.e., by phone, in person or by SF 363.
    j. *This is a survey document.*—Check "yes" or "no" as applicable (primarily used by military activities).
    k. *Seal numbers and condition.*—Check appropriate block to indicate condition of seals at delivery. Enter seal numbers. Explain when there is a variance between seal numbers shown on transportation documentation and numbers of seals on vehicles. Explanation may be continued in item 13.
    l. *Inspection date.*—Check appropriate block. Attach document(s) as required, when reporting damage, pilferage or partial loss.
    m. *Disposition date.*—Check appropriate block and attach document(s) as required.
12. Discrepancy Data (When necessary, multiple lines may be used for each requisition line item involved):
    (a) *Acquisition document and/or transportation control number.*—Enter applicable acquisition document number e.g., requisition or purchase request and/or transportation control number.
    (b) *Commodity Description and/or National Stock Number (NSN).*—Enter noun description of commodity and/or National Stock Number.
    (c) *Type of pack.*—Enter the 2 position code from section C to describe type of pack for shipment involved. (Codes applicable for CONEX, SEAVAN, MILVAN or other consolidation container will be entered in item 9 only.)
    (d) *Quantity discrepant (pieces).*—Enter actual number of pieces of freight that are discrepant as evidenced by the covering bill of lading or governing transportation document.
    (e) *Type and cause code.*—Enter the 2 position code as shown in section D that most closely identifies the cause or type of discrepancy.
    Issue Data (May be obtained from packing list or authorized shipping document accompanying the shipment i.e, GSA or DD Form 1348–1, direct delivery purchase document, etc.)
    (f) *Unit of issue.*—Enter the 2 letter abbreviation for type of unit under which material was issued.
    (g) *Units billed/shipped.*—Enter actual number of units of issue billed (invoiced) or shipped as evidenced by the applicable shipping document.
    (h) *Discrepant units.*—Enter actual number of units discrepant.
    (i) *Discrepant weight.*—Enter weight of discrepant quantity.
    (j) *Value or cost of repairs.*—Enter acutal value of loss sustained, cost of repairs and/or cost to rea?oper (materials and labor), as appropriate. Enter value of material when reporting over/astray freight.
13. *Remarks.* This item is for use in providing detailed information or other data required by items referencing this item. Information should specify facts and not personal opinions unless substantiated by documentation, e.g., affidavits or certified statements. Other discrepancies or deficiencies in transportation such as improper loading, stowing, handling, blocking, bracing, lashing, excessive transit time, improper placarding or labeling of hazardous materials, etc., should be described in this item. When the discrepancy involves classified material, enter the applicable acquisition document or transportation control number and the appropriate security classification code, e.g., "S" (secret), "C" (confidential).
14. *Responsibility.* The transportation or appropriate receiving personnel normally would make this determination based on findings and factual evidence available and check the appropriate block. If sufficient evidence to make such a determination is not available, check "other" and specify appropriate activity.
15. *Distribution of Copies.* Enter name and address of office(s) to receive copies as directed by agency regulations.
16. *Prepared by*
    a. *Typed name, title and telephone extension.* Type name, title and commercial telephone number of the person whose signature is entered in item 16b.
    b. *Signature.* Signature of person preparing this report.

17. *Discrepancy Data (continuation of item 12).* This item is a continuation of items 12a thru 12J, if required.

18. *Remarks.* (Continuation of item 13). This item is a continuation of item 13, if required.

19. *Action for Reviewing Officials.* Sections a, b, c and d under this item are for use in connection with inventory and financial adjustments of accounts in accordance with indiviudal service/agency regulations. Section e will be completed by an official authorized to approve the report for use as a survey document and/or inventory and financial adjustment of accounts or when individual agency or service regulations require approval by an official other than the individual shown in item 16A.

20. *Action by Finance Center.* For use by finance center, as required (primarily for DOD).

Section B

Code	Type of Shipment Code (Item 11d)
A	Motor, truckload
B	Motor, less than truckload
C	Van (unpacked, uncrated personal or Government property)
D	Driveaway, truckaway, towaway
E	Bus
F	Military Airlift Command (MAC)
G	Parcel post, surface
H	Parcel post, air
I	Government trucks, for shipment outside local delivery area
J	Small package carrier
K	Rail, carload*
L	Rail, less than carload*
M	Freight forwarder
N	LOGAIR (commercial air charter service—Air Force controlled)
O	Organic military air
P	Through Government bill of lading (TGBL)
Q	Air freight, air express, air charter (commercial)
R	Expedited air freight
S	Reserved
T	Air freight forwarder
U	Quicktrans (commercial air charter service—Navy controlled)
V	SEAVAN
W	Water, river, lake coastal (commercial)
X	Reserved
Y	Intratheater airlift service
Z	MSC (Military Sealift command—controlled contract or arranged space)
2	Government watercraft, barge lighter
3	RORO (roll-on, roll-off)
4	ARFCOS (Armed Forces Courier Service)
5	United Parcel Service
6	Military official mail (MOM)
7	Weapon System Pouch Service
8	Pipeline
9	Local delivery, by Government or commercial truck including deliveries between air or water terminals and adjacent activities. Within CONUS, the local delivery area is defined in tariffs governing local application of carrier service as filed with regulatory authorities.

*Includes trailer/container-on-flat-car (excluding SEAVAN).

Section C

Code	Type of Pack Code (Item 12c or 17c)
BD	Bundle
BE	Bale

Section C—Continued

Code	Type of Pack Code (Item 12c or 17c)
BG	Bag, burlap or cloth
BL	Barrel
BS	Basket
BX	Box
CA	Cabinet
CB	Carboy
CC	Household goods containers, wood, type II (Fed. Spec. PPP-B-580)
CL	Coil
CN	Can
CO	Container, other than CU, CW or X
CR	Crate
CS	Case
CT	Carton
CU	Container, Navy cargo, transporter
CW	Container, commercial highway lift (PTTC)
CY	Cylinder
DB	Dufflebag
DR	Drum
EC	Engine container
ED	Engine cradle or dolly
FK	Footlocker
HA	Hamper
KE	Keg
LS	Loose (not packaged)
MN	Multiwall container (formerly referred to as triple wall or triwall secured or attached to pallet)
MX	Mixed (more than one type of shipping container)
PC	Piece
PL	Pail
PT	Palletized unit load (other than code MW)
RL	Reel
RO	Roll
RT	Roll-on/roll-off trailer
SA	Sack, paper
SB	Skid box
SD	Skid
SH	Sheet
SL	Spool
SW	Suitcase
TB	Tub
TK	Trunk
TU	Tube
UX	Unitized (unitized cargo on roll-on/roll-off vehicles is considered roll-on/roll-off)
VE	Vehicle
VO	Vehicle in operating condition
VS	Sea-van-tote
WR	Wrapped
X	Container, CONEX (second position based on CONEX number, will be assigned as follows):
0	00000 to 99999
1	100000 to 199999
2	200000 to 299999
3	300000 to 399999
4	400000 to 499999
5	500000 to 599999
6	600000 to 699999
7	700000 to 799999
8	800000 to 899999
9	900000 to 999999

A-MSCVAN (MSC leased/controlled SEAVAN or MILVAN)
Y-MILVAN
Z-SEAVAN
(Second position identifies the loading data and loaded capacity as follows):
A Loaded to capacity by ocean carrier.
B Loaded to capacity by military terminal.
C Loaded to capacity by military shipping activity.
D Loaded to capacity by vendor/commercial supplier.
E Loaded to capacity by contract shipment consolidation facility.
F Loaded to less than capacity by military shipping activity, loading completed by contract shipment consolidation facility.
3 Loaded to less than capacity by military shipping activity.
4 Loaded to less than capacity by vendor/commercial supplier.
5 Loaded to less than capacity by contract shipment consolidation facility.
L Loaded to less than capacity by military shipping activity, loading completed by military terminal.
M Loaded to less than capacity by vendor/commerical supplier, loading completed by military terminal.
N Loaded to less than capacity by contract shipment consolidation facility, loading completed by military terminal.
T Loaded to less than capacity by military shipping activity, loading completed by ocean carrier.
U Loaded to less than capacity by vendor/commerical supplier, loading completed by ocean carrier.
V Loaded to less than capacity by contract shipment consolidation facility, loading completed by ocean carrier.
W Loaded to less than capacity by vendor/commercial supplier, loading completed by contract shipment consolidation facility.
Z Empty MILVAN or SEAVAN.

Section D

Code	Type and Cause Code (Item 12e or 17e)
	Astray
A3	Incomplete marking or missing label or tag
A4	Defaced or illegible marking
AA	Unknown
	Overage
05	Improper documentation
03	Incomplete marking or missing label or tag
04	Defaced or illegible marking
OK	Improper loading or stowing
OO	Unknown
	Shortage
SL	Leakage, spoilage, or evaporation
S5	Improper documentation
ST	Theft
SP	Pilferage
SI	Status "W" cargo (MMC terminal use only)
SK	Improper loading or stowing
SS	Unknown
	Damage
DF	Fire
DK	Improper loading, stowing, lashing, blocking and bracing
D6	Materials handling equipment
D1	Marine casualty
DG	Spoilage
DQ	Rough handling
D2	Stevedoring
DE	Water damage
DW	Wreck
DV	Vandalism
DZ	Concealed damage
DD	Unknown, visible or apparent damage
	Other
XB	Broken, missing, improper, or inadequate seals
XC	Carrier tariff or tender agreements, Government transportation regulations not observed on other than classified or protected material
XH	Excess transit time
X3	Incomplete marking or missing label or tag
X4	Defaced or illegible marking
XJ	Improper carrier handling, service or equipment
XK	Improper loading, stowing, lashing, blocking or bracing (when no actual damage is involved)
XM	Improper marking or labeling of dangerous or hazardous material
XN	Misconsignment
XR	Government transportation regulations, carrier tariff or tender agreements, not observed on classified or protected material
XX	Not specified above (describe in remarks)

9. Sections 101–40.4906–8 and 101–40.4906–9 are added to read as follows:

§ 101–40.4906–8 GSA Form 2485, Cost Comparison for Shipping Household Goods (commuted rate system versus actual expense method).

Note.—The form illustrated in § 101–40.4906–8 is filed as part of the original document and does not appear in this volume.

§ 101–40.4906–9 GSA Form 3080, Household Goods Shipment Report.

Note.—The form illustrated in § 101–40.4906–8 is filed as part of the original document and does not appear in this volume.

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c))

Dated: December 17, 1980.

R. G. Freeman III,

Administrator of General Services.

[FR Doc. 80–40330 Filed 12–29–80; 8:45 am]

BILLING CODE 6820–AN–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 33

National Wildlife Refuges in Illinois, Iowa, Minnesota and Wisconsin; Sport Fishing

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special regulations.

SUMMARY: The Director has determined that the opening to sport fishing of certain National Wildlife Refuges is compatible with the objectives for which the areas were established, will utilize a renewable natural resource, and will provide additional recreational opportunity to the public. These special regulations describe the conditions under which sport fishing will be permitted on portions of certain National Wildlife Refuges in Illinois, Iowa, Minnesota and Wisconsin.

DATES: Effective on December 30, 1980 for duration of calendar year 1981, subject to exceptions noted below for individual refuge areas.

FOR FURTHER INFORMATION CONTACT: The Area Manager or appropriate Refuge Manager at the address or telephone number listed below:

George G.P. Bekeris, Area Manager, U.S. Fish and Wildlife Service, 530 Federal Building & U.S. Court House, 316 North Robert Street, St. Paul, MN 55101.

James Heinecke, Refuge Manager, Big Stone National Wildlife Refuge, 25 N.W. 2nd Street, Ortonville, MN 56278. Telephone: (612) 839–3700.

John Toll, Refuge Manager, Horicon National Wildlife Refuge, Route #2, Mayville, WI 53050. Telephone: (414) 387–2658.

James M. Carroll, Jr., Refuge Manager, Necedah National Wildlife Refuge, Star Route, Necedah, WI 54646. Telephone: (608) 565–2551.

David Heffernan, Refuge Manager, Rice Lake National Wildlife Refuge, Route 2, McGregor, MN 55760. Telephone: (218) 768–2402.

Ronald Papike, Refuge Manager, Sherburne National Wildlife Refuge, Route #2, Zimmerman, MN 55398. Telephone: (612) 389–3323.

Omer N. Swenson, Refuge Manager, Tamarac National Wildlife Refuge, Rural Route, Rochert, MN 56578. Telephone: (218) 847–4355.

Robert Howard, Refuge Manager, Upper Mississippi Wildlife and Fish Refuge, 122 W. 2nd Street, Winona, MN 55987. Telephone: (507) 452–4232.

SUPPLEMENTARY INFORMATION: Sport fishing on portions of the following refuges shall be in accordance with all applicable State and Federal regulations, subject to additional special regulations and conditions as indicated. Portions of refuges which are open to sport fishing are designated by signs and/or delineated on maps. Special conditions applying to individual refuges and maps are available at refuge headquarters or from the Office of the Area Manager (addresses listed above).

The Refuge Recreation Act of 1962 (16 U.S.C. 460k) authorizes the Secretary of the Interior to administer such areas for public recreation as an appropriate incidental or secondary use only to the extent that it is practicable and not inconsistent with the primary objectives for which the area was established. In addition, the Refuge Recreation Act requires (1) that any recreational use permitted will not interfere with the primary purpose for which the area was established; and (2) that funds were available for the development, operation and maintenance of the permitted forms of recreation.

The recreational use authorized by these regulations will not interfere with the primary purposes for which these National Wildlife Refuges were established. This determination is based upon consideration of, among other things, the Service's Final Environmental Statement on the Operation of the National Wildlife Refuge System published in November 1976. Funds are available for the administration of the recreational activities permitted by these regulations.

§ 33.5 Special regulations; sport fishing for individual wildlife refuge areas.

Minnesota

Big Stone National Wildlife Refuge

Sport fishing on Big Stone National Wildlife Refuge is allowed between sunrise and sunset during the State fishing season. Summer fishing shall be from the shoreline only except that fishing from boats without motors is permitted on the Minnesota River channel canoe trail which is designated by signs. Winter ice fishing is permitted in accordance with the state season except that ice fishing west of the Highway 75 dam, terminates on January 31. Portable fish shelters may be used but may not be left overnight.

Rice Lake National Wildlife Refuge

Sport fishing is permitted on the Rice Lake National Wildlife Refuge, Aitkin County, Minnesota, and the Sandstone Unit, Pine County, Minnesota, only on those areas designated by signs as being open to fishing. These areas comprise approximately 80 acres. The open season for sport fishing extends from May 16, 1981 through November 30, 1981, inclusive. Fishing is allowed between sunrise and sunset only. The use of canoes and boats, without motors, is allowed for sport fishing on that portion of Rice River posted as open to fishing and on the Twin Lakes fishing area only.

Sherburne National Wildlife Refuge

Sport fishing is permitted on Sherburne National Wildlife Refuge in accordance with State seasons and regulations. Special conditions include the following: Fishing is only allowed on the St. Francis River at designated access sites during daylight hours. Boats without motors are allowed on the portion of the river as noted in the refuge brochure. A permit must be obtained from the refuge manager before using a shelter for ice fishing.

Tamarac National Wildlife Refuge

Sport fishing is permitted on the Tamarac National Wildlife Refuge in areas designated on maps or by signs as being open to fishing. Fishing shall be in accordance with all applicable State and/or White Earth Reservation regulations.

All sport fishing is subject to the following conditions:

1. Only that part of Tamarac Lake north of the dike is open during regular State season.

2. Fishing on Two Island, Wauboose, Lost, and Blackbird lakes is permitted only from the State season opening in May through Labor Day.

3. Bank fishing is permitted 50 yards either side of the Ottertail River bridges on County Roads No. 26 and No. 126 only.

Wisconsin

Horicon National Wildlife Refuge

Sport fishing is permitted on the Horicon National Wildlife Refuge, Wisconsin, only on the approximately 5 acres designated by signs as being open to fishing from May 15, 1981 through September 15, 1981, inclusive. Sport fishing shall be in accordance with all applicable State regulations subject to the following conditions:

1. The use of boats is not permitted.

2. Fishing during daylight hours only.

Necedah National Wildlife Refuge

Sport fishing is permitted on the Necedah National Wildlife Refuge, Wisconsin, only on the areas designated by signs as being open to fishing. Sport fishing shall be in accordance with all applicable State regulations subject to the following conditions:

Fishing is permitted only on the Sprague and Goose Pools, including the outlets of these pools as far south as the Sprague-Mather Road, from January 1 through March 15, 1981, and from June 1, through September 15, 1981, and from December 15, through December 31, 1981. Fishing is allowed between sunrise and sunset only. The use of boats, without motors, is permitted.

Illinois, Iowa, Minnesota, Wisconsin

Upper Mississippi River Wild Life and Fish Refuge

Sport fishing, commercial fishing, and the taking of frogs, turtles, crayfish and clams on the Upper Mississippi River Wild Life and Fish Refuge, are permitted on all water areas of the refuge. The refuge water areas comprise 125,000 acres. All fish, frogs, turtles, crayfish and clams shall be taken in accordance with all applicable state regulations and seasons. All sport and commercial fishing on the Spring Lake Closed Area of the Upper Mississippi River Wild Life and Fish Refuge in Carroll County, Illinois, is prohibited from October 1 through December 20, 1981. All persons, including their helpers, exercising the privilege of commercial fishing on the Spring Lake Closed Area must possess a valid commercial fishing permit issued by the Refuge Manager and must comply with the conditions which are set forth in the permit.

December 17, 1980.

Richard E. Toltzmann,

Acting Area Manager.

[FR Doc. 80-40489 Filed 12-29-80; 8:45 am]

BILLING CODE 4310-55-M

Proposed Rules

Federal Register
Vol. 45, No. 251
Tuesday, December 30, 1980

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 1001, 1002, 1004, 1006, 1007, 1011–1013, 1030, 1032, 1033, 1036, 1040, 1044, 1046, 1049, 1050, 1062, 1064, 1065, 1068, 1071, 1073, 1075, 1076, 1079, 1093, 1094, 1096–1099, 1102, 1104, 1106, 1108, 1120, 1124–1126, 1131–1139

Handling of Milk in Federal Milk Marketing Areas; Extension of Time for Filing Comments on Reconstituted Milk Impact Statement

7 CFR Parts and Marketing Areas

1001 New England.
1002 New York-New Jersey.
1004 Middle Atlantic.
1006 Upper Florida.
1007 Georgia.
1011 Tennessee Valley.
1012 Tampa Bay.
1013 Southeastern Florida.
1030 Chicago Regional.
1032 Southern Illinois.
1033 Ohio Valley.
1036 Eastern Ohio-Western Pennsylvania.
1040 Southern Michigan.
1044 Michigan Upper Peninsula.
1046 Louisville-Lexington-Evansville.
1049 Indiana.
1050 Central Illinois.
1062 St. Louis-Ozarks.
1064 Greater Kansas City.
1065 Nebraska-Western Iowa.
1068 Upper Midwest.
1071 Neosho Valley.
1073 Wichita, Kansas.
1075 Black Hills, S. Dakota.
1076 Eastern South Dakota.
1079 Iowa.
1093 Alabama-West Florida.[1]
1094 New Orleans-Mississippi.
1096 Greater Louisiana.
1097 Memphis, Tenn.
1098 Nashville, Tenn.
1099 Paducah, Kentucky.
1102 Fort Smith, Ark.
1104 Red River Valley.
1106 Oklahoma Metropolitan.
1108 Central Arkansas.
1120 Lubbock-Plainview, Texas.
1124 Oregon-Washington.
1125 Puget Sound, Washington.
1126 Texas.
1131 Central Arizona.
1132 Texas Panhandle.
1133 Inland Empire.
1134 Western Colorado.
1135 Southwestern Idaho-Eastern Oregon.[1]
1136 Great Basin.
1137 Eastern Colorado.
1138 Rio Grande Valley.
1139 Lake Mead.

[1] A final decision on whether or not to adopt a proposed new order for this marketing area is pending before the Department.

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Extension of time to submit additional comments or proposals.

SUMMARY: On November 7, 1980, the Department issued a preliminary impact statement concerning the potential effect of proposals to change the regulatory treatment of reconstituted milk under all Federal milk orders. Interested parties were invited to submit comments on the impact statement and also any alternative proposals that would mitigate any adverse economic impacts of the proposals. This notice extends the initial 45-day filing period, which would have expired on January 2, 1981.

DATE: Comments and proposals should be submitted by February 16, 1981, to assure their consideration in this matter.

ADDRESS: Comments and proposals (two copies) should be mailed to: Deputy Administrator, Marketing Program Operations, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Robert F. Groene, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250 (telephone: 202–447–4824).

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Pre-Notice of hearing: issued November 13, 1979; published November 16, 1979 (44 FR 65989). Extension of time: issued January 15, 1980; published January 18, 1980 (45 FR 3593). Preliminary Impact Statement: issued November 7, 1980; published November 17, 1980 (45 FR 75956).

The Community Nutrition Institute, a fluid milk processor, and three individual consumers have requested that a public hearing be held on proposed changes in all Federal milk marketing orders. The proposals relate to the regulatory treatment of reconstituted milk products.

A preliminary impact statement presenting an analysis of the potential impact of the proposals was issued by the Department on November 7, 1980. The public was invited to submit by January 2, 1981, comments on the impact statement and also any additional proposals that would mitigate any adverse economic impacts of the proposals.

The Department has received requests from the National Milk Producers Federation and other producer groups for an extension of the comment period. The producer organizations indicate that an additional 45 days is needed in view of the time that was involved in distributing copies of the impact statement to interested parties, the complex nature of the issues involved, and the time constraints stemming from the several holidays in the initial comment period.

An extension of the comment period is reasonable under these circumstances. Accordingly, notice is hereby given that the time for filing comments on the preliminary impact statement and alternative proposals is extended from January 2, 1981, to February 16, 1981.

Signed at Washington, D.C., on December 22, 1980.

William T. Manley,

Deputy Administrator, Marketing Program Operations.

[FR Doc. 80-40503 Filed 12-29-80; 8:45 am]
BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

9 CFR Part 91

Animal Export Regulations; Pseudorabies Test of Export Swine

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the animal export regulations to require that all swine to be exported from the United States, except swine for immediate slaughter, shall be handled in accordance with certain procedures and be negative to an official pseudorabies test or tests. This action is necessary to provide assurance that swine exported

from the United States, except swine exported for immediate slaughter, are not infected with or exposed to pseudorabies. The intended effect of this action is to provide assurance to the animal health authorities of other countries that swine exported from the United States, except swine exported for immediate slaughter, are not infected with or exposed to pseudorabies.

DATE: Comments on or before March 2, 1981.

ADDRESS: Written comments to Deputy Administrator, USDA, APHIS, VS, Room 821, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

FOR FURTHER INFORMATION CONTACT: Dr. Harold A. Waters, USDA, APHIS, VS, Room 826, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–8383. The Draft Impact Analysis describing the options considered in developing this proposed rule and the impact of implementing each option is available from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–8695.

SUPPLEMENTARY INFORMATION: This proposed action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been classified "significant". Notice is hereby given in accordance with the administrative procedure provisions in 5 U.S.C. 553, that pursuant to 21 U.S.C. 105, 112, 113, 114a, 120, 121, 134b, 134f, 612, 613, 614, 618; 46 U.S.C. 466a, 466b; 37 FR 28464, 28477; 38 FR 19141, the Animal and Plant Health Inspection Service is considering amending Part 91, Title 9, Code of Federal Regulations.

On Friday, February 16, 1979, there was published in the **Federal Register** (44 FR 10306–10313) regulations intended to prevent the spread of pseudorabies in the United States. Pseudorabies, also known as Aujeszky's disease, mad itch, and infectious bulbar paralysis, is primarily a disease of swine caused by a herpes virus.

Susceptible animals other than swine are not known to become carriers and are not known to transmit the disease after a period of 21 days following exposure to the disease. Therefore, animals other than swine are believed not to be potential spreaders of pseudorabies after a period of 21 days since their last exposure to the virus.

Swine are more resistent to pseudorabies than most other livestock, and some swine develop an inapparent carrier state. Such swine are capable of transmitting the disease to other animals even though these carrier swine are apparently healthy. The number and severity of outbreaks of pseudorabies have increased dramatically throughout the world during the past 3 years. This trend is expected to continue and to cause serious financial losses to swine producers and the swine industry in general. For this reason, pseudorabies in swine has become a significant factor in the United States Export Animal health Program. In order to prevent the exportation of swine (for other than slaughter purposes), which may be infected with or exposed to pseudorabies, certain testing requirements are needed. Therefore, present § 91.5(c) (Specific export requirements for swine) would be redesignated § 91.5(c)(1) and additional requirements which the Department believes would prevent the exportation of swine (except swine exported for immediate slaughter) infected with or exposed to pseudorabies would be added in proposed § 91.5(c)(2).

Specifically, proposed § 91.5(c)(2) would provide exporters with two options under which swine, other than swine for immediate slaughter, could be exported.

Proposed § 91.5(c)(2)(i) would require that swine to be exported, except swine for immediate slaughter be (A) from a qualified pseudorabies negative herd, (B) found negative to an official pseudorabies test within 30 days prior to the date of export, (C) moved directly from the qualified pseudorabies negative herd to the port of embarkation after such test, and (D) physically separated so as to prevent physical contact with other animals or effluent drainage therefrom during such movement.

In lieu of the proposed requirements in § 91.5(c)(2)(i) an exporter could export swine in accordance with proposed § 91.5(c)(2)(ii) which would require that swine to be exported, except swine to be exported for immediate slaughter, be physically separated so as to prevent physical contact with other animals or effluent drainage therefrom. Further, the proposal would require that the swine are found negative to two official pseudorabies tests at intervals of not less than 30 days nor more than 60 days between tests during such separation. The last test would be required to be conducted within 30 days prior to the date of export. After such tests, the swine would be required to be moved directly to the port of embarkation and physically separated so as to prevent physical contact with all other animals and the effluent drainage therefrom during such movement.

The Department believes that the requirements in proposed § 91.5(c)(2)(i) would provide reasonable assurance that the swine to be exported are not infected with or exposed to pseudorabies. Such swine would be from a qualified pseudorabies negative herd, as defined in Title 9, Code of Federal Regulations, § 85.1(ee). A qualified pseudorabies negative herd is monitored for pseudorabies at regular intervals and the entrance of other swine into such a herd is restricted to swine which have been found negative to two official pseudorabies tests not less than 30 days or more than 60 days apart before being added to the herd or are from another qualified pseudorabies negative herd. Therefore, herds of swine which have attained qualified pseudorabies negative herd status are far less likely to contain swine which are either exposed to or infected with pseudorabies than the remainder of the swine population.

Proposed § 91.5(c)(2)(i) would require that swine to be exported from qualified pseudorabies negative herds be moved directly from such herds to the port of embarkation and be physically separated so as to prevent physical contact with other animals and effluent drainage therefrom during such movement. This physical separation could be attained in any manner. The intention is that swine do not come into physical contact with other animals or their effluent drainage. This requirement would insure that such swine to be exported only come into physical contact with other swine from qualified pseudorabies negative herds prior to arrival at the port of embarkation.

To further insure that swine to be exported, except swine exported for immediate slaughter, are not infected with or exposed to pseudorabies, proposed § 91.5(c)(2)(i) would require that such swine be found negative to an official pseudorabies test within 30 days prior to the date of export. Such official test would be conducted prior to the swine being moved to the port of embarkation. The Department believes that the requirement that the negative finding to the official pseudorabies test be within 30 days prior to the date of export is necessary to reduce the risk of tested swine becoming infected with pseudorabies between the test and the date of export and gives an exporter a reasonable amount of time in which to have the swine tested.

As stated above, proposed § 91.5(c)(2)(ii) would provide exporters with a second method by which swine, except swine exported for immediate slaughter, could be exported. Under this provision, such swine to be exported, other than for immediate slaughter, would be required to be physically

separated from other animals and effluent drainage therefrom so that no new sources of infection with pseudorabies could be introduced into the group of swine intended for export. This physical separaton could be attained in any manner (artificial barriers, natural barriers or even distance). The intention is that such swine do not come into physical contact with other animals or the effluent drainage. During such physical separation, the group of swine to be exported would be required to be found negative to two official pseudorabies tests at intervals of not less than 30 nor more than 60 days between tests. The Department believes that the official pseudorabies tests would provide reasonable assurance that the swine so tested are neither infected with nor exposed to pseudorabies. The interval which would be required between the two tests is necessary to allow any swine exposed to pseudorabies at the time of the first test to incubate the disease long enough to become positive to the second test. Further, proposed § 91.5(c)(2)(ii) would require that the last test be conducted within 30 days prior to the date of export because the Department believes that this requirement would reduce the risk of the tested swine becoming infected with pseudorabies between the test and the date of export. Further, 30 days would give and exporter a reasonable amount of time in which to have the swine tested. To eliminate the risk of infection with or exposure to pseudorabies, proposed § 91.5(c)(2)(ii) would require that after such tests the swine be moved directly to the port of embarkation and during such movement be physically separated so as to prevent physical contact with other animals or effluent drainage therefrom.

Proposed new footnotes 7 and 8 would be referred to in proposed § 91.5(c)(2). Proposed new footnote 7 would appear directly after the term "qualified peudorabies negative herd" and would refer the reader to Title 9, Code of Federal Regulations, § 85.1(e) which contains the definition of that term. Proposed new footnote 8 would appear directly after the term "official pseudorabies test" and would refer the reader to Title 9, Code of Federal Regulations, § 85.1(q) which contains the definition of that term. Further, proposed new footnote 8 would inform the reader that copies of the test protocols (Recommended Mimimum Standards for Diagnostic Tests Employed in the Diagnosis of Pseudorabies) were published as a Veterinary Services Notice, May 17, 1978, and are available upon request from Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

The Department believes that these proposed new footnotes are necessary to clarify the terms "qualified pseudorabies negative herd" and "official pseudorabies test". The additon of proposed footnotes 7 and 8 would require that present footnote 7 and the reference thereto be renumbered footnote 9; present footnote 8 and the reference thereto be renumbered footnote 10; and present footnote 9 and the reference thereto be renumbered footnote 11.

Accordingly, Part 91, Title 9, Code of Federal Regulations, would be amended in the following respects:

1. In § 91.5, paragraph (c) would be redesignated as paragraph (c)(1) and a new paragraph (c)(2) and new footnotes 7 and 8 would be added to read:

§ 91.5 Specific export requirements.

* * * * *

(c) *Swine.* * * *

(2) Swine to be exported, except swine to be exported for immediate slaughter, shall be:

(i)(A) From a qualified pseudorabies negative herd;[7]

(B) Found negative to an official pseudorabies test [8] within 30 days prior to the date of export;

(C) Moved directly from the qualified pseudorabies negative herd to the port of embarkation after such test; and

(D) Physically separated so as to prevent physical contact with other animals or the effluent drainage therefrom during such movement; or

(ii)(A) Physically separated so as to prevent physical contact with other animals or effluent drainage therefrom;

(B) During such physical separation, found negative to two official pseudorabies tests [8] at intervals of not less than 30 days nor more than 60 days between tests during such separation. The last test shall be conducted within 30 days prior to the date of export;

(C) Moved directly to the port of embarkation after such tests; and

(D) Physically separated so as to prevent physical contact with other animals or effluent drainage therefrom during such movement.

§ 91.9 [Amended]

2. In § 91.9 present footnote 7 and the reference thereto would be redesignated footnote 9; in § 91.13 present footnote 8 and the reference thereto would by designated footnote 10; and in § 91.33 present footnote 9 and the reference thereto would be deisgnated footnote 11.

All written submissions made pursuant to this notice will be made available for public inspection at the Federal Building, 6505 Belcrest Road, Room 825, Hyattsville, Maryland, during regular hours of business (8 a.m. to 4:30 p.m., Monday to Friday, except holidays) in a manner convenient to the public business (9 CFR 1.27(b)).

Comments submitted should bear a reference to the dat and page number of this issue in the **Federal Register.**

Done at Washington, D.C., this 22nd day of December 1980.

Jerry C. Hill,

Deputy Assistant Secretary for Marketing and Transportation Services.

[FR Doc. 80-40552 Filed 12-29-80; 8:45 am]

BILLING CODE 3410-34-M

[7] A qualified pseudorabies negative herd is defined in § 85.1(ee) of this chapter.

[8] "Official pseudorabies test" is defined in § 85.1(q) of this chapter. Copies of the test protocols (Recommended Minimum Standards for Diagnostic Tests Employed in the Diagnosis of Pseudorabies) published as a Veterinary Services Notice, May 17, 1978, are available upon request from Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration (NOAA)

15 CFR Parts 923 and 931

Advance Notice of Proposed Rulemaking for Improving Coastal Management in the United States

AGENCY: National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Advance notice of proposed rulemaking (ANPR).

SUMMARY: Pub. L. No. 96-464, the Coastal Zone Management Improvement Act of 1980 (the Act), which amended the Coastal Zone Management Act of 1972 (CZMA), requires the Secretary of Commerce to issue regulations for improving the administration of the Federal coastal zone management program established by the CZMA. This notice deals with proposed rules for: (1) Focusing state management efforts on achieving significant improvements in meeting certain national coastal management objectives; (2) enhancing the protection of nationally significant coastal resources; (3) allocating among eligible states grants to administer approved state coastal management programs; (4) awarding grants to eligible states to mitigate adverse coastal impacts caused by coal and alternative

ocean energy activities; (5) awarding grants to eligible coastal states for preserving specific coastal areas, redeveloping urban waterfronts and ports, and providing access to public beaches and coastal waters; (6) reviewing and evaluating the performance of coastal states with respect to adherence to approved coastal management programs and achievement of significant improvement in meeting national coastal management objectives; and (7) awarding grants to assist eligible states in preserving islands.

NOAA will publish a separate advance notice of proposed rulemaking outlining issues relevant to clarifying the term "directly affected" in Section 307 of the CZMA.

This advance notice of proposed rulemaking is issued to provide interested persons with an early opportunity to contribute to the development of these regulations. It is designed to elicit both views on the issues posed below and identification of other issues that should be addressed. Interested persons are invited to submit detailed written comments.

DATE: Comments should be received by January 31, 1981.

ADDRESS: Submit comments concerning the advance notice to: Jane P. Rogers, Deputy Director, Office of Policy, Evaluation and External Relations, Office of Coastal Zone Management, 3300 Whitehaven Street, NW., Washington, D.C. 20235.

FOR FURTHER INFORMATION CONTACT: Jane P. Rogers, Dan Hoydysh or Vickie Allin, Office of Policy, Evaluation and External Relations, (202–634–4245).

SUPPLEMENTARY INFORMATION:

I. Authority

This advance notice of proposed rulemaking is issued under authority of Section 317 of the CZMA and Sections 5, 7 and 9 of the Act.

II. Availability of Comments

All comments submitted in response to this advance notice of proposed rulemaking will be available for examination during normal business hours in Room 310, Page Building Number 1, 2001 Wisconsin Avenue, NW., Washington, D.C. 20235.

III. Mailing List

Any person interested in receiving public regulatory documents as they are developed during this rulemaking should submit his/her name, address, affiliation, and phone number to the Deputy Director, Policy, Evaluation, and External Relations at the above address in order to be placed on the mailing list.

IV. Proposed and Final Rules

NOAA will issue proposed rules to implement the Act after comments received in response to this ANPR have been evaluated. NOAA plans to issue the proposed rules in April 1981 and final rules in July 1981.

V. Regulatory Issues

A. General Background

The CZMA was enacted in 1972 to encourage and assist states in developing and implementing management programs to preserve, protect, develop, and where possible, to restore or enhance the resources of our nation's coast. The primary purpose of the 1980 amendments is to reaffirm the nation's commitment to the wise use and management of our coastal resources through the coastal zone management program. To this end, Section 306, which provides funds to coastal states to implement approved coastal management programs, was reauthorized for five years by the Act, and certain key provisions of the CZMA were strengthened to require significant improvements in state coastal management programs.

B. Legislative Amendments and Issues to be Resolved Through Rulemaking

1. *Improving Coastal Zone Management—Sections 303/306*

The following provisions of the Act relate to improving coastal management:

—Section 303 was amended to clarify national coastal policy by describing specific national objectives that warrant full consideration during the implementation of approved State coastal management programs.

—Section 306(a) was amended to encourage more effective coastal management by requiring states with approved programs to expend an increasing proportion of administrative grants (up to a maximum of 30 percent unless a state agrees to a higher percentage) on activities that will result in significant improvement in achieving the national coastal objectives specified in Section 303.

—Section 312 was amended to require the Secretary to evaluate the extent to which a state addresses the national coastal objectives in Section 303 and to reduce or withdraw up to 30 percent of the financial assistance available to any coastal state under Section 306 if that state is failing to make "significant improvement" in achieving these objectives.

Comments are requested with respect to the following and any other relevant issues:

—What guidelines or standards should be used in determining what constitutes a "significant improvement" in achieving the coastal management objectives specified in Section 303? Against what baseline should improvements be measured?

—What types of management activities may a state perform as a means of making significant improvements?

—How long should an activity be eligible to be considered an "improvement?" One year? If longer, based on what factors?

—How should priorities be set for determining in which areas of national concern a state needs to make significant improvements?

—How should the phrase "increasing proportion of each grant" be defined? Against what baseline should the increasing proportion be measured?

—What guidelines and procedures should be followed to determine the amount of funding that will be withheld or withdrawn if the state has failed to make "significant improvements"?

2. *Protecting Resources of National Significance—Section 306(i)*

New Section 306(i) encourages states to increase protection of coastal resources of national significance by inventorying and designating such resources and developing "specific and enforceable standards" for their protection. The Secretary is directed to monitor state progress in carrying out these activities and to deny grants under section 306A to states that have not made "satisfactory progress" in accomplishing these tasks by September 30, 1984.

Comments are requested with respect to the following and any other relevant issues:

—What criteria should be provided to states to guide them in their determination of whether a resource is one of national significance?

—How should "satisfactory progress" in achieving the objectives of Section 306(i) be measured?

—When should states begin activities designed to protect nationally significant resources in order to support a finding of satisfactory progress by 1984?

—How should "specific and enforceable standards" be defined?

—To what extent have some states with approved programs already satisfied the requirements of Section 306(i) and how should this compliance be demonstrated?

3. *Allocating Administrative Grants—Section 306(b)*

Section 306(b) requires that administrative grants under Section 306 be allocated among coastal states with approved programs in accordance with rules and regulations that take into account "the extent and nature of the shoreline and area covered by the plan, population of the area, and other relevant factors."

Comments are requested with respect to the following and any other relevant issues:

—How should the shoreline, coastal area and populaton factors be weighted in the formula used to allocate administrative grants?

—What other factors are "relevant" and how much weight should they be given?

4. *Resource Management Improvement Grants—Section 306A*

New Section 306A establishes a grant program to assist states in preserving and restoring specific areas, redeveloping urban waterfronts and ports, and providing access to public coastal areas and coastal waters. Section 306A grants may be used for acquiring interests in land, low-cost construction projects, engineering designs and specifications, and educational interpretive and management costs determined by the Secretary to be consistent with the purposes of the section. No state is eligible to receive Section 306A grants unless it is making "satisfactory progress" in activities designed to result in significant improvements as discussed above.

Comments are requested with respect to the following and any other relevant issues:

—What methodology should be followed for allocating 306A grants, i.e. should grants be allocated by formula or competitively? If by formula, what factors should be included? If competitively, what criteria should be used?

—How should funds available under 306A be allocated among the three purposes of (1) preserving and restoring specific areas, (2) redeveloping urban waterfronts and ports, and (3) providing public access to coastal areas and coastal waters.

—What should be the allowable uses and costs that are eligible under section 306A.

5. *Coal and Alternative Ocean Energy Impact Grants—Section 308(c)(3)*

The Act established a new Section 308(c)(3) under the Coastal Energy Impact Program (CEIP), authorizing the Secretary to make grants to eligible coastal states for preventing or mitigating unavoidable environmental and recreational losses in the coastal zone resulting from the "transportation, transfer or storage of coal or from alternative ocean energy activities." Funds available under Section 308(c)(3) must be allocated among eligible states in accordance with "rules and regulations * * * which shall take into account the number of coal or alternative ocean energy facilities, the nature of their impacts, and other relevant factors * * *"

Comments are requested with respect to the following and any other relevant issues:

—How should "coal transportation, transfer or stroage" activities and facilities be defined? Should facilities be water dependent in order to qualify a state for impact assistance?

—How should "alternative ocean energy activities" be defined?

—How should coal and alternative ocean energy impact grants be allocated among eligible states? Should one formula be developed that includes coal and alternative ocean energy facilities? Should available funds be split between coal and alternative energy impacts and separate formulas developed? Should a competitive system be used rather than state-by-state allocations based upon a formula?

—How should eligibility of coastal states for coal and alternative ocean energy grants be determined? Should states not receiving OCS formula grants be given priority consideration?

—What should be the allowable uses of these grants? Should the same uses eligible under environmental and recreational loss grants (Selection 308(b)(5)(c)) be allowed or should uses be restricted—e.g., planning only or planning and land acquisition only?

6. *Review of Performance (Evaluation)—Section 312*

Section 312 requires a "continuing review of the performance of coastal states with respect to coastal management." This review must include a written evaluation which assesses the extent to which the state has: (1) Implemented and enforced its approved program; (2) addressed the coastal management needs identified in Section 303(2) (A)–(I); and (3) adhered to the terms of any grant, loan or cooperative agreement funded under the CZMA, as amended. The Act requires that a public meeting be conducted as part of each evaluation and that opportunity be provided for oral and written comment by the public. Evaluation reports must be issued following each review of state performance. The Secretary is directed to reduce financial assistance under the Act by up to 30 percent if it is determined that a state is not making significant improvement in achieving the coastal management objectives identified in Section 303(2)(A)–(I) and to withdraw program approval and financial assistance if it is found that a state is failing to adhere to or is unjustifiably deviating from its approved program or the terms of any grant or cooperative agreement and refuses to remedy the deviation. The statute outlines procedural safeguards (such as notice to the state and an opportunity for a public hearing) that must be observed if the Secretary finds that program approval and financial assistance should be withdrawn.

Comments are requested with respect to the following and any other relevant issues:

—Should the regulations allow use of alternative types of evaluation, such as evaluation by third parties, self-evaluations or nationwide evaluation with respect to specific national objectives? If so, what alternatives should be considered?

—What should the evaluation team review to determine whether the state has (1) implemented and enforced its approved program (2) addressed the coastal management needs identified in Section 303 (2) (A)–(I), and (3) adhered to the terms of any grant, loan, or cooperative agreement?

—Should state coastal zone management programs and coastal energy impact programs be evaluated in a separate or integrated manner? For example, should the CEIP evaluation be conducted on the same schedule as the CZM porogram evaluation? How should the CEIP be assessed with respect to consistency with CZM program goals? Should there be separate regulations for CEIP evaluations?

—What factors, criteria or standards should be developed for determining whether a state is "adhering to" its approved program, "addressing" the national coastal management needs identified in Section 303(2)(A)–(I), and "implementing and enforcing" the approved program or is "unjustifiably deviating from" the program?

—At what point in the grant cycle should evaluation site visits take place and draft and final findings be issued? Should a uniform approach be adopted, or should timing be set on a state by state basis? Should timing be established by regulation or should it be left flexible?

—What should be the guidelines for withdrawing program approval and financial assistance to any state that is unjustifiably deviating from its approved program or the terms of any grant, or cooperative agreement and refuses to remedy the deviation?

—What procedures should be established for providing oral and written comments and for holding public meetings? What procedures should be used for distributing evaluation reports?

7. *Island Preservation—Section 315*

Section 315 of the Act authorizes the Secretary to make grants for (1) acquiring, developing and operating estuarine sanctuaries, and (2) acquiring lands to provide for the preservation of islands or portions thereof. Regulations implementing the estuarine sanctuary program were issued by NOAA in 1974 (15 CFR Part 921).

Comments are requested with respent to the following and any other relevant issues.

—For what purposes should island preservation grants be made? For example, should such grants be made only for the purpose of preserving islands, or portions thereof in their natural state, should they encompass acquisition for compatible uses such as research, education, or public recreational access, should they encompass other purposes and, if so, what purposes?

—Should the procedures for administration of the island preservation program be integrated with or separate from those of the estuarine sanctuary program with respect to programmatic objectives, grant application

process, public participation, and operation and management of acquired lands?

—How should appropriations for Section 315 be allocated between island preservation and the estuarine sanctuary program?

—By what criteria should grant applications for island preservation be evaluated? Should certain types of islands, such as barrier islands, be given priority over others for awards?

VI. Availability of Funds for Public Participation

In order to promote a full and fair determination of the issues involved, OCZM is making available $5,000 to compensate persons eligible under the criteria set forth in NOAA regulations (15 CFR Part 904) for their participation in this proceeding. The closing date for the receipt of applications for compensation is March 1, 1980.

Available Fund: A total fund of $5,000 is available to compensate eligible applicants. This fund may be distributed among one or more applicants, or, at the discretion of the Administrator, not distributed at all.

Eligible Persons: In accordance with the criteria of 15 CFR 904.3, persons who represent an interest the presentation of which can reasonably be expected to contribute substantially to a fair determination of the issues described above may be eligible for compensation from these funds. In determining eligibility and the amount of compensation, the Administrator may take into account:

(a) Whether the interest will be adequately represented otherwise;

(b) The need to encourage participation by segments of the public who may have little economic incentive to participate;

(c) The importance of the representation to a fair balance of interests;

(d) The number and complexity of the issues presented;

(e) The importance of public participation; and

(f) The applicant's resources available for participation.

Eligible Costs: The Administrator may compensate eligible persons for some or all of the reasonable costs incurred in participating including:

(1) Salaries for participants or employees of participants;

(2) Fees for consultants, experts, contractual services, and attorneys;

(3) Travel and travel related costs such as lodging, meals, tipping, telephone calls, etc.; and

(4) Document reproduction, postage, etc.

Procedures for applying: Applications may be filed with the Office of General Counsel, National Oceanic and Atmospheric Administration, Department of Commerce, 14th Street & Constitution Avenue, NW., Washington, D.C. 20230, no later than March 1, 1980, and shall contain the information required by and be filed in accordance with NOAA's financial participation regulations, 15 CFR 904.4.

Dated: December 19, 1980.

Robert W. Knecht,

Acting Assistant Administrator for Coastal Zone Management.

[FR Doc. 80-40480 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-08-M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1020

Proposed Methodology for Commission Consideration of Findings Under Section 9(c) of the Consumer Product Safety Act

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes a regulation setting forth its general methodology for Commission consideration of the various findings under section 9(c) of the Consumer Product Safety Act. These findings are required for the issuance or material amendment of consumer product safety standards or bans. To the extent section 9(c) requires the Commission to evaluate the effect of a rule in terms of reduced risks and increased costs, this document contains the Commission policy on risk assessment and economic considerations, including benefit and cost issues, relevant to issuance of consumer product safety standards or bans.

DATES: (1) Written comments concerning the proposed rule must be received by March 2, 1981. Comments or other relevant information received after this date will be considered only to the extent practicable.

(2) There will be an opportunity for interested persons to orally present data, views, or arguments on Tuesday, February 3, 1981, at 9:30 a.m. Those wishing to make oral presentations should notify the Office of the Secretary by Tuesday, January 27, 1981. Additionally, a summary or copy of testimony is to be submitted to the Office of the Secretary two working days prior to the public meeting.

(3) The Commission proposes that this rule become effective 30 days after publication of the final rule in the **Federal Register.**

ADDRESS: Written comments, preferably in five copies, should be sent to: Office of the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207. Comments received may be seen in the Office of the Secretary, Third floor, 1111 18th St., NW., Washington, D.C. during working hours (8:30 a.m.–5:00 p.m.) Monday through Friday. Persons wishing to make oral presentations should contact Richard Danca in the Office of the Secretary. These oral presentations will be held in the Commission's 3rd floor hearing room at the address above.

FOR FURTHER INFORMATION CONTACT: Carole Roth, Office of the General Counsel, Consumer Product Safety Commission, Washington, D.C. 20207 (202–634–7770). Persons wishing to make oral presentations should contact: Richard Danca, Office of the Secretary (202–634–7700).

SUPPLEMENTARY INFORMATION: In this document the Commission proposes a regulation setting forth its general methodology for Commission consideration of the various findings under section 9(c) (15 U.S.C. 2058(c)) of the Consumer Product Safety Act (CPSA). The seven separate findings of section 9(c)(1) and 9(c)(2) are required to be made by the Commission prior to promulgating a consumer product safety rule under the Act or a material amendment to such a rule. (This includes consumer product safety standards or bans under sections 7 and 8 of the CPSA, respectively. (15 U.S.C. 2056, 2057)). In addition, the Commission is required to include its section 9(c) findings in the rules. To revoke a consumer product safety rule, the Commission is required to make the negative finding that the rule is not reasonably necessary to address an unreasonable risk of injury. (See section 9(e).)

The section 9(c) findings relate to the risk which will be eliminated or reduced by a rule and the costs of a rule. While these findings are made in issuing individual consumer product safety rules, the Commission believes that a rule generally interpreting the requirements of section 9(c) will assist the public in understanding CPSC decision-making processes regarding these findings and will be helpful to the Commission in providing an overall approach for consideration of the findings in individual cases.

The provisions of the regulation below are essentially self-explanatory. The regulation follows section 9(c) subsection by subsection. Certain subsections are highlighted in this preamble. While this Part only applies

to consumer product safety rules, it may be useful for rules issued under other sections of the CPSA or under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1211 et seq.), the Flammable Fabrics Act (FFA) (15 U.S.C. 1191 et seq.), the Poison Prevention Packaging Act of 1970 (PPPA) (15 U.S.C. 1471 et seq.) and the Refrigerator Safety Act (RSA) (15 U.S.C. 1211 et seq.) to the extent these other statutory provisions require findings similar to the 9(c) findings. The Commission emphasizes that Part 1020 is a general interpretive rule; as provided in proposed § 1020.2(c) below, individual rule may incorporate in their 9(c) findings information or approaches not specifically mentioned here or may omit portions of the information discussed in this Part. If a substantial departure from this rule occurs, an explanation will be provided in the individual rule.

The Commission notes that the process of describing benefits and costs of a rule for the purpose of section 9(c) is a complex one. While the Commission prepares individually articulated findings as required by the section, information considered under the various findings may overlap since the findings are interrelated (e.g., the finding concerning the approximate number of consumer products subject to the rule (§ 1020.6 below) provides information useful in calculating the various costs of a rule (§ 1020.7 below) and also helps determine the finding involving the extent of consumer exposure to the products being regulated (§ 1020.5 below on the nature and degree of the risk).)

The Commission also points out that benefits and costs of its rules, when described in numerical terms, may often, because of the inherent uncertainties in risk estimation, best be represented by a range of values rather than a single point estimate. This fact is recognized in several places in the rule proposed below. Section § 1020.5 on the degree and nature of the risk of injury includes statements in both the acute and chronic area that estimates of the number and kinds of injuries or illnesses that will be affected by a rule may be expressed as a range of possible harm and may reflect any uncertainties involved in estimating risks to humans. Similarly, § 1020.7 on cost recognizes that cost estimates are likely to be expressed as ranges of costs.

The Commission, furthermore, emphasizes that while the findings of section 9(c) can be related to the elements of analyzing benefits and costs, the Commission uses quantified cost-benefit analyses as one of many tools in regulatory decisionmaking and does not rely solely on the cost-benefit outcome to regulate. Commission decisions to issue consumer product safety rules are premised on a thorough consideration of the benefits and costs. The Commission notes that it is often difficult to assign monetary values to human suffering in a meaningful way for regulatory purposes. (Therefore, § 1020.5(a)(4) and § 1020.5(b)(5) provide that the Commission, *where feasible*, estimates the costs of injuries or illnesses that will be eliminated by a rule.) The Commission believes that the ultimate issues involved in issuing health and safety regulations are likely to require judgments on values much as on judgments characterized by numerical estimations. In this regard it should be noted that the legislative history of the CPSA indicates that the Commission is not required to conduct a cost-benefit analysis prior to promulgating a consumer product safety rule. (H.R. Rep. No. 1153, 92nd Cong., 2nd Sess. 33 (1972).)

While the Commission is not required to conduct a formal cost-benefit analysis prior to issuing a consumer product safety rule, the Commission is required to find that the rule is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with the regulated product. (Section 9(c)(2)(A) of the CPSA.) This is the central finding for issuance of a consumer product safety rule since it is made after and based upon the individual findings contained in section 9(c)(1) of the CPSA. A number of court cases have interpreted this finding to mean that the Commission must find that the expected benefits of a rule bear a reasonable relationship to the anticipated costs. (See *Aqua Slide "N" Dive* v. *CPSC*, 569 F.2d 831, at 842 (5th Cir. 1978); *Southland Mower Co.* v. *CPSC*, 619 F.2d 499, at 523 (5th Cir. 1980).) This test, which does not require the Commission to find that the quantifiable costs are outweighed by the quantifiable benefits but rather to determine that the total benefits, in the judgment of the Commission, justify the costs, is incorporated in the proposal below at § 1020.10(c).

As a means of designing the most effective regulations, the proposed regulation provides for consideration of alternatives to a mandatory consumer product safety standard or ban. These are listed at § 1020.8(b) below.

Conclusion

The Commission is proposing this rule for public comment in order to have the benefit of diverse views on the complicated and often controversial subjects dealt with in the rule and may revise the rule in the final version as a result of the comments. In addition, as the state of the art in the area of risk assessment or economic analysis for health and safety regulations advances and the Commission's procedures in this area change, the Commission will amend this rule, as needed and appropriate.

In addition to written comments, because of the importance of this interpretive rule, interested persons will be afforded an opportunity to make an oral presentation of data, views, or arguments on any aspect of the proposed rule on February 3, 1981. The proceedings for the oral presentation will be held at 9:30 am at the Commission's third floor hearing room at 1111 18th St., NW., Washington, D.C. The Commission's procedural regulations for oral presentation, 16 CFR Part 1109, (40 FR 49122), shall govern this proceeding.

The Commission is particularly interested in receiving written and oral comments on the following three issues:

1. Whether, in considering costs and benefits of proposed regulations, the Commission should ever assign a monetary value to life, types of injuries, and pain and suffering and if so, in what circumstances;

2. Whether the Commission should discuss in the rule its methodology or methodologies available for assessing risk, particularly risk from chronic hazards such as carcinogens, including specification of preferred risk assessment models (e.g. linear, multistage, and so forth); and

3. Whether the Commission should discuss in detail in the rule the types of indirect benefits (e.g. pain and suffering avoided) it expects from regulations and the methods used for assigning values to such indirect benefits.

The Commission proposes that this rule become effective 30 days after publication of the final rule.

Accordingly, pursuant to the provision of the Consumer Product Safety Act (section 9(c), Pub. L. 92-572, 86 Stat. 1216), the Commission proposes to add a new Part 1020 to Title 16 as follows:

PART 1020—METHODOLOGY FOR COMMISSION CONSIDERATION OF FINDINGS UNDER SECTION 9(c) OF THE CONSUMER PRODUCT SAFETY ACT

Subpart A—General

Sec.

Authority: Sec. 9(c), Pub. L. 92–573, 86 Stat. 1216; 15 U.S.C. 2058(c).

Subpart A—General

§ 1020.1 Purpose.

(a) The purpose of this Part 1020 is to set forth the methodology the Commission will generally use in making the findings required by section 9(c) of the Consumer Product Safety Act (CPSA) (15 U.S.C. 2058(c)) for issuance or material amendment of consumer product safety rules. For revocation of consumer product safety rules, the Commission must find that the rule is not reasonably necessary to eliminate or reduce an unreasonable risk of injury. (Section 1020.10 of the rules below may be helpful in this regard.)

(b) The various findings under section 9(c) can be related to the elements of analyzing the expected costs to industry and consumers of Commission regulatory action in the light of the health and safety benefits to be obtained. To the extent section 9(c) mandates the use by the Commission of evaluations of the effect of a rule, this Part contains the Commission policy on benefit and cost considerations relevant to issuance of consumer product safety rules.

§ 1020.2 Scope.

(a) This Part contains the Commission's general policy for making findings under section 9(c) of the Consumer Product Safety Act prior to promulgating a consumer product safety standard or ban under sections 7 and 8 of the CPSA, respectively, or a material amendment to such a standard or ban.

(b) Regulations issued under other sections of the Consumer Product Safety Act or under the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1211, et seq.), the Flammable Fabrics Act (FFA) (15 U.S.C. 1191, et seq.), the Poison Prevention Packaging Act of 1970 (PPPA) (15 U.S.C. 1471 et. seq.), and the Refrigerator Safety Act (RFA) (15 U.S.C. 1211, et. seq.) will be issued in accordance with the findings required by the appropriate statutory authority. However, to the extent these other statutory provisions require findings similar to the 9(c) findings, the kinds of information and methodologies discussed in this Part may be used by the Commission.

(c) In issuing individual consumer product safety rules, the Commission may find it necessary to consider information or approaches not specifically mentioned in this rule in order to make the section 9(c) findings. Similarly, in individuals cases, it may not be appropriate or necessary for making section 9(c) findings to consider all of the information discussed in this Part. Where a substantial departure from this rule occurs, the departure will be fully explained in the individual rule.

(d) The Commission makes preliminary section 9(c) findings when it proposes a consumer product safety rule or a material amendment to such a rule. These preliminary findings may be subject to revision in issuing the final rule based on public comments received on the proposed rule.

§ 1020.3 Definitions.

(a) The term "risks of acute injury or illness" means the potential for injury or illness which can occur immediately or shortly after a single or limited number of exposures to a consumer product. The injuries associated with acute risks are characterized by sudden or short onset and temporary or permanent damage. Examples include the injury which can result from contact with a sharp blade or exposure to a faulty electrical connection.

(b) The term "risks of chronic injury or illness" means the potential for injury or illness which can occur after a significant period of time following single or multiple exposures to a consumer product. The injuries or illnesses associated with chronic risks are often characterized by lengthy duration or frequent recurrence over a long time. Examples include the contracting of a form of cancer or other progressive or persistent disease after a single or continual exposure to various levels of a certain chemical.

(c) The term "risks assessment" means an evalulation, in qualitative or quantiative terms or both, of the effects of exposure to hazards in consumer products. The evaluation includes an analysis of the nature of the hazard and the likelihood of injury or illness that will result from exposure to certain products. Assessing the likelihood of injury or illness may require the development of ranges of risk estimates based partly on data and partly on scientific or medical theory. The evaluation may also take into account factors other than the overall magnitude of the risk, such as the special vulnerability of children, the elderly or the handicapped; the foreseeability or hidden nature of the risk; and to what extent the manner or duration of product use affects injuries.

Subpart B—Specific Findings under Section 9(c)(1)

§ 1020.5 The degree and nature of the risk of injury the rule is designed to eliminate or reduce.

This finding by the Commission is fundamental to a determination of the benefits that can be expected from a consumer product safety rule. The Commission evaluates the frequency and severity of risks of both acute and chronic injury or illness, which are discussed separately below:

(a) *Acute injury or illness.* The Commission shall prepare a qualitative discussion of the kind and extent of acute harm that results from exposure to the product being regulated. The Commission may base this finding on engineering, medical, scientific, or human factor analyses or injury potential. Where practicable and appropriate, however, in assessing the risks of acute injury or illness, the Commission also prepares a quantified risk assessment as part of its analysis of the degree and nature of the risk of injury. If such quantification is not possible in particular cases, the Commission explains why a quantitative assessment has not been prepared. The following steps are generally used in assessing risks of acute injury or illness:

(1) The Commission estimates the number and kinds of injuries and illnesses annually associated with the hazard being regulated. This estimate can include a range of possible harm, reflecting whatever uncertainties may exist in the data and theory used in deriving the estimate. Data sources for these estimates include but are not limited to the Commission's National

Electronic injury Surveillance System (NEISS), which provides information on injuries treated in hospital emergency rooms; death certificates; news clips and consumer complaints available to the Commission; and data from burn treatment centers and poison control centers.

(2) The Commission then estimates the number and kinds of injuries or illnesses which would be eliminated annually if all consumer products subject to the rule were in compliance with the rule.

(3) If determinable, factors such as expected industry compliance with the rule and the rate of product replacement by consumers are considered to arrive at an estimate of the number and kinds of injuries or illnesses which would be eliminated after promulgation of the rule.

(4) The Commission, where feasible, estimates the "costs" of the injuries or illnesses that will be eliminated by a rule to arrive at a determination of the safety or health benefits of a rule. Where a numerical description of these costs is not possible, the Commission describes them in qualitative terms. Costs may include indirect costs (e.g., social costs, lost wages, pain and suffering) as well as direct medical costs associated with injuries or illnesses.

(5) Risk assesssment for acute risks may involve consideration of such factors as the special vulnerability of certain populations such as children, the elderly, or the handicapped; the foreseeability of the risk by the consumer; and to what extent the manner or duration of product use affects injuries.

(b) *Chronic injury or illness.* The Commission prepares a qualitative discussion of the kind and extent of chronic harm that results from exposure to the product being regulated. Where practicable and appropriate, the Commission uses a quantified risk assessment as discussed in paragraph (a) of this section as a tool in regulatory decisionmaking. Many chronic risks of injury or illness, such as cancer, typically occur years after first exposure, making it difficult to link incidence of disease to exposure to specific consumer products. The Commission must often evaluate risk on the combined basis of scientific theory and available empirical evidence rather than using injury data alone. The following steps will generally be used in assessing risks of chronic injury or illness. (Where a quantitative assessment is not possible in particular cases, the Commission explains why):

(1) The Commission evaluates whether the substances in the products in question are likely to cause chronic illness in humans. In some instances, this evaluation will be based on the experience of workers or other populations exposed to the substance for long periods. In other instances, the evaluation will be based on animal experiments. Data from predictive *in vitro* tests and chemical structure-activity relationships will also be used in evaluating a chronic hazard. With regard to carcinogenic risks, the Commission is assisted by the work and conclusions of various expert research organizations, including but not limited to the International Agency for Research on Cancer (IARC) and the National Cancer Institute (NCI) as well as other regulatory agencies such as the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA).

(2) The Commission assesses the nature and extent of consumer exposure to the substances in the products being regulated. A theoretical model may be developed to determine typical consumer exposure. For example, in the case of a gas released from an aerosol product, the Commission might use predictions concerning the likely concentration of the chemical in the air and the likely amount inhaled by a consumer, based on assumptions concerning the quantity of chemical released under a specified set of conditions and the rate of air exchange.

(3) Combining the evaluation of the chronic injury or illness potential of the substance in the products and the exposure evaluation, the Commission assesses the risk to consumers from the consumer products. Where feasible, the assessment includes an estimate of the number or range of numbers of incidents of disease or deaths associated with exposure to the product, and the number of incidents which will be eliminated by the rule. Where numerical assessments are made, the Commission will explain any assumptions made as well as the extent to which the resulting conclusions may be uncertain.

(4) In evaluating the risk from a potential carcinogen, the Commission is assisted by scientific work concerning risk assessment, such as the Interagency Regulatory Liaison Group document entitled Scientific Basis for Identification of Potential Carcinogens and Estimation of Risks, (44 FR 39858, July 6, 1979) and the Regulatory Council's cancer policy, Regulation of Chemical Carcinogens (44 FR 60038; October 17, 1979).

(5) As with risks of acute injury or illness, where feasible, the Commission estimates the "costs" of the injuries or illnesses that will be eliminated by a rule to arrive at a determination of the benefits of a rule.

(6) Risk assessment for chronic risks may involve consideration of such factors as the special vulnerability of certain populations, the foreseeability of the risk by the consumer, and to what extent the manner or duration of product use affects the risk.

§ 1020.6 The approximate number of consumer products, or types or classes thereof, subject to such rule.

Information from this finding serves two purposes: it helps determine the extent of consumer exposure to the products being regulated, thus aiding in risk assessment and it provides a basis for calculating the various costs of the rule to industry and consumers. The Commission considers the following elements in making this finding:

(a) The Commission attempts to determine current production and sales of the products or the product types or classes covered by the rule. It also taken into account expected changes in production and sales as a result of the rule and other relevant changes such as long-term trends in production or sales or the use of close substitutes. Sources for these estimates include published data of federal and other government units, private publications, direct contact with manufacturers and distributors, industry trade associations, consumer surveys, and direct staff observation.

(b) While consumer product safety rules do not apply to products already in consumers' hands, estimates of the stock of goods to which consumers are exposed are useful in assessing risk. Therefore, on a case-by-case basis, the Commission considers such estimates. Factors which are taken into account in estimating the stock in consumers' hands include previous production, expected product life, product maintenance, and consumer patterns of use and abuse.

(c) Where the products potentially covered by a rule include items used in the consumer environment and items used in industrial settings, the Commission develops criteria for distinguishing among the products to identify those consumer products covered by the rule.

(d) Complete description of all of the individual products involved may not be feasible for rules which potentially affect a wide range of products for a specific hazard (e.g., rules setting requirements for consumer products containing a certain chemical). In such cases, the Commission considers representative information about the

types and classes of products subject to the rule.

§ 1020.7 The need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need.

This finding requires that the Commission consider four factors: the need for the products being regulated, the effect of the rule on the utility of the products for their users, the effect of the rule on the cost of the products, and the effect of the rule on the availability of the products. Each factor is discussed separately below:

(a) The Commission measures the need for a product by the extent to which the product is bought by the public, the uses to which it is put, and the extent to which close substitutes exist.

(b) The Commission evaluates the potential effect of its action on the utility of the product for its users by describing or analyzing how the functional attributes of the product may be changed, how the esthetic appeal of the product may be altered, and how other kinds of utility that may attach to the product may be modified. Particularly in case of a product ban, where close substitutes for the regulated product exist, the Commission takes the characteristics of these substitutes into account in evaluating the overall effect of the rule on the consumer. Sources for the evaluation of a rule's impact on utility include the opinions of the Commission's technical staff and comments from manufacturers, trade associations, and consumers, as well as comments from the public generally.

(c) The Commission considers the following kinds of costs (costs may be expressed as a range of costs):

(1) *Costs to affected firms.* The Commission estimates costs to manufacturers and others in the chain of distribution of producing and distributing complying products or where appropriate, of no longer being able to produce or distribute the regulated product. These cost estimates are based on CPSC determinations as to reasonable costs of compliance and on estimates by producers and others as to actual expected costs, including any significant costs of capital, labor, materials, distribution and sales. The Commission considers possible shifts in product lines by firms reacting to a rule. The Commission considers all significant production and distribution effects to estimate the total impact on firms.

(2) *Costs to consumers.* CPSC estimates the cost to consumers of compliance with a CPSC rule. Such costs include estimated changes in product price, utility, and availability as a result of a rule. Where there may be significant changes in the value of the product because of such factors as changes in quality, durability, or maintenance costs, these are included in the estimates of cost to consumers.

(3) *Other effects.* The Commission discusses any other significant costs of a rule such as changes in sales and employment for some firms, effects on international trade, competitive disruptions, or other changes in normal business practice. The Commission may consider how any such effects may be offset by changes in the market for close substitutes. (e.g., substitute products may increase sales and employment for other firms.)

(d) The Commission discusses whether the availability of products will be affected by a rule, taking into account such factors as whether changes in the state of technology are required by a rule, how fast affected firms can adapt to a rule, and the availability of substitute products or new technologies to fill consumers' needs.

§ 1020.8 Any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety.

This finding requires the Commission to consider alternatives to the rule or parts of the rule which will accomplish the objective of the rule but will be less disruptive to industry. The Commission considers the following elements under this finding:

(a) The Commission considers effects the rule may have on processes of production, distribution and sale of the products subject to the rule. Particular attention is given to effects on small business, on competition, and on foreign trade.

(b) The Commission considers alternative ways, consistent with protecting the public health and safety, to minimize any adverse impacts identified. Such alternatives may include different effective dates; different substantive requirements, including labeling requirements; the use, where feasible, of performance rather than design requirements; and voluntary standards or information disclosure by CPSC rather than mandatory CPSC regulations. The Commission also may consider, where appropriate and authorized by law, such regulatory alternatives as exemptions for small business and differing requirements according to the type of firm or product regulated ("tiering").

Subpart C—Summary Findings Under Section 9(c)(2)

§ 1020.10 The rule (including its effective date) is reasonably necessary to eliminate or reduce and unreasonable risk of injury associated with such product.

This is the central finding for issuance or material amendment of a consumer product safety rule. It concerns the relationship between the anticipated injury or illness reduction from a rule and the costs of the rule. The Commission takes the following steps in making this finding:

(a) The Commission reviews the information contained in the individual findings for a rule under section 9(c)(1) of the CPSA.

(b) The Commission considers the expected effectiveness of a rule in eliminating or reducing the number of accidents, injuries and illnesses and their costs, in light of the costs to the public of eliminating or reducing the hazards.

(1) A variety of factors may be involved in estimating the effectiveness of a rule in addressing a risk, including engineering, scientific, behavorial and enforcement considerations; and predictions about the response of industry and the public in general.

(c) The Commission may make this finding if it concludes that the expected benefits of a rule bear a reasonable relationship to the anticipated costs.

§ 1020.11 The promulgation of the rule is in the public interest.

Issuance of rules where the benefits bear a reasonable relationship to the costs (i.e., rules which are reasonably necessary to address an unreasonable risk of injury) will generally also be in the public interest. However, where a rule is reasonably necessary to address and unreasonable risk of injury, some other factor may make issuance of the rule more or less desirable. Under this finding, the Commission, where it has found a rule to be reasonably necessary to address an unreasonable risk of injury, reviews any other relevant factors; such as adequacy of voluntary actions and societal concerns, such as environmental, energy, or international trade concerns, to determine whether issuance of the rule is in the best interest of the public.

§ 1020.12 In the case of a rule declaring the product a banned hazardous product, that no feasible consumer product safety standard under this Act would adequately protect the public from the unreasonable risk of injury associated with the product.

Under this finding, the Commission looks at the particular product being regulated and determines whether a standard, including a labeling rule, could be designed and met so as to render what is being regulated safe. The Commission consider only "feasible" standards. "Feasibility" under this provision means technically and economically possible within a reasonable time period, given current technology or technology expected to be developed in the near future.

Dated: December 23, 1980.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 80-40495 Filed 12-29-80; 8:45 am]

BILLING CODE 6355-01-M

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16 CFR Part 1201

Proposed Interpretation of Architectural Glazing Materials Safety Standard; Decision on Petition CP 78-18

AGENCY: Consumer Product Safety Commission.

ACTION: Proposed interpretation; decision on petition.

SUMMARY: The Commission's safety standard for architectural glazing materials applies to several products, including bathtub and shower doors and enclosures. The Commission is proposing an interpretation of the standard that clarifies that the terms "bathtub doors and enclosures" and "shower door and enclosure" do not include glazing materials in a window located over a bathtub or within a shower stall and in the exterior wall of a building. The interpretation is intended to resolve questions which have arisen among firms whose activities are subject to regulation by the standard. This proposed interpretation grants a portion of a petition from the National Glass Dealers Association. The Commission has denied the other portions of that petition, which requested amendments to the standard, and in this notice explains the reasons for its decision.

DATE: Comments on the proposed interpretation should be submitted by March 2, 1981. The interpretation is proposed to become effective 30 days after it is published in final form.

ADDRESS: Comments should be submitted to the Office of the Secretary, consumer Product Safety Commission, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT: Harry I. Cohen, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 492-6453.

SUPPLEMENTARY INFORMATION: In January 1977 the Consumer Product Safety Commission issued a safety standard to reduce unreasonable risks of injury associated with architectural glazing materials and certain products incorporating those materials (42 FR 1428; 16 CFR Part 1201). The standard prescribes tests to ensure that the glazing materials either do not break when impacted with a specified energy or break with such characteristics that they are less likely than other glazing materials to present an unreasonable risk of injury. The standard became effective on July 6, 1977.

The standard is applicable to glazing materials used in six specific products and to the products themselves. These products, each defined in the standard, are storm doors, doors, bathtub doors and enclosures, shower doors and enclosures, sliding glass doors (patio-type), and glazed panels. On August 28, 1980 the Commission revoked the provisions applicable to glazed panels (45 FR 57383). Therefore, as of August 28, 1981, the standard will apply only to five products and the glazing materials used in those products.

Bathtub and shower windows

The standard defines the term "bathtub doors and enclosures" to mean "assemblies of panels and/or doors that are installed on the lip of or immediately surrounding a bathtub" (§ 1201.2(a)(2)). The standard defines the term "shower door and enclosure" to mean "an assembly of one or more panels installed to form all of part of the wall and/or door of a shower stall" (§ 1201.2(a)(30)).

Since the effective date of the standard, firms whose activities are regulated by the standard have raised the question of whether these definitions include glazing materials in a window that is located over a bathtub or within a shower stall and in the exterior wall of a building. The definitions of bathtub and shower doors and enclosures contain no specific exemption for glazing materials in such windows. The text of § 1201.2(a)(2), if read literally, could include glazing material in an exterior wall window located above a bathtub because that window could be interpreted as being "immediately surrounding" the bathtub. Similarly, the text of § 1201.2(a)(30), if read literally, could include glazing material in an exterior wall window because that window could be interpreted as forming "all or part of the wall * * * of a shower stall."

In September, 1978 the National Glass Dealers Association (NGDA) petitioned the Commission to amend the architectural glazing standard (Petition CP 78-18). A portion of the petition requested amendments to the definitions of bathtub and shower doors and enclosures to exclude any glazing material in a window that is located over a bathtub or within a shower stall and in the exterior wall of a building.

The Commission, when it issued the standard in 1977, did not intend to include within the definitions of bathtub and shower doors and enclosures any item of glazing material that is contained in a window in an exterior wall of a building. In response to the petition, the Commission has reevaluated its original intention and found that it was appropriate to exclude from the standard glazing material in such windows. The Commission is aware of no injuries that have been associated with exterior wall windows surrounding bathtubs or within shower stalls. In addition, a common sense understanding of doors and enclosures would include the panels used to assemble bathtubs and showers inside the house, but not the actual walls of the house.

The existing definitions of bathtub and shower doors and enclosures could reasonably be interpreted either to include or exclude the glazing materials in exterior wall windows. Therefore, the Commission has decided to propose for public comment an interpretation of the architectural glazing standard that clarifies the Commission's original and present intention that the standard does not apply to such glazing materials. This initiation of a proceeding provides NGDA with the relief that it sought on this issue and the Commission has thus granted the portion of NGDA's petition concerning bathtub and shower exterior windows.

Because the Commission clarification does not amend the standard, the provisions of section 9(e) of the Consumer Product Safety Act do not apply. Nevertheless, the Commission wants to obtain the views of any member of the public who may be affected by it. Therefore, the Commission proposes the clarification below as an interpretation. If issued in final form, the interpretation will be codified in a new Subpart C so that anyone referring to the standard will also be able to refer to the interpretation.

Other portions of petition

Aside from the bathtub and shower exterior window issue, NGDA's petition requested amendments to the Commission's architectural glazing standard. As discussed below, the Commission has denied these other portions of the petition, and this **Federal Register** document shall serve as the Commission's publication of its reasons for denial, as required by section 10 of the CPSA:

1. NGDA has requested amendments to the glazed panel provisions of the standard. However, the Commission revoked all of the glazed panel provisions on August 28, 1980, to become effective on August 28, 1981.

Before revoking the glazed panel provisions, the Commission solicited public comment on possible amendments to them. The Commission evaluated these comments before deciding to revoke the glazed panel provisions in final form. The Commission's **Federal Register** documents that proposed and issued the revocation fully discuss the Commission's reasons for revoking the provisions instead of amending them (44 FR 31218, May 31, 1979; 45 FR 57383, August 28, 1980). Briefly, the Commission determined that enforcement of glazed panel provisions by local building officials would be more effective than a federal enforcement program (45 FR 57388).

Because the glazed panel provisions of the standard have been revoked, the Commission has denied the portions of the NGDA petition that concern those provisions.

2. NGDA has also requested that six products containing glazed materials be deleted from the architectural glazing standard. If this were done, the standard would still apply to the glazing materials contained in the six products (after the glazed panel revocation becomes effective, five products).

NGDA's position is that application of the standard to the six products is unnecessary because consumers would be adequately protected by the applicability of the standard to the glazing materials incorporated into the six products. For example, a storm door need not fall within the standard because the glazing material comprising the storm door panel is within the standard.

The Commission disagrees with the NGDA position and has decided to deny this portion of the petition.[1] Under the existing standard, installers and fabricators of architectural glazing products must certify that their products comply with the standard. This certification is a useful enforcement tool because most violations of the standard thus far have resulted from the intentional use of noncomplying glazing materials by installers and fabricators. If the standard were amended as requested by NGDA, installers and fabricators would no longer be "manufacturing" a product within the standard and they would not have to issue any certification. If the Commission did not have the certification requirement to use as an enforcement tool against installers and fabricators who use noncomplying glazing material, consumers would not be protected as well as they currently are.

3. Finally, the NGDA petition requested terminology changes in the standard. One was to add the phrase "or installations" to the term "architectural glazing products." The other was to define and use the term "installers" so that it is distinguished from the term "fabricators." NGDA's primary reason for requesting these changes is that installers are more familiar with these terms than the ones currently contained in the standard. NGDA has described the changes as "technical" ones that would have no impact on consumer protection.

The Commission does not dispute that segments of the glazing industry might well be more familiar with the terms "installations" and "installers" than with the terms now used in the standard. However, the Commission has no indication that the installers are confused about the application of the standard to them and their activities. To the contrary, the Commission's numerous contacts with the installers all indicate a high level of awareness on their part. In large part because of the educational efforts of NGDA and other glazing trade associations, the Commission believes that this level of awareness will continue. If any terminology changes are made to the standard now, the Commission cannot be sure that new questions will not be raised and uncertainty about applicability of the standard fostered. Therefore, the Commission has decided to deny this portion of the petition.

Conclusion

The Commission has denied the portions of the NGDA petition concerning amendments to the glazed panel provisions, deletion of six products, and changes in terminology. The Commission has granted the portion concerning bathtub and shower doors and enclosures and, accordingly, pursuant to sections 7 and 9 of the Consumer Product Safety Act, 15 U.S.C. 2056, 2058, the Commission proposes to amend Title 16, Chapter II, Subchapter B, Part 1201 of the Code of Federal Regulations, by adding a new Subpart C, as follows:

PART 1201—SAFETY STANDARD FOR ARCHITECTURAL GLAZING MATERIALS

Subpart A—The Standard

* * * * *

Subpart B [Reserved]

* * * * *

Subpart C—Statements of Policy and Interpretation

§ 1201.40 Interpretation concerning bathtub and shower doors and enclosures.

(a) *Purpose and background.* The purpose of this section is to clarify the scope of the terms "bathtub doors and enclosures" and "shower door and enclosure" as they are used in the Standard at Subpart A. The Standard lists the products that are subject to it (§ 1201.1(a)). This list includes "bathtub doors and enclosures," a term defined in the Standard to mean "assemblies of panels and/or doors that are installed on the lip of or immediately surrounding a bathtub" (§ 1201.2(a)(2)). The list also includes "shower doors and enclosures," a term defined to mean "(assemblies) of one or more panels installed to form all or part of the wall and/or door of a shower stall" (§ 1201.2(a)(30)). Since the Standard became effective on July 6, 1977, the question has arisen whether the definitions of these products include glazing materials in a window that is located over a bathtub or within a shower stall and in the exterior wall of a building. The definitions of the terms "bathtub doors and enclosures" and "shower door and enclosure" contain no specific exemption for glazing materials in such windows. If read literally, the Standard could include glazing materials in an exterior wall window located above a bathtub because that window could be interpreted as being "immediately surrounding" the bathtub. Similarly, the Standard, if read literally, could include glazing materials in an exterior wall window because that window could be interpreted as forming "all or part of the wall * * * of a shower stall."

(b) *Interpretation.* When the Consumer Product Safety Commission issued the Standard, it did not intend the standard to apply to any item of glazing material in a window that is located

[1] The vote on this portion was 4 to 1, with Commissioner Sloan voting to grant.

over a bathtub or within a shower stall and in the exterior wall of a building. The Commission clarifies that the Standard does not apply to such items of glazing material or such windows. This interpretation applies only to the terms "bathtub doors and enclosures" and "shower door and enclosure" and does not affect the applicability of the Standard to any other product.

(Secs. 7, 9 of the Consumer Product Safety Act (15 U.S.C. 2056, 2058))

Dated: December 23, 1980.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 80-40496 Filed 12-29-80; 8:45 am]

BILLING CODE 6355-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 271

[Docket No. RM79-76 (Texas-7)]

Ceiling Prices

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Federal Energy Regulatory Commission is authorized by section 107(c)(5) of the Natural Gas Policy Act of 1978 to designate certain types of natural gas as high-cost gas where the Commission determines that the gas is produced under conditions that present extraordinary risks or costs. Under section 107(c)(5), the Commission issued a final regulation designating natural gas produced from tight formations as high-cost gas subject to an incentive price (18 CFR 271.703). The rule establishes procedures for jurisdictional agencies to submit to the Commission recommendations of areas for designation as tight formations. This notice of proposed rulemaking contains the recommendation of the Texas Railroad Commission that the Lower Wilcox Formation be designated as a tight formation under § 271.703(d).

DATE: Comments on the proposed rule are due on January 21, 1981.

PUBLIC HEARING: No public hearing is scheduled in this docket as yet. Written requests for a public hearing are due on January 7, 1981.

ADDRESS: Comments and requests for hearing must be filed with the Office of the Secretary, 825 North Capitol Street, N.E., Washington, D.C. 20426.

FOR FURTHER INFORMATION CONTACT: Leslie Lawner, (202) 357-8299 or John Bassett/Ting Chin, (202) 357-8595.

SUPPLEMENTARY INFORMATION:

Issued: December 19, 1980.

I. Background

On December 11, 1980, the Railroad Commission of Texas (Texas) submitted to the Commission a recommendation, in accordance with § 271.703 of the Commission's final regulations (45 FR 56034, August 22, 1980), that the Lower Wilcox Formation, located in the southeastern part of the State of Texas, be designated as a tight formation. Pursuant to § 271.703(c)(4) of the regulations, this Notice of Proposed Rulemaking is hereby issued to determine whether Texas' recommendation that the Lower Wilcox Formation be designated a tight formation should be adopted. Texas' recommendation and supporting data are on file with the Commission and are available for public inspection.

II. Description of Recommendation

Texas recommends that the Lower Wilcox Formation, encountered in the southern portion of Austin County, the northern portion of Wharton County, and the eastern portion of Colorado County, Texas, be designated as a tight formation. The particular area being recommended entails a 2.5 mile radius around a well which is located 467 feet from the southwestern boundary and 650 feet from the northwestern boundary of the Frank R. Moore Survey A-377 in Austin County. (A more detailed description of the recommended area is contained in the recommendation on file with the Commission.) The Lower Wilcox Formation is located below the Claiborne Formation and above the Midway Formation. The top of the recommended portion of the Lower Wilcox Formation is located at an approximate depth of 11,700 feet and the base is located at an approximate depth of 12,700 feet, giving a thickness of 1,000 feet.

III. Discussion of Recommendation

Texas claims in its submission that evidence gathered through information and testimony presented at a public hearing convened by Texas on this matter demonstrates that:

(1) The average *in situ* gas permeability throughout the pay section of the proposed area is not expected to exceed 0.1 millidarcy.

(2) The stabilized production rate, against atmospheric pressure, of wells completed for production from the recommended formation, without stimulation, is not expected to exceed the maximum allowable production rate set out in § 271.703(c)(2)(i)(B); and

(3) No well drilled into the recommended formation is expected to produce more than five (5) barrels of oil per day.

Texas further asserts that existing State and Federal regulations assure that development of this formation will not adversely affect any fresh water aquifers that are or are expected to be used as a domestic or agricultural water supply.

Accordingly, pursuant to the authority delegated to the Director of the Office of Pipeline and Producer Regulation by Commission Order No. 97, issued in Docket No. RM80-68 (45 FR 53456, August 12, 1980), notice is hereby given of the proposal submitted by Texas that the Lower Wilcox Formation, as described and delineated in Texas' recommendation as filed with the Commission, be designated as a tight formation pursuant to § 271.703.

IV. Public Comment Procedures

Interested persons may comment on this proposed rulemaking by submitting written data, views or arguments to the Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, on or before January 21, 1981. Each person submitting a comment should indicate that the comment is being submitted in Docket No. RM79-76 (Texas—7), and should give reasons including supporting data for any recommendations. Comments should include the name, title, mailing address, and telephone number of one person to whom communications concerning the proposal may be addressed. An original and 14 conformed copies should be filed with the Secretary of the Commission. Written comments will be available for public inspection at the Commission's Office of Public Information, Room 1000, 825 North Capitol Street, N.E., Washington, D.C., during business hours.

Any person wishing to present testimony, views, data, or otherwise participate at a public hearing should notify the Commission in writing that they wish to make an oral presentation and therefore request a public hearing. Such request shall specify the amount of time requested at the hearing. Requests should be filed with the Secretary of the Commission no later than January 7, 1981.

(Natural Gas Policy Act of 1978, 15 U.S.C. §§ 3301-3432)

Accordingly, the Commission proposes to amend the regulations in

Part 271, Chapter I, Title 18, Code of Federal Regulations, as set forth below, in the event Texas' recommendation is adopted.

Kenneth A. Williams

Director, Office of Pipeline and Producer Regulation.

Section 271.703(d) is amended by adding new subparagraph (27) to read as follows:

§ 271.703 Tight Formations.

* * * * *

(d) *Designated tight formations.* The following formations are designated as tight formations. A more detailed description of the geographical extent and geological parameters of the designated tight formations is located in the Commission's official file for Docket No. RM79–76, as subindexed below, and is also located in the official files of the jurisdictional agency that submitted the recommendation.

* * * * *

(11) through (26) [Reserved]

(27) *Lower Wilcox Formation in Texas*

(i) *Delineation of formation.* The Lower Wilcox Formation is found in the southern portion of Austin County, the northern portion of Wharton County, and the eastern portion of Colorado County, Texas.

(ii) *Depth.* The top of the Lower Wilcox is located at an approximate depth of 11,700 feet and the base is located at an approximate depth of 12,700 feet, giving a thickness of 1,000 feet.

[FR Doc. 80–40392 Filed 12–29–80; 8:45 am]

BILLING CODE 6450–85–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 18

Transportation in Bond and Merchandise in Transit; Proposed Customs Regulations Amendments Relating to the Assessment of Liquidated Damages Under Carrier's Bonds

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: Bonded carriers are responsible for shortages, irregular deliveries, or nondeliveries of imported merchandise received by them to be transported from one port to another. In the case of any shortage, failure to deliver, or direct delivery to the consignee or other person of any duty-free merchandise, the bonded carrier is subject to a penalty imposed by Customs as liquidated damages in an amount equal to the value of the merchandise not to exceed $25 in any one shipment.

Customs has determined that the maximum penalty has failed to act as a deterrent to future violations and does not cover the administrative costs of processing the penalty. This document proposed to amend the Customs Regulations to increase the penalty to a minimum of $50 and a maximum of $100, in any one shipment, to be determined within the discretion of the district director.

Bonded carriers are also responsible for any internal revenue taxes or other taxes due to the United States on the missing merchandise. While customs duties are included in these taxes, they are not expressly mentioned. Accordingly, this document also proposes to include the term "duties" within the category of liabilities assumed by bonded carriers for shortage, nondelivery, or irregular delivery of merchandise.

DATE: Comments must be received on or before March 2, 1981.

ADDRESS: Comments (preferably in triplicate) may be addressed to the Commissioner of Customs, Attention: Regulations and Research Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Room 2426, Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Legal Aspects: William G. Rosoff, Carriers, Drawback and Bonds Division, 202–566–5856; Operational Aspects: Thomas Hargrove, Cargo Processing Division, 202–566–5354; U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229.

SUPPLEMENTARY INFORMATION:

Background

Generally, when merchandise is imported into the United States it must be entered for Customs purposes at the first port at which the merchandise arrives. However, under certain circumstances, imported merchandise may be placed in a Customs bonded warehouse or transported from the first port in the United States to another port. This procedure postpones final Customs formalities, including payment of duties due, until the merchandise arrives at the other port. The merchandise then may be entered, warehoused, or exported. In order to forward imported merchandise to another port, the merchandise must be transported in bond; that is certain Customs documents are required to support the movement and the carriers must be bonded by Customs for this purpose. Carriers bonded to transport merchandise in bond must follow certain procedures specified in Part 18, Customs Regulations (19 CFR Part 18), and they will incur penalties if shipments, together with the necessary documents, are not properly transported and delivered to Customs at the port of destination.

Section 18.10, Customs Regulations (19 CFR 18.10), lists five types of entries or withdrawals which may be made for merchandise to be transported in bond. Under § 18.8, Customs Regulations (19 CFR 18.8), carriers of merchandise transported in bond are responsible for any shortage, irregular delivery, or nondelivery at the port of destination or port of exit of bonded merchandise received by them. If there is a shortage, irregular delivery, or nondelivery, the bonded carrier is assessed liquidation damages under its bond. The amount of the liquidated damages depends on the dutiable status of the merchandise and the type of nonperformance by the carrier.

Section 18.8(b)(1), Customs Regulations (19 CFR 18.8(b)(1)), provides that if there is a shortage, irregular delivery, or nondelivery of duty-free merchandise, the penalty to be imposed as liquidated damages will be an amount equal to the value of the missing merchandise, not to exceed $25 in any one shipment.

In addition to the penalties prescribed by § 18.8(b)(1), § 18.8(c), Customs Regulations (19 CFR 18.8(c)), provides that the bonded carrier is also responsible to pay any internal revenue taxes or other taxes owed to the United States on the missing merchandise, as well as all costs, charges, and expenses caused by the failure to make the required transportation, report, and delivery.

Discussion

Customs has determined that the maximum amount of the penalty imposed as liquidated damages assessed against the carrier's bond for shortage, nondelivery, or irregular delivery of duty-free merchandise is insufficient to act as a deterrent to future violations. In addition, the $25 maximum penalty permitted under § 18.8(b)(1) does not nearly meet the administrative costs to Customs of processing claims for liquidated damages. In a study performed in the Houston, Texas, Customs Region, it was

concluded that the cost of processing the simplest liquidated damages case is $41.50. The cost to Customs has increased since that study was made.

Accordingly, Customs proposes to amend § 18.8(b)(1) to increase the amount of the liquidated damages that can be assessed to a minimum of $50 and maximum of $100, in any one shipment, to be determined within the discretion of the district director.

Although the provisions of § 18.8(c) have been used to collect customs duties under a carrier's bond on any missing merchandise, and the authority to collect duties under the carrier's bond has been recognized by the U.S. Customs Court in *Art Craft Jewelry Co. v United States*, 64 Cust. Ct. 414, C.D. 4010 (1970), the term "duties" does not expressly appear in § 18.8(c). Accordingly, for purposes of clarity, Customs proposes to amend § 18.8(c) to expressly include the term "duties" among the liabilities imposed upon a carrier in the case of shortage, nondelivery, or irregular delivery of merchandise.

Customs Forms

If this proposal is adopted, Customs Forms 3587 ("Carrier's Bond"), 3588 ("Private Carrier's Bond"), and 3855 ("Bond of Customs Cartman or Lighterman") would be revised to conform to the proposed amendments.

Authority

These amendments are proposed under the authority of R.S. 251, as amended, and sections 551, 623, 624, 46 Stat. 742, as amended, 759, as amended, (19 U.S.C. 66, 1551, 1623, 1624).

Comments

Before adopting this proposal, consideration will be given to any written comments, preferably in triplicate, submitted timely to the Commissioner of Customs. Comments submitted will be available for public inspection in accordance with § 103.8(b), Customs Regulations (19 CFR 103.8(b)), during regular business hours at the Regulations and Research Division, Headquarters, U.S. Customs Service, 1301 Constitution Avenue, NW., Room 2426, Washington, D.C. 20229.

Applicability of Executive Order 12044

This document is subject to the Treasury Department directive published in the Federal Register on November 8, 1978 (43 FR 52120), implementing E.O. 12044, "Improving Government Regulations," and was the subject of Work Plan 79–11, approved by the Department on May 1, 1979.

In the directive, the Treasury Department stated that it considers each regulation or amendment to an existing regulation published in the Federal Register and codified in the Code of Federal Regulations to be "significant". However, regulations which are nonsubstantive, are essentially procedural, do not materially change existing or establish new policy, and do not impose substantial additional requirements or costs on, or substantially alter the legal rights or obligations of, those affected, with Secretarial approval, may be determined not to be significant. Accordingly, it has been determined that this proposal does not meet the criteria in the directive for "significant" regulations.

Drafting Information

The principal author of this document was Laurie Strassberg Amster, Regulations and Research Division, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

Proposed Amendments

It is proposed to revise § 18.8(b)(1) and (c), Customs Regulations (19 CFR 18.8(b)(1), (c)), to read as follows:

§ 18.8 Liability for shortage, irregular delivery, or nondelivery; penalties.

* * * * *

(b) Penalties imposed as liquidated damages under the carrier's bond for shortage, failure to deliver, or irregular delivery shall be as follows:

(1) In the case of shortage, failure to deliver, or delivery direct to the consignee or other person of any merchandise free of duty, a minimum of $50 and a maximum of $100, in any one shipment, to be determined within the discretion of the district director.

* * * * *

(c) In addition to the penalties described in paragraph (b) of this section, the carrier shall pay any internal-revenue taxes, duties, or other taxes accruing to the United States on the missing merchandise, together with all costs, charges, and expenses caused by the failure to make the required transportation, report, and delivery.

William T. Archey,

Acting Commissioner of Customs.

Approved: December 15, 1980.

Richard J. Davis,

Assistant Secretary of the Treasury.

[FR Doc. 80-40341 Filed 12-29-80; 8:45 am]

BILLING CODE 4810-22-M

19 CFR Part 132, 141, and 142

Proposed Customs Regulations Amendments Relating to Quota Merchandise, Statistical Information, and Merchandise Released Under the Immediate Delivery Procedure

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: Pub. L. 95–410, the "Customs Procedural Reform and Simplification Act of 1978," made significant changes in the Customs laws relating, in part, to the entry and warehousing of imported merchandise. Amendments to the Customs Regulations implementing these changes were recently published; however, several sections of the Customs Regulations need further changes. This document proposes to amend the Customs Regulations to:

(1) Clarify the procedure relating to quota merchandise when the quota is nearing fulfillment;

(2) Remove a mandatory requirement to aggregate statistical information from multiple invoices;

(3) Clarify the circumstances under which a district director may authorize release of merchandise from warehouse under a special permit; and

(4) Clarify what documentation may be filed after merchandise is released under the immediate delivery procedure.

DATE: Comments must be received on or before March 2, 1981.

ADDRESS: Written comments should be addressed to the Commissioner of Customs, Attention: Regulations and Reserach Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Room 2426, Washington, D.C. 20229.

FOR FURTHER INFORMATION CONTACT: Relating to quota merchandise—Helen Rohrbaugh, Duty Assessment Division, (202–566–8592); Relating to statistical information—William L. Marchi, Duty Assessment Division, (202–566–8235); Relating to merchandise released under the immediate delivery procedure—Benjamin H. Mahoney, Entry Procedure and Penalities Division, (202–566–5778), U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229.

SUPPLEMENTARY INFORMATION:

Background

Pub. L. 95–410, the "Customs Procedural Reform and Simplification Act of 1978," made significant changes in the Customs laws relating, in part, to the entry and warehousing of imported merchandise. Final amendments to the Customs Regulations implementing these Changes were published in the

Federal Register on August 9, 1979, as T.D. 79–221 (44 FR 46794).

Based upon recent experience and further review, Customs has determined that several sections of the Customs Regulations amended by T.D. 79–221 need further changes. Accordingly, this document proposes to amend the following sections of the customs Regulations:

1. Section 132.13(a)(1), Customs Regulations (19 CFR 132.13(a)(1)), to clarify the procedure relating to quota merchandise when the quota is nearing fulfillment;

2. Sections 141.61(e)(1(i) and (f)(2), Customs Regulations (19 CFR 141.61(e)(1)(i), (f)(2)), to remove a mandatory requirement to aggregate statistical information from multiple invoices;

3. Section 142.21(f), Customs Regulations (19 CFR 142.21(f)), to clarify the circumstances under which a district director may authorize release of merchandise from warehouse under a special permit; and

4. Section 142.22(b), Customs Regulations (19 CFR 142.22(b)), to clarify what documentation may be filed after merchandise is released under the immediate delivery procedure.

Discussion of Proposed Changes

Section 132.13(da)(1)

As amended by T.D. 79–221, the first sentence of § 132.13(a)(1)(ii) provides that "Except in emergency cases, as provided for in § 142.21(e)(2) of this chapter, absolute quota merchandise shall not be released under this immediate delivery procedure if the quota is nearing fulfillment." To correct an inconsistency in the regulations, this sentence subsequently was amended by T.D. 80–26, published in the Federal Register on January 21, 1980 (45 FR 3901), to provide that "Absolute quota merchandise shall not be released under the immediate delivery procedure if the quota is nearing fulfillment."

A question of interpretation has been raised as to whether absolute quota merchandise could be released under the immediate delivery procedure if the quota were not nearing fulfillment. To clarify this point, this document proposes to further amend § 132.13(a)(1)(ii) to provide that except as provided for in § 142.21(e)(2) (relating to perishable merchandise of a class approved by Headquarters subject to an absolute quota) and § 142.21(g) (relating to release of merchandise when authorized by Headquarters), absolute quota merchandise shall not be released under the immediate delivery procedure.

Section 132.12, Customs Regulations, relating to the opening of potentially filled quotas, provides a procedure in paragraph (c)(2) to be used in the event quantities specified on entry summaries for consumption or withdrawals for consumption shall be prorated against the quota quantity.

This document further proposes to amend § 132.13(a)(1) by deleting the last sentence of § 132.13(a)(1)(ii) and by adding a new § 132.13(a)(1)(iii) to provide that the procedure set forth under § 132.13(c)(2), relating to the opening of protentially filled quotas, also applies to tariff and absolute quota when the quota is nearing fulfillment.

Sections 141.61(e)(1)(i) and (f)(2)

Section 141.61 (e)(1)(i), as amended by T.D. 79–221, provides that if a class or kind of merchandise from the same country of origin subject to the same statistical reporting number is included in more than one invoice, the information shall be combined and reported under one statistical reporting number. That section also provides that when consolidating information from several invoices under one reporting number, a worksheet itemizing the entered value of the merchandise from each invoice shall be attached to the appropriate form.

Section 141.61(f)(2), as amended by T. D. 79–221, relating to values on multiple invoices, requires that the aggregate of the entered values of all the merchandise on each of the multiple invoices be shown on an attached worksheet.

The new procedures relating to aggregating statistical information were proposed initially to reduce the loss of statistical data because detailed information on line items of the Tariff Schedules of the United States Annotated (TSUSA) valued under $250 was not reported. By combining data under one TSUSA number, many line items valued under $250 could be included in the detailed data. Additionally, many TSUSA line items on Customs entry summaries could be eliminated, thus realizing significant savings in computer processing time.

The effective date for implementing these sections was September 10, 1979. However, after publication of T.D. 79–221 on August 9, 1979, a number of individual customhouse brokers, their trade association, and other interested parties advised Customs of serious problems and burdens they were experiencing in attempting to establish procedures to comply with the new regulations.

After reviewing this matter, Customs found there was merit to these complaints. Accordingly, a notice was published in the Federal Register as T. D. 79–248 on September 24, 1979 (44 FR 55001), delaying implementation of §§ 141.61 (e)(1)(i) and (f)(2), to January 1, 1980. Subsequently, on October 26, 1979, Customs field personnel were directed by Customs Headquarters to advise importers, brokers, and other interested parties that there would be an indefinite delay in implementing these sections.

Customs has determined that the problems and financial burden that the new requirements would impose on certain segments of the importing public outweigh the benefits to be gained in reducing processing costs and time, and providing more complete statistical data.

On the other hand, some importers and nonautomated brokers prefer to aggregate the TSUSA numbers. A practice has been established in many locations to permit entry summaries to be filed in this manner.

Therefore, Customs has determined to permit importers and brokers, at their option, to either:

1. Aggregate the TSUSA number regardless of the number of invoices involved; or

2. List the TSUSA number within each invoice.

This document proposes to amend §§ 141.61 (e)(1)(i) and (f)(2) to provide that the broker and importer may use either procedure.

Section 142.21(f)

Section 142.21(f), Customs Regulations (19 CFR 142.21(f)), as amended by T.D. 79–221, provides that at the discretion of the district director, merchandise may be released from a warehouse under a special permit provided the importer has on file one of the types of Customs bonds provided for in § 142.4, Customs Regulations (19 CFR 142.4).

The purpose of this provision is to avoid unnecessary delay in releasing merchandise from a bonded warehouse when an importer must travel a great distance from (1) the bonded warehouse to the customhouse to file the withdrawal for consumption with estimated duties attached, and (2) the customhouse to the bonded warehouse to obtain release of the merchandise.

Under § 142.21(f), an importer may obtain prompt release of merchandise from a bonded warehouse by filing Customs Form 3461. The importer may accumulate several of these forms over a period of days and then make one trip to the customhouse within the required 10-day period to file the withdrawal for consumption with estimated duties attached.

However, it appears that some importers, who do not travel great distances between their bonded warehouses and the customhouse and, therefore, can obtain prompt release of merchandise from the warehouse, may take advantage of the benefit of § 142.21(f) merely to forestall the payment of estimated duties until 10 days after release of the merchandise from the bonded warehouse.

This document proposes to amend § 142.21(f) to ensure that the procedure will not be used by some importers merely to delay payment of estimated duties. Section 142.21(f) would be amended to provide that the district director may authorize release from warehouse under a special permit only under the following circumstances:

1. The warehouse is located a considerable distance from the customhouse and actual release of the merchandise from the warehouse could not be effected within the next full busines day after the day of the payment of duty, and

2. The district has sufficient manpower to permit such practice.

Section 142.22(b)

Section 142.21, Customs Regulations (19 CFR 142.21), as amended by T.D. 79–221, provides that merchandise may be released under a special permit for immediate delivery, in accordance with section 448(b), Tariff Act of 1930, as amended, under circumstances relating to the following:

1. Contiguous countries,
2. Fresh fruits and vegetables,
3. Agency of the U.S. Government,
4. Articles of a trade fair,
5. Quota-class merchandise,
6. Release from warehouse followed by warehouse withdrawal for comsumption, and
7. When authorized by Headquarters.

Section 142.22(b), Customs Regulations (19 CFR 142.22(b)), lists the documentation which must be filed after the release of merchandise for which a special permit for immediate delivery had been issued. They are:

1. An entry summary for consumption, with estimated duties attached, an entry summary for warehouse, or an entry summary for entry under a temporary bond;
2. A withdrawal for consumption, with estimated duties attached;
3. An entry for transportation and exportation, immediate transportation without appraisement, or direct exportation; or
4. An application to destroy.

Section 142.28, Customs Regulations (19 CFR 142.28), provides, in part, that an entry for exportation, or for transportation and exportation, or an application to destroy, may be filed for merchandise released under a special permit for immedate delivery and later found to be prohibited.

A question of interpretation was raised by Customs personnel as to under what circumstances, relating to the release of merchandise under the immediate delivery procedure of § 142.21, would the transportation entries specified in § 142.22(b)(3) be used. Transportation entries may be used only with respect to the release of fresh fruits and vegetables under § 142.21(b) and absolute quota merchandise under § 142.21(e)(2). However, § 142.22(b)(3) does not set forth these two circumstances under which the transportation entries may be used. Therfore, an ambiguity may be raised concerning the proper document to be used.

In a related matter, § 142.28 provides for the use of an entry for exportation, or for transportation and exportation, or an application to destroy merchandise released and later found to be prohibited. However, neither § 142.22(b)(3) nor § 142.22(b)(4) makes any reference to mechandise released under the immediate delivery procedure and later found to be prohibited. An ambiguity also may be raised with regard to the proper documents to be used.

This document proposes to amend § 142.22(b)(3) to provide that the transportation entries shall be filed only in the circumstances under §§ 142.21 (b) and (e)(2), and to provide that an entry for exportation, or for transportation and exportation, shall be filed in the circumstance under § 142.28.

Similarly, this document proposes to amend § 142.22(b)(4) to provide that an application to destroy shall be filed in the circumstances under § 142.21 (b) and (e)(2), and § 142.28.

Two additional changes to § 142.22(b) are proposed in this document. It is proposed to amend § 142.22(b)(1) to clarify that the entry summary documents may be filed in any of the circumstances listed in § 142.21 except for merchandise released from warehouse under § 142.21(f). It is proposed to amend § 142.22(b)(2) to clarify that a withdrawal for consumption shall be filed only for merchandise released from warehouse under § 142.21(f).

Inapplicability of Executive Order 12044

This document is not subject to the provisions of the Treasury Department directive implementing E.O. 12044, "Improving Government Regulations" because T.D. 79–221, to which these amendments relate, was in process before May 22, 1978, the effective date of the directive. The proposal has been under extensive study by Customs, the International Trade Commission, and the Bureau of Census since T.D. 79–221 was published on August 19, 1979.

Authority

These amendments are proposed under the authority of R.S. 251, as amended (19 U.S.C. 66), section 484, 552, 553, 557, 624, 46 Stat. 722, as amended, 742, as amended, 744, as amended, 759, (19 U.S.C. 1484, 1552, 1553, 1557, 1624,); 92 Stat. 888, (Pub. L. 95–410), October 3, 1978).

Comments

Before adopting this proposal, consideration will be given to any written comments, preferably in triplicate, that are submitted timely to the Commissioner of Customs. Comments submitted will be available for public inspection in accordance with § 103.8(b), Customs Regulations (19 CFR 103.8(b)), during regular business hours at the Regulations and Research Division, Headquarters, U.S. Customs Service, 1301 Constitution Avenue NW., Room 2426, Washington, D.C. 20229.

Drafting Information

The principal author of this document was Charles D. Ressin, Regulations and Research Division, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

Proposed Amendments

It is proposed to amend Parts 132, 141, and 142, Customs Regulations (19 CFR Parts 132, 141, 142), in the following manner:

PART 132—QUOTAS

1. It is proposed to revise the first sentence of § 132.13(a)(1)(ii) to read as follows:

§ 132.13 Quotas after opening.

(a) *Procedure when nearing fulfillment.*—(1) *For release of merchandise.*

* * * * *

(ii) *Absolute.* Except as provided for in § 142.21 (e)(2) and (g) of this chapter, absolute quota merchandise shall not be released under the immediate delivery procedure.

2. It is proposed to remove the last sentence of § 132.13(a)(1)(ii).

3. It is proposed to add a new § 132.13(a)(1)(iii) to read as follows:

§ 132.13 Quotas after opening.

(a) *Procedure when nearing fulfillment.*—(1) *For release of merchandise.* * * *

(iii) *Quota Proration.* When it is determined that entry summaries for consumption or withdrawals for consumption must be amended to permit only the quantity of tariff-rate and absolute quota merchandise determined to be within the quota, the entry summaries for consumption or withdrawals for consumption must be returned to the importer for adjustment. The time of presentation for quota purposes in that event shall be the same as the time of the initial presentation of the entry summaries for consumption or withdrawals for consumption provided—

(A) An adjusted entry summary for consumption, or withdrawals for consumption, with estimated duties attached, is deposited within 5 working days after Headquarters authorizes release of the merchandise, and

(B) The importer takes delivery of the merchandise within 15 working days after release is authorized.

PART 141—ENTRY OF MERCHANDISE

1. It is proposed to revise § 141.61(e)(1)(i) to read as follows:

§ 141.61 Completion of entry and entry summary documentation.

* * * * *

(e) *Statistical information*—(1) *Information required on entry summary or withdrawal form*—(i) *Where form provides space*—(A) *Single invoice.* For each class or kind of merchandise subject to a separate statistical reporting number, the applicable information required by the General Statistical Headnotes, Tariff Schedules of the United States Annotated ("TSUSA"), shall be shown on the appraisement entry, Customs Form 7500; the entry summary, Customs Form 7501 or 7502; the transportation entry and manifest of goods, Customs Form 7512, when used to document an incoming vessel shipment proceeding to a third country by means of an entry for transportation and exportation, or immediate exportation; the rewarehouse entry, Customs Form 7519; the manufacturing warehouse entry, Customs Form 7521; the withdrawal form, Customs Form 7505 or 7506; or the record of vessel/aircraft foreigh repair or equipment purchase, Customs Form 226, in the space provided.

(B) *Multiple invoices.* If a class or kind of merchandise from the same country of origin subject to the same statistical reporting number is included in more than one invoice, the importer may, at his option (1) list each invoice separately on the appropriate form listed under paragraph (e)(1)(i)(A) of this section and for each class or kind of merchandise within each invoice subject to a separate statistical reporting number, report the applicable information required by the General Statistical Headnotes, Tariff Schedules of the United States Annotated (TSUSA); or (2) combine the information for each class or kind of merchandise and report it under one statistical reporting number for all invoices. When consolidating information from several invoices under one reporting number, a worksheet itemizing the entered value of the merchandise from each invoice in the manner prescribed in paragraph (f)(2)(ii) of this section shall be attached to the appropriate form.

§ 141.61 [Amended]

2. It is proposed to revise § 141.61(f)(2) to read as follows:

* * * * *

(f) *Value of each invoice.* (1) * * *

(2) *Multiple invoices.* (i) If the importer or his agent elects the first option specified in paragraph (e)(1)(i)(B) of this section, the information required to be restated by paragraph (f)(1) of this section for a single invoice shall be restated for each invoice. The required information shall be shown on a worksheet attached to the form or placed across columns (2a) or (2b) on Customs Form 7501 and 7502, and in the same general location on Customs Forms 7505, 7506, 7519, and 7521.

(ii) If the importer or his agent elects the second option specified in paragraph (e)(1)(i)(B) of this section, the information required to be restated by paragraph (f)(1) of this section for a single invoice shall be restated for each invoice. The final amount in the summary computation shall represent the aggregate of the entered values of all the merchandise on each of the multiple invoices. The required information shall be shown on an attached worksheet.

(iii) The worksheet also shall contain:

(A) A statistical reporting number restatement for the merchandise from each invoice subject to the same statistical reporting number from the same country of origin, and

(B) An aggregate total value which represents the entered value.

(iv) To permit the identification of the merchandise entered under each reporting number, each class or kind of merchandise from one country reported under a single statistical reporting number shall be coded identically on each invoice and on the worksheet.

PART 142—ENTRY PROCESS

1. It is proposed to revise § 142.21(f) to read as follows:

§ 142.21 Merchandise eligible for special permit for immediate delivery.

* * * * *

(f) *Release from warehouse followed by warehouse withdrawal for consumption.* Merchandise may be released from warehouse under a special permit—

(1) At the discretion of the district director when

(i) The warehouse is located a considerable distance from the customhouse and actual release of the merchandise from the warehouse could not be effected within the next full business day after the day of the payment of duty, and (ii) The district has sufficient manpower to permit such practice;

(2) The importer shall have on file one of the types of Customs bonds provided for in § 142.4; and

(3) The immediate delivery permit shall be annotated to state that a warehouse withdrawal for consumption will be filed for this merchandise.

2. It is proposed to revise § 142.22(b) to read as follows:

§ 142.22 Application for special permit for immediate delivery.

(a) * * *

(b) *Customs custody.* Merchandise for which a special permit for immediate delivery has been issued under § 142.21 shall be considered to remain in Customs custody until the filing of one of the following:

(1) An entry summary for consumption, with estimated duties attached, an entry summary for warehouse, or an entry summary for entry under a temporary importation bond, which may be filed in any of the circumstances under § 142.21 except for merchandise released from warehouse under § 142.21(f);

(2) A withdrawal for consumption, with estimated duties attached, which shall be filed only for merchandise released from warehouse under § 142.21(f);

(3) An entry for transportation and exportation, immediate transportation without appraisement, or direct exportation, which shall be filed in those circumstances under § 142.21(b) and (e)(2); or entry for transportation and exportation, or direct exportation, which shall be filed in the circumstances under § 142.28 or

(4) An application to destroy, which shall be filed in those circumstances

under §§ 142.21(b) and (e)(2), and § 142.28.

William T. Archey,

Acting Commissioner of Customs.

Approved: December 16, 1980.

Richard J. Davis,

Assistant Secretary of the Treasury.

[FR Doc. 80-40340 Filed 12-29-80; 8:45 am]

BILLING CODE 4810-22-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

[Docket No. 80N-0497]

Shipping Temperature Requirements for Certain Biological Products

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations to require that certain adsorbed biological products be maintained at temperatures between 1° and 10° C. This proposal is being made to assure that the safety, purity, and potency of the biological products are maintained during shipment.

DATE: Comments by March 2, 1981.

ADDRESS: Comments may be addressed to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Paul K. Hiranaka, Bureau of Biologics (HFB-620), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.

SUPPLEMENTARY INFORMATION: Diphtheria Toxoid Adsorbed, Tetanus Toxoid Adsorbed, and Pertussis Vaccine Adsorbed are vaccines that are used individually and in combination to produce active immunity against the diseases Diphtheria, Tetanus, and Pertussis, respectively. The dating periods for these vaccines, as prescribed in § 610.53(a) (21 CFR 610.53(a)), are based on data relating to usage, clinical experience or laboratory tests that establish the period beyond which the products cannot be expected beyond reasonable doubt to yield their specific results and retain their safety, purity, potency, and effectiveness provided that the products are maintained at the recommended temperatures. Biological products that may become unstable during transport when subjected for short periods of time to temperatures other than those prescribed in § 610.53 must be transported at temperatures prescribed in § 600.15(a) (21 CFR 600.15(a)) to assure that the products will retain their safety, purity, potency, and effectiveness throughout their dating periods.

The agency has reviewed and placed on file with the Dockets Management Branch, FDA, data from two studies concerning the physical appearance of biological products adsorbed on aluminum salts at temperatures below 2° C and above 8° C. One study was conducted by the agency's Bureau of Biologics and the other study was conducted by a licensed manufacturer of Diptheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed. The studies demonstrate that biological products adsorbed on aluminum salts undergo physical changes, ranging from the development of very granular suspensions to the development of large strands of aggregated material which are difficult or impossible to resuspend, when the products are subjected to freezing temperatures. Similar, but not as drastic, effects were observed in some products exposed to temperatures above 10° C.

Data available to the agency demonstrate the continued satisfactory stability when the products are stored at temperatures of 2° C to 8° C. Data on some biological products, such as live Measles, Mumps and Rubella Virus Vaccines demonstrate a decrease in potency when the products are not maintained at appropriate temperatures during shipment. As a result of the data demonstrating effects of inappropriate shipping temperatures on potency of live Measles, Mumps and Rubella Virus Vaccines, and because of the changes in the resuspension characteristics of Diptheria, Tetanus Toxoid and Pertussis Vaccines, adsorbed, alone or in combination, the agency believes that inappropriate shipping temperatures may cause unacceptalbe variability of the dose or may otherwise affect the desired or expected response resulting from the use of the products. Therefore, the agency believes it is in the interest of public health to require that Diptheria, Tetanus Toxoid and Pertussis Vaccines, Adsorbed, alone or in combination, be required to be maintained at temperatures between 1° C to 10° C during shipment. Accordingly, the agency is proposing to amend § 600.15 to require that certain adsorbed biological products be maintained at temperatures between 1° C and 10° C during shipment. Special precautions should be taken when shipping these products in chemical ice or wet ice to assure that the ice does not contact the product container and lower the temperature below 1° C.

It should be noted that existing § 600.15(b) provides for exemptions from the shipping temperature requirements. Manufacturers proposing such an exemption for their adsorbed vaccines should submit supporting data to the Director, Bureau of Biologics, in the form of an amendment to their product license application. The agency also encourages all interested persons to submit available data relating the physical effects resulting from storage at temperatures below 1° C and above 10° C and the effects on the safety, purity, potency, and effectiveness of these products.

The agency has determined pursuant to 21 CFR 25.24(d)(10) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 701, 52 Stat. 1040-1042 as amended, 1050-1051 as amended, 52 Stat. 1055-1056 as amended (21 U.S.C. 321, 352, 371)); the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 600 in § 600.15(a) by alphabetically adding "Diphtheria and Tetanus Toxoids Adsorbed"; "Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed"; "Diphtheria Toxoid Adsorbed"; "Pertussis Vaccine Adsorbed"; "Tetanus and Diphtheria Toxoids Adsorbed (For Adult Use)"; and "Tetanus Toxoid Adsorbed" to read as follows:

§ 600.15 Temperatures during shipment.

* * * * *

(a) *Products*

Product	Temperature
* * * * *	
Diphtheria and tetanus toxoids adsorbed.	Between 1° and 10° C.
Diphtheria and tetanus toxoids and pertussis vaccine adsorbed.	Do.
Diphtheria Toxoid adsorbed	Do.
* * * * *	
Pertussis vaccine adsorbed	Between 1° and 10° C.
* * * * *	
Tetanus and diphtheria toxoids adsosrbed (for adult use).	Between 1° and 10° C.
Tetanus toxoid adsorbed	Do.
* * * * *	

* * * * *

Interested persons may, on or before March 2, 1981 submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, as amended by Executive Order 12221,, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Dockets Management Branch, Food and Drug Administration.

Dated: December 18, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–40285 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[EE–17–78]

Custodial Accounts for Regulated Investment Company Stock; Amendment of Notice of Proposed Rulemaking

AGENCY: Internal Revenue Service, Treasury.

ACTION: Amendment of notice of proposed rulemaking.

SUMMARY: This document contains proposed amendments to a notice of proposed rulemaking which was published in the Federal Register on February 10, 1978 (43 FR 5852). That notice contains proposed regulations relating to custodial accounts for regulated investment company stock. Changes to the applicable tax law were made by the Employee Retirement Income Security Act of 1974, the Tax Reform Act of 1976, and the Revenue Act of 1978. The regulations would provide the guidance needed to comply with those Acts and would affect public school teachers and employees of certain tax exempt organizations.

DATES: Written comments and requests for a public hearing must be delivered or mailed by March 2, 1981. The amendments and the original notice of proposed rulemaking are proposed to be effective for contributions to custodial accounts made after December 31, 1973.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T (EE–17–78), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: H. B. Hartley of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224, Attention: CC:LR:T, 202–566–3287 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR Part 1) relating to custodial accounts for regulated investment company stock under section 403(b)(7) of the Internal Revenue Code of 1954. On February 10, 1978, the **Federal Register** published proposed amendments to the Income Tax Regulations under section 403 of the Internal Revenue Code (43 FR 5852). The regulations in this document are being proposed in order to replace portions of those earlier proposed regulations which were rendered obsolete by section 154 of the Revenue Act of 1978 (92 Stat. 2801, 26 U.S.C. 403). The proposed regulations are issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (68A Stat. 917, 26 U.S.C. 7805).

The proposed regulations published in the **Federal Register** on February 10, 1978, provided that a section 403(b)(7) custodial account could make no distributions to the employee until the employee attained age 65, unless the employee (A) died or became disabled, or (B) attained age 55 and left the service of the employer. Section 154 of the Revenue Act of 1978 changed this requirement. That Act provides that no distributions can be made from a custodial account before the employee attains age 59½, unless the employee (A) dies or becomes disabled, (B) separates from service, or (C) encounters financial hardship.

Comments and Requests for A Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably six copies) to the Commissioner of Interior Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be published in the **Federal Register.** Persons who requested a public hearing on the original notice of proposed rulemaking, as published February 10, 1978, need not again request a hearing if their original comments involved only issues not affected by the amendments contained in this notice. Any such persons who do not submit comments and request a public hearing on these amendments will be individually contacted by the Internal Revenue Service to ascertain whether they still desire to testify at any hearing held on the proposed regulations. Persons who originally commented and requested a public hearing on issues affected by these amendments will not be so contacted.

Drafting Information

The principal author of these proposed regulations is H. B. Hartley of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations, both on matters of substance and style.

Proposed amendments to the regulations

The proposed amendments to 26 CFR Part 1 are as follows:

Paragraph 1. Paragraph (h)(2)(vi) of proposed § 1.403(b)–1, published in the **Federal Register** on February 10, 1978, (43 FR 5852), is amended by striking the third sentence thereof.

Par. 2. Paragraphs (h)(2)(vii) and (h)(2)(viii) of proposed § 1.403(b)–1, published in the **Federal Register** on February.10, 1978, (43 FR 5852), are redesignated as paragraphs (h)(2)(viii) and (h)(2)(ix) respectively, and a new paragraph (h)(2)(vii) is added to read as follows:

§ 1.403(b)–1 Taxability of beneficiary under annuity purchased by a section 501(c)(3) organization or public school.

* * * * *

(h) *Custodial accounts*—* * *

(2) *Description of custodial account.*

* * *

(vii) The custodial agreement must provide that the custodian is not to make any distributions to the employee or to his or her beneficiaries before the

employee attains age 59½, unless the employee (A) becomes disabled or dies, (B) leaves the service of the employer, or (C) encounters financial hardship, as determined under paragraph (h)(13).

* * *

Par. 3. Paragraph (h)(4)(ii) of proposed § 1.403(b)–1(h), published in the **Federal Register** on February 10, 1978, (43 FR 5852), is amended by adding the following new sentence to the end thereof:

§ 1.403(b)–1 Taxability of beneficiary under annuity purchased by a section 501(c)(3) organization or public school.

* * * * *

(h) *Custodial accounts*—* * *

(4) *Distributions*—* * *

(ii) * * * Any purchase and distribution of an annuity contract under this subdivision (ii) can occur only at a time when distributions are otherwise permitted under the provisions of paragraph (h)(2) (vi) or (vii).

Par. 4. A new paragraph (h)(13) to read as follows is added at the end of proposed § 1.403(b)–1, published in the **Federal Register** on February 10, 1978 (43 FR 5852):

§ 1.403(b)–1 Taxability of beneficiary under annuity purchased by a section 501(c)(3) organization or public school.

* * * * *

(h) *Custodial accounts*—* * *

(13) *Determination of financial hardship*—(i) For purposes of paragraph (h)(2)(vii), distribution will be on account of financial hardship if—

(A) The distribution is necessary in light of immediate and heavy financial needs of the employee,

(B) The distribution would meet the requirements for a hardship distribution under a profit-sharing plan qualified under section 401(a) of the Code, and

(C) An independent person or persons (designated as provided in paragraph (h)(13)(iii)) has determined, in accordance with uniform and nondiscriminatory standards established at the time that person or persons are designated, that the conditions described in (A) and (B) above exist.

(ii) No distribution based upon financial hardship can exceed the amount determined pursuant to paragraph (h)(13)(iii) to be required to meet the immediate financial need created by the hardship and not reasonably available from other resources of the employee.

(iii) No distributions based upon financial hardship shall be made except following written notification to the custodian by an independent person (or persons) of a determination by that person of the existence of a qualifying financial hardship and of the amount required to be distributed to meet the need created by the hardship. The independent person must be designated by the employer before any distributions based upon financial hardship are made. The independent person can be any person other than the employee, the custodian, an employee or director of the regulated investment company, or any other person who would be a disqualified person within the meaning of section 4975 if the custodial account were a qualified plan under section 401. All determinations by the independent person must be made in accordance with uniform and nondiscriminatory standards which are established at the time the person is designated.

William E. Williams,

Commissioner of Internal Revenue.

[FR Doc. 80–40461 Filed 12–29–80; 8:45 am]

BILLING CODE 4830–01–M

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26 CFR Part 1

[LR–261–79]

Income Tax; Charitable Contribution of Property Elected Under the Asset Depreciation Range System

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains a proposed regulation relating to the treatment of eligible property elected under the Asset Depreciation Range System and retired by charitable contribution.

DATES: Written comments and requests for a public hearing must be delivered or mailed by March 2, 1981. The amendment to the regulations is proposed to be effective with respect to property retired after December 30, 1980.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T (LR–261–79), Washington, D.C. 20224.

FOR FURTHER INFORMATION, CONTACT: Harold T. Flanagan, Jr., of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224 (Attention: CC:LR:T, 202–566–3459).

SUPPLEMENTARY INFORMATION:

Background

This document contains a proposed amendment to the Income Tax Regulations (26 CFR Part 1) under section 167 of the Internal Revenue Code of 1954. This amendment to the regulations is proposed to be issued under the authority contained in sections 167 and 7805 of the Internal Revenue Code (85 Stat. 508, 26 U.S.C. 167; 68A Stat. 917, 26 U.S.C. 7805).

General Rule

The proposed regulation would require that a charitable contribution of eligible property which is elected under the Asset Depreciation Range system be treated as an extraordinary retirement. Upon retirement of the asset, the unadjusted basis of the contributed property will be removed from the vintage account and an adjustment will be made to the depreciation reserve.

Comments and Requests for a Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably six copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be published in the **Federal Register.**

Drafting Information

The principal author of this proposed regulation is Harold T. Flanagan, Jr., of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both on matters of substance and style.

Proposed amendment to the regulations

The proposed amendment to 26 CFR Part 1 is as follows:

Section 1.167(a)–11(d)(3)(ii) (relating to definitions of ordinary and extraordinary retirements) is amended by adding a new subdivision (*d*) after subdivision (*c*), to read as follows:

§ 1.167(a)–11 Depreciation based on class lives and asset depreciation ranges for property placed in service after December 31, 1970.

* * * * *

(d) *Special rules for salvage, repairs and retirements.* * * *

(3) *Treatment of retirements.* * * *

(ii) *Definitions of ordinary and extraordinary retirements.* * * *

(*d*) The asset is section 1245 property which is retired after December 30, 1980 by a charitable contribution for which a

deduction is allowable under section 170.

* * * * *

William E. Williams,

Acting Commissioner of Internal Revenue.

[FR Doc. 80-40499 Filed 12-29-80; 8:45 am]

BILLING CODE 4830-01-M

26 CFR Part 301

[EE-28-78]

Inspection of Applications for Tax Exemption and Similar Material

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to public inspection of applications for tax exemption, applications for determination of the qualification of pension and other plans, and other related material. Changes to the applicable law were made by the Employee Retirement Income Security Act of 1974 and the Tax Reform Act of 1976. The regulations would provide the public guidance on how the documents may be obtained for inspection, and would affect all persons wishing to inspect the documents, as well as those persons submitting them.

DATES: Written comments and requests for a public hearing must be delivered or mailed by March 2, 1981.

The amendments are generally proposed to be effective for applications for tax exemption filed after October 31, 1976, and applications for determination letters for pension and other plans that are filed after September 2, 1974.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T:EE-28-78, Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: Paul G. Accettura of the Employee Plans and Exempt Organizations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224, Attention: CC:LR:T:EE-28-78, 202-566-3422 (Not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Regulations on Procedure and Administration (26 CFR Part 301) under section 6104(a)(1)) of the Internal Revenue Code of 1954. The amendments are proposed to conform the regulations under section 6104(a)(1)(A) to section 1201(d) of the Tax Reform Act of 1976 (90 Stat. 1667), and the regulations under section 6104(a)(1) (B), (C) and (D) to section 1022(g) of the Employee Retirement Income Security Act of 1974 (88 Stat. 940). The amendments are to be issued under the authority contained in sections 6104(a)(1)(A), 6104(a)(1)(B) and 7805 of the Internal Revenue Code of 1954 (72 Stat. 1660, 88 Stat. 940, 68A Stat. 917; 26 U.S.C. 6104(a)(1)(A), 6104(a)(1)(B), 7805).

Public Inspection of Applications for Tax Exemption

Code section 6104(a)(1)(A) was amended by the Tax Reform Act of 1976. Prior to the amendment, the public could inspect approved applications for tax exemption and supporting documents filed by tax exempt organizations. The amendment extends the material open to public inspection to include documents or letters issued by the Internal Revenue Service which relate to approved applications for tax exemption.

Public Inspection of Applications for Determination Letters Filed for Deferred Compensation Plans

Code section 6104(a)(1) was also amended by the Employee Retirement Income Security Act of 1974 ("ERISA"). ERISA authorizes public inspection of applications for determination letters and supporting documents filed after September 2, 1974, concerning the qualification of a pension, profit-sharing, stock bonus, annuity or bond purchase plan, or an individual retirement account or annuity. It also authorizes public inspection of applications for tax exemption and supporting documents filed for a related trust or custodial account. Any letter or document issued by the Internal Revenue Service after September 2, 1974, which relates to the qualification of a plan or account, or the exempt status of a related trust or custodial account, is also available for public inspection.

Applications and other documents are not open to public inspection, however, if a plan has fewer than 26 participants, inspection is then limited to plan participants.

Material Withheld From Inspection

An applicant may request that information relating to a trade secret, patent, process, style of work, or apparatus not be open to public inspection. The information will be withheld from public inspection if the Secretary determines that public disclosure would adversely affect the applicant. In the case of pension or other plan, the information will also be withheld from inspection by plan participants.

National defense information is not open to inspection by the public or a plan participant whether or not the applicant requests that it be withheld. In the case of a pension or other plan, information from which an individual's compensation (including deferred compensation) may be ascertained is also not open to inspection by the public or a plan participant whether or not the applicant requests that it be withheld.

Comments and Requests for a Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably eight copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be publish in the **Federal Register.**

Drafting Information

The principal author of these proposed regulations was Paul G. Accettura of the Employee Plans and Exempt Organizations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service participated in developing the regulation, both on matters of substance and style.

Proposed Amendments to the Regulations

The proposed amendments to 26 CFR Part 301 are as follows:

Paragraph 1. The following new §§ 301.6104(a)-1 through 301.6104(a)-6 are added in the appropriate place:

§ 301.6104(a)-1 Public inspection of material relating to tax-exempt organizations.

(a) *Application for tax exemption and supporting documents.* If the Internal Revenue Service determines that an organization described in section 501(c) or (d) is exempt from taxation for any taxable year, the application for tax exemption upon which the determination is based, together with any supporting documents, is open to public inspection. Some applications for tax exemption have been destroyed and therefore are not available for inspection. For purposes of determining the availability for public inspection, a claim for tax exemption filed to reestablish exempt status after denial

thereof under the provisions of section 503 or 504 (as in effect on December 31, 1969), or under the corresponding provisions of any prior revenue law, is considered an application for tax exemption.

(b) *Letters or documents issued by the Internal Revenue Service with respect to an application for tax exemption.* If an application for tax exemption is filed with the Internal Revenue Service after October 31, 1976, and is open to public inspection under paragraph (a) of this section, then any letter or document issued to the applicant by the Internal Revenue Service which relates to the application is also open to public inspection. For rules relating to when a letter or document is issued, see § 301.6110–2(h). Letters or documents to which this paragraph applies include, but are not limited to—

(1) Favorable rulings and determination letters (see § 601.201(n)(1)) issued in response to applications for tax exemption,

(2) Technical advice memoranda (see § 601.201(n)(9)) issued with respect to an approved, or subsequently approved, application for tax exemption, and

(3) Letters issued in response to an application for tax exemption that propose a finding that the organization is not entitled to be exempt from tax, if the organization is subsequently determined, on the basis of the application, to be exempt from tax.

(c) *Requirement of exempt status.* An application for tax exemption, supporting documents, and letters or documents issued by the Internal Revenue Service that relate to the application will not be open to public inspection before the organization filing the application is determined, on the basis of the application, to be exempt from taxation for any taxable year. On the other hand, if the organization is determined to be exempt for any taxable year, the material will not be withheld from public inspection on the ground that the organization is determined not to be exempt for any other taxable year.

(d) *Documents included in the term "application for tax exemption". For purposes of this section—*

(1) *Prescribed application form.* If a form is prescribed for an organization's application for tax exemption, the application for tax exemption includes the form and all documents and statements the Internal Revenue Service requires to be filed with the form.

(2) *No prescribed application form.* If no form is prescribed for an organization's application for tax exemption, the application for tax exemption includes:

(i) The application letter and a copy of the articles of incorporation, declaration of trust, or other instrument of similar import that sets forth the permitted powers or activities of the organization,

(ii) The bylaws or other code of regulations,

(iii) The latest financial statement showing assets, liabilities, receipts and disbursements,

(iv) Statements showing the character of the organization, the purpose for which it was organized, and its actual activities,

(v) Statements showing sources of income and receipts and the disposition thereof, and whether or not any income or receipts is credited to surplus or may insure to the benefit of any private shareholder or individual, and

(vi) Any other statements or documents the Internal Revenue Service requires to be filed with the application letter.

(3) *Prohibited transactions.* An application for tax exemption does not include a request for a ruling as to whether a proposed transaction is a prohibited transaction under section 503.

(e) *Supporting documents defined.* For purposes of this section, "supporting documents", as used with respect to an application for tax exemption, means any statement or document not described in paragraph (d) of this section that is submitted by an organization is support of its application. For example, a legal brief submitted in support of an application for tax exemption is a supporting document.

(f) *Statement of exempt status.* In addition to having the opportunity to inspect material relating to tax exempt organizations, a person may request a statement setting forth the following information:

(1) The subsection and paragraph of section 501 (or the corresponding provision of any prior revenue law) under which an organization has been determined, on the basis of an application open to public inspection, to qualify for exemption from taxation, and

(2) Whether the organization is currently held to be exempt.

The request for the statement must be made in the same manner as a request for inspection (see § 301.6104(a)–6).

(g) *Withholding of certain information from public inspection.* For rules relating to certain information contained in an application for tax exemption and related material which will be withheld from public inspection, see § 301.6104(a)–5(a).

(h) *Procedures for inspection.* For rules relating to procedures for public inspection of applications for tax exemption and related material, see § 301.6104(a)–6.

(i) *Material not open to public inspection under section 6104 or 6110.* Under section 6110 certain written determinations issued by the Internal Revenue Service are made available for public inspection. Section 6110 does not apply, however, to matters on which the determination of availability for public inspection is made under section 6104. Accordingly, § 301.6110–1(a) describes matters which, for purposes of section 6110, are considered within the ambit of section 6104. Some determination letters and other documents relating to tax exempt organizations that are not open to public inspection under section 6104(a)(1)(A) and this section are nevertheless within the ambit of section 6104 for purposes of section 6110. These determination letters and other documents are therefore not available for public inspection under either section 6104 or section 6110. They include, but are not limited to—

(1) Unfavorable rulings or determination letters (see § 601.201(n)) issued in response to applications for tax exemption,

(2) Rulings or determination letters revoking or modifying a favorable determination letter (see § 601.201(n)(6)),

(3) Technical advice memoranda (see § 601.201(n)(9)) relating to a disapproved application for tax exemption or the revocation or modification of a favorable determination letter,

(4) Any letter or document filed with or issued by the Internal Revenue Service relating to whether a proposed or accomplished transaction is a prohibited transaction under section 503,

(5) Any letter or document filed with or issued by the Internal Revenue Service relating to an organization's status as an organization described in section 509(a) or 4942(j)(3), unless the letter or document relates to the organization's application for tax exemption, and

(6) Any other letter or document filed with or issued by the Internal Revenue Service which, although it relates to an organization's tax exempt status as an organization described in section 501 (c) or (d), does not relate to that organization's application for tax exemption, within the meaning of paragraph (d).

§ 301.6104(a)–2 Public inspection of material relating to pension and other plans.

(a) *Material open to inspection.* Except as provided in § 301.6104(a)–4 with respect to plans having fewer than 26 participants, an application for a determination letter which is filed with

the Internal Revenue Service after September 2, 1974, together with supporting documents filed by the applicant in support of the application, will be open to public inspection under section 6104(a)(1)(B) (i) and (ii). An application for a determination letter and supporting documents will be open to public inspection whether or not the application is withdrawn by the applicant, and whether or not the Internal Revenue Service determines that the plan, account, or annuity to which the application relates is qualified or that any related trust or custodial account is exempt from tax.

(b) *Documents included in the term "application for a determination letter"*—(1) *Employees' plans and individual retirement plans.* For purposes of this section, the term "application for a determination letter" includes the documents that an applicant files with respect to a request that the Internal Revenue Service determine the qualification of—

(i) A pension, profit-sharing, or stock bonus plan under section 401(a),

(ii) An annuity plan under section 403(a), or

(iii) A bond purchase plan under section 405(a), or

(iv) An individual retirement account or annuity described in section 408 (a), (b) or (c).

(2) *Tax exempt trusts or custodial accounts.* The term "application for a determination" letter also includes the documents an applicant files with respect to a request that the Internal Revenue Service determine the exemption from tax under section 501(a) of an organization forming part of a plan or account described in subparagraph (1) of this paragraph, or a custodial account described in section 401(f).

(3) *Master, prototype and pattern plans.* The term "application for a determination letter" also includes documents which an applicant files with respect to a request for approval of a master, prototype, pattern or other such plan or account.

(4) *Prescribed forms and application letters.* With respect to an application for a determination letter described in this paragraph (b) for which a application form is prescribed, the application for a determination letter includes the form and all documents and statements required to be filed in connection with the form. With respect to an application for a determination letter for which no application form is prescribed, the application for a determination letter includes the application letter and all documents and statements the Internal Revenue Service requires to be submitted with the application letter.

(c) *Documents not constituting an "application for a determination letter".* The following are not applications for a determination letter for purposes of this section:

(1) An incomplete application that is returned without action for proper completion,

(2) An application that is returned without action to the applicant for failure to notify all interested parties in accordance with the regulations under section 7476 (relating to declaratory judgments), and

(3) A request for a ruling as to whether a proposed transaction is a prohibited transaction under section 4975.

(d) *Supporting documents.* "Supporting documents", as used with respect to an application for a determination letter which is open to public inspection under this section, means any statement or document submitted in support of the application which is not specifically required by the application form or the Internal Revenue Service. For example, a legal brief submitted in support of an application for a determination letter is a supporting document.

(e) *Applicant.* For purposes of this section, § 301.6104(a)–3 (relating to Internal Revenue Service letters and documents open to public inspection) and § 301.6104(a)–5) relating to the withholding of certain information from public inspection), an "applicant" includes, but is not limited to, an employer, plan administrator (as defined in section 414(g)), labor union, bank, or insurance company that files an application for a determination letter.

§ 301.6104(a)–3 Public inspection of Internal Revenue Service letters and documents relating to pension and other plans.

(a) *In general.* Except as provided in § 301.6104(a)–4 with respect to plans having fewer than 26 participants, a letter or other document issued by the Internal Revenue Service after September 2, 1974, is open to public inspection under section 6104(a)(1)(B)(iv) and this section, if it is issued with respect to—

(1) The qualification of a pension, profit-sharing or stock bonus plan under section 401(a), an annuity plan under section 403(a), a bond purchase plan under section 405(a), or an individual retirement account or annuity described in section 408 (a), (b) or (c),

(2) The exemption from tax under section 501(a) of an organization forming part of such a plan or account, or a custodial account described in section 401(f), or

(3) The approval of a master, prototype, pattern or other such plan or account.

(b) *Scope.* Internal Revenue Service letters and documents open to public inspection under section 6104(a)(1)(B)(iv) and this section are not limited to those issued in response to an application for a determination letter described in § 301.6104(a)–2. They are, however, limited to those issued by the Internal Revenue Service to the person or organization which either did or could file an application for a determination letter for the plan, account or annuity to which the letter or document relates. If such person or organization designates a representative having a power of attorney, however, then the letter or document will be open to inspection if issued to the representative. For rules relating to when a letter or document is issued, see § 301.6110–2(h). Internal Revenue Service letters and documents are open to public inspection under section 6104(a)(1)(B)(iv) and this section whether or not the Internal Revenue Service determines that the plan, account or annuity to which the letter or document relates is qulified or that any related trust or custodial account is exempt from tax.

(c) *Letters and documents open to public inspection.* Internal Revenue Service letters and documents open to public inspection under section 6014(a)(1)(B)(iv) and this section include, but are not limited to:

(1) Determination letters relating to the qualification of a plan, account or annuity described in paragraph (a) (1) of this section (see § 601.201 (o)),

(2) Technical advice memoranda (see § 601.201(n)(9)) relating to the issuance of such determination letters,

(3) Technical advice memoranda relating to the continuing qualification of a plan, account or annuity previously determined to be qualified, or to the qualification of a plan, account or annuity for which no determination letter has been issued,

(4) Letters or documents revoking or modifying any prior favorable determination letter or denying the qualification of a plan, account or annuity for which no determination letter has been issued,

(5) Determination letters relating to the exemption from tax of a trust or custodial account described in paragraph (a) (2) of this section (see § 601.201 (o) (2) (i) (*b*)), or

(6) Opinion letters relating to the acceptability of the form of any master, prototype or other such plan or account

(see § 601.201 (p) (q)) or notification letters issued with respect to pattern plans.

(d) *Extent letter or document open to public inspection.* A letter or document issued by the Internal Revenue Service is open to public inspection under section 6104(a) (1) (B) (iv) and this section only to the extent it relates directly to the qualification of a plan, account or annuity, the exemption from tax of a related organization or custodial account, or the approval of a master, prototype, pattern or other such plan. Any part of the letter or document which does not directly relate to such qualification, exemption or approval is not open to public inspection. For example, a letter to an employer which concludes that an employees' plan is not qualified and the related trust is not tax exempt will be open to public inspection. However, that same letter may also assert an income tax deficiency because employer contributions to the trust are, therefore, not deductible. In such a case, that part of the letter relating to the tax deficiency will be deleted before the letter is opened to public inspection.

(e) *Letters or documents issued with respect to tax return examination.* In the case of an examination of a taxpayer's return or consideration of a taxpayer's claim for credit or refund, no letter or document issued to the taxpayer before the preliminary or "30-day" letter described in § 601.105 (d) (1) is issued to the taxpayer will be open to public inspection under section 6104 (a) (1) (B) (iv) and this section. The "30-day" letter and any statutory notice of deficiency subsequently issued to the taxpayer under section 6212 will be open to public inspection to the extent provided in paragraph (d) of this section. If any letter or document other than a statutory notice of deficiency is issued to the taxpayer after the "30-day" letter is issued, such letter or document will be open to inspection to the extent provided in paragraph (d) of this section only if it finally resolves or otherwise disposes of a plan qualification or tax exemption issue raised in the "30-day" letter.

(f) *Letters or documents issued after September 2, 1974.* Section 6104(a) (1) (B) (iv) and this section apply to letters or documents issued by the Internal Revenue Service after September 2, 1974, even though the relevant application for a determination letter or other initiating correspondence from the applicant was filed with the Internal Revenue Service before September 2, 1974.

§ 301.6104(a)–4 Requirement for 26 or more plan participants.

(a) *Inspection by plan participants.* In the case of a plan, annuity or account described in § 301.6104(a)–2(b) and § 301.6104(a)–3(a) that has fewer than 26 participants, material described in §§ 301.6104(a)–2 and 301.6104(a)–3 as open to public inspection is only open to inspection by a plan participant or the participant's authorized representative. This limitation does not apply, however, with respect to documents which an applicant files with respect to a request for approval of a master, prototype, pattern or other such plan (see § 301.6104(a)–2(b)(3)) or to opinion, notification or other such letters issued by the Internal Revenue Service with respect to such plans (see § 301.6104(a)–3(a)(3)).

(b) *Determining number of plan participants—(1) In general.* For purposes of determining whether a plan has fewer than 26 participants, the number of plan participants will be the number indicated on the most recent annual return filed for the plan under section 6058. Where an annual return indicates the number of participants both at the beginning and end of the plan year, the number indicated on the return means the number at the end of the plan year. If no annual return has been filed for the plan, then the number of plan participants will be the number indicated on the most recent application for a determination letter filed for the plan. If, however, the number of plan participants is increased prior to final Internal Revenue Service action on the application, the number of plan participants will be that increased number.

(2) *Decreasing number of plan participants.* If a plan having 26 or more participants, as indicated on an annual return or application for a determination letter, subsequently files an annual return indicating fewer than 26 plan participants, then material relating to the plan which is issued or received by the Internal Revenue Service after the date the annual return is filed will be open to inspection only by plan participants or their authorized representatives. Similarly, if a plan having 26 or more participants as indicated on an annual return or an application for a determination letter, subsequently files an application for a determination letter which indicates fewer than 26 plan participants, then that application and related material as well as any other material relating to the plan which is received or issued by the Internal Revenue Service after the date of receipt of that application, will be open to inspection only by plan participants or their authorized representatives. In either case, material open to public inspection pursuant to the number of plan participants indicated on previous annual returns or applications for a determination letter will remain open to public inspection.

(3) *Increasing number of plan participants.* If a plan having fewer than 26 plan participants, as indicated on an annual return or application for a determination letter, files a subsequent return or application indicating 26 or more plan participants, all the plan's prior applications and other material received or issued by the Internal Revenue Service after September 2, 1974, will be open to public inspection regardless of the number of plan participants indicated on any prior return or application.

(c) *Plan participant.* Solely for purposes of determining who is a plan participant permitted to inspect material relating to a plan having fewer than 26 participants, the term "plan participant" includes, but is not limited to, former employees (such as certain retired and terminated employees) who have a nonforfeitable right to benefits under the plan. An individual who is merely a beneficiary of an employee or former emplyee is not a plan participant, unless the individual is a beneficiary of a deceased former employee and is receiving benefits or entitled to receive future benefits under the plan. The term "plan participant" also includes the administrator, executor, or trustee of the estate of a deceased plan participant. That material may be available for inspection to an individual under this paragraph does not constitute a determination by the Internal Revenue Service that the individual is a plan participant for any purpose other than inspection under section 6104 (a) (1) (B).

(d) *Authorized representative.* "Authorized representative" means the representative of a plan participant designated by the participant in writing to inspect material described in §§ 301.6104(a)–2 and 301.6104(a)–3. The document designating the authorized representative must be signed by the plan participant and must specify that the representative is authorized to inspect the material. The document, or a copy, must be filed with the office of the Internal Revenue Service in which the authorized representative is to inspect the material. A copy which is reproduced by a photographic process need not be certified as a true and corrrect copy of the original.

§ 301.6104(a)–5 Withholding of certain information from public inspection.

(a) *Tax exempt organizations*—(1) *Trade secrets, patents, processes, styles of work, or apparatus.* An organization whose application for tax exemption is open to public inspection under section 6104(a)(1)(A) and § 301.6104(a)–1 may in writing request the withholding of information contained in the application or supporting documents which relates to any trade secret, patent, process, style of work, or apparatus of the organization. The information will be withheld from public inspection if the Commissioner determines that the disclosure of such information would adversely affect the organization. Requests for withholding information from public inspection should be filed with the office with which the organization files the documents containing the information. The request must clearly identify the material desired to be withheld (the document, page, paragraph, and line) and must state why the information should not be open to public inspection. The organization will be notified of the Commissioner's determination as to whether the information will be withheld from public inspection.

(2) *National defense material.* The Internal Revenue Service will withhold from public inspection any information which is submitted by an organization whose application for tax exemption is open to inspection under section 6104(a)(1) (C) or (D) should not be included in an application for a determination letter, supporting documents, or any other document open to inspection under section 6104(a)(1)(A) and § 301.6104(a)–1, if the Commissioner determines that public disclosure would adversely affect the national defense.

(b) *Pension and other plans*—(1) *Applicant's exclusion of certain information.* Except as provided in subparagraph (2) of this paragraph, information that, in the opinion of the applicant, is of the type described in section 6104(a) (1) (B). Accordingly, an applicant should not include in an application for a determination letter or supporting documents confidential compensation information as described in subparagraph (4) of this paragraph. Neither should an applicant include information relating to any trade secret, patent, process, style of work or apparatus, the disclosure of which would be adverse to the applicant.

(2) *Exception for separate document.* The rule that an applicant should exclude from an application for a determination letter or other documents information of the type in section 6104(a) (1) (C) or (D) does not apply—

(i) In the case of the separate schedule to certain applications for a determination letter which is provided for the purpose of setting forth confidential compensation information (as described in subparagraph (4) of this paragraph) which must be submitted by the applicant,

(ii) If the applicant determines that it is impossible to provide the Internal Revenue Service with sufficient information to support an application for a determination letter without submitting what is believed to be information of the type described in section 6104(a)(1)(C) or (D), or

(iii) If the Internal Revenue Service requests that the applicant submit information of the type described in section 6104(a)(1)(C) and (D).

In a case described in subdivision (ii) or (iii) of this subparagraph, the applicant is to set forth the information in a document separate from the remainder of the application for a determination letter or other documents. The separate document is to state why the information is to be withheld from public inspection under section 6104(a)(1)(C) or (D). If the Internal Revenue Service has not requested the information, the separate document is to also state why it is impossible to provide the Internal Revenue Service sufficient information to support the application for a determination letter without including information which is to be withheld. The separate document should clearly identify the relevant portion of the application for a determination letter or other document (the document, page, paragraph, and line) to which the information set forth in the separate document relates. The Internal Revenue Service will withhold from public inspection (including inspection by a plan participant or authorized representative) information contained in the separate document if the Commissioner determines that the information is in fact information of the type described in section 6104(a)(1)(C) or (D), and, in the case of information relating to any trade secret, patent, process, style of work or apparatus, the Commissioner further determines that disclosure would be adverse to the applicant.

(3) *National defense material.* The Internal Revenue Service will withhold from public inspection (including inspection by a plan participant or authorized representative) any information which is included in an application for a determination letter or supporting documents if the Commissioner determines that public disclosure would adversely affect the national defense. The information will be withheld whether or not submitted on a separate document pursuant to subparagraph (2) of this paragraph.

(4) *Confidential compensation information.* If an application for a determination letter, supporting document, or related letter or document referred to in section 6104(a)(1)(B) and §§ 301.6104(a)–2 and 301.6104(a)–3 contains information (including aggregate figures) from which an individual's compensation (including deferred compensation) may be ascertained, that information is not open to public inspection (including inspection by a plan participant or authorized representative). Confidential compensation information includes the amount of benefit a specific plan participant may expect to receive at normal or early retirement age and the amount of the employer's contributions under the plan that may be allocated to a specific plan participant. However, so long as a plan has more than one participant, the amount of benefit provided under the plan to plan participants, in general, at normal or early retirement, age, or the amount of the employer's contributions under the plan that are allocable to plan participants, in general, does not constitute confidential compensation information. Further, a description of the numbers of individuals covered and not covered by a plan, listed by compensation range, does not constitute confidential compensation information.

§ 301.6104(a)–6 Procedural rules for inspection.

(a) *Place of inspection; tax exempt organizations and pension and other plans.* Material relating either to tax exempt organizations or to pension and other plans that is open to public inspection under section 6104(a)(1) and § 301.6104(a)–1 through § 301.6104–3 will be made available for inspection at the Freedom of Information Reading Room, National Office, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224, and in the office of any district director of internal revenue.

(b) *Request for inspection*—(1) *Tax exempt organizations and pension and other plans; public inspection.* Material relating to either tax exempt organizations or pension and other plans that is open to public inspection under section 6104(a)(1) and §§ 301.6104(a)–1 through § 301.6104–(a)–3 will be available for inspection only upon request. If inspection at the National Office is desired, a request should be made in writing to the Commissioner of Internal Revenue,

Attention: Freedom of Information Reading Room, 1111 Constitution Avenue, N.W., Washington, D.C. 20224. Requestes for inspection in the office of a district director should be made in writing to the district director's office. The requests must describe the material to be inspected in reasonably sufficient detail so that Internal Revenue Service personnel can locate the material. If a tax-exempt organization has more than one application for tax exemption open to public inspection, or if a pension or other plan has more than one application for a determination letter open to public inspection, only the most recent application and related material will be made available for inspection unless the request states otherwise. Further, in the case of a pension or other plan, only Internal Revenue Service documents issued or delivered after the date of the filing of the most recent application for a determination letter will be made available for inspection, unless the request states otherwise.

(2) *Pension and other plans; inspection by plan participant or authorized representative.* As described in § 301.6104(a)–4, material relating to plans having fewer than 26 participants is only open to inspection by a plan participant or authorized representative. In the case of such a plan, the rules described in subparagraph (1) of this paragraph apply, except that the request for inspection must be in writing. The request for inspection must include satisfactory evidence that the person requesting inspection is a plan participant (see § 301.6104(a)–4 (c)) or an authorized representative of such a plan participant within the meaning of § 301.6104(a)–4 (d).

(c) *Time and extent of inspection.* A person requesting inspection will be notified when the material will be made available for inspection. The material will be made available for inspection at times that will not interfere with its use by the Internal Revenue Service or exclude other persons from inspecting it. In addition, the Commissioner or district director may limit the number of applications for tax exemption, applications for a determination letter, supporting documents, or letters and documents issued by the Internal Revenue Service that will be made available to any person for inspection on a given date. Inspection will be allowed only in the presence of an Internal Revenue Service employee and only during regular business hours.

(d) *Copies.* Notes may be taken of the material open for inspection. Copies may be made manually or, if a person provides the equipment, photographically at the place of inspection. Photographic copying is subject to reasonable supervision with regard to the facilities and equipment used. A fee will be charged for copies of the material furnished by the Internal Revenue Service. Copies will be certified upon request.

§§ 301.6104–2, 301.6104–3 and 301.6104–4 [Redesignated as §§ 301.6104(b)–1, 301.6104(c)–1 and 301.6104(d)–1]

Par. 2. Sections 301.6104–2, 301.6104–3 and 301.6104–4 are redesignated §§ 301.6104(b)–1, 301.6104(c)–1 and 301.6104(d)–1, respectively.

William E. Williams,

Acting Commissioner of Internal Revenue.

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DEPARTMENT OF LABOR

Office of Pension and Welfare Benefit Programs

29 CFR Part 2520

Proposed Revision of Annual Return/Reports and Regulations Regarding Plans Which Participate in a Master Trust

AGENCY: Department of Labor.

ACTION: Notice of proposed revision of annual report forms and annual reporting regulations.

SUMMARY: This document contains proposed revisions to the Form 5500, (annual return/report form) filed under the Employee Retirement Income Security Act of 1974 (the Act) and a proposed revision of related employee benefit plan annual reporting regulations. If adopted, these revisions would affect the reporting of financial information by plans which participate in a master trust.

DATES: Written comments (at least three copies) concerning the proposed revisions must be received by the Department on or before February 13, 1981. The revisions, if adopted, will be effective for plan years beginning on or after January 1, 1981.

ADDRESS: Written comments should be addressed to "Master Trust", Office of Reporting and Plan Standards, Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N–4508, 200 Constitution Avenue, N.W., Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT: John Christensen, Pension and Welfare Benefit Programs, U.S. Department of Labor, Washington, D.C. 20216, (202) 523–8684 or Roger Thomas, Office of the Solicitor, Plan Benefits Security Division, U.S. Department of Labor, Washington, D.C. 20210, (202) 523–8602. These are not toll free numbers.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Department has under consideration proposed revisions to 29 CFR 2520.103–1, relating to the contents of the annual report, Form 5500 (annual return/report), and instructions thereto. The annual return/report provides financial information regarding an employee benefit plan to the Department of Labor (the Department) and the Internal Revenue Service. The plan administrator must make the annual return/report available for examination by plan participants and beneficiaries.

The proposed revisions relate to the treatment of plans participating in master trusts for annual reporting purposes. Generally, a master trust is a trust maintained by certain financial institutions to hold the assets of several plans that are all sponsored by a single employer or by several employers which are under common control. The Department has been advised that when the assets of several plans are combined in a single master trust, significant economies in recordkeeping and asset management expenses can often be achieved.

The Department's annual reporting requirements are set forth at 29 CFR 2520.103–1 *et seq.* In accordance with these regulations plans generally file annual reports on Forms of the 5500 Series (Forms 5500, 5500–C, and 5500–K). The annual report includes financial statements, which include a statement of assets and liabilities (Item 13 of Form 5500) and a statement of income, expenses and changes in net assets (Item 14 of Form 5500). Plan assets, liabilities, income and expenses are grouped in categories and sub-categories ("line items"). In general, the instructions to the forms currently require that if the assets of two or more plans are maintained in one trust (as in the case of a master trust), the statement of assets and liabilities and the statement of income, expenses, and changes in net assets should be completed by entering the allocable portion of each line item for the plan in question. [1]

The department has received correspondence from representatives of banks and the banking industry with regard to the treatment of master trusts

[1] This rule does not apply with respect to common or collective trusts. See 29 CFR 2520.103–3.

for annual reporting purposes.[2] This correspondence has generally expressed the view that the current method of reporting is confusing and presents financial information relating to a plan's participation in a master trust in a manner which they characterize as misleading. These letters have generally recommended that a plan which participates in a master trust report the value of the plan's interest in the master trust as a single asset under item 13, and that the plan's share of earnings and realized and unrealized gains and losses of the master trust be reported as a single figure representing the increase or decrease in the value of the plan's interest in the master trust under item 14. With respect to the schedules of assets held for investment, loans or leases in default or classified as uncollectable, party in interest transactions and reportable transactions required in item 22(a), the banking representatives have generally recommended that such schedules be filed by the master trust, instead of by individual plans.

Upon consideration of these comments, the Department is proposing revisions to the forms and the regulations to obtain financial information from plans which participate in a master trust in a manner which the Department believes more accurately reflects the financial condition of each plan participating in the master trust. The Department expects that the revisions will reduce or eliminate uncertainty on the part of the public as to the reporting requirements for such plans. The proposed revisions, which largely utilize the concepts suggested by the commentators with certain modifications, are described below.

Investment Accounts

According to representatives of banks serving as trustees of master trusts, master trusts commonly include various types of investment funds in which assets of participating plans are pooled for investment purposes, such as equity funds, real-estate funds, bond funds, and money-market funds. These pooled investment funds within the master trust may be managed by the trustee or by other investment managers. Under some master trusts, the assets of the plans participating in the master trust must be allocated among these investment funds in such a manner that each plan has the same percentage interest in each pooled investment fund within the master trust as in the master trust as a whole. Other master trusts, however, permit fiduciaries of each plan, such as the plan's investment committee, to specify the portion of the plan's interest in the master trust to be allocated to each separate fund within the master trust. Thus, for example, such fiduciaries may direct that 60% of the plan's interest in the master trust be allocated to the master trust's equity fund, 30% to the master trust's bond fund, 10% to the master trust's real-estate fund, and nothing to the master trust's money-market fund. If each plan's assets are allocated in this manner, each plan will ordinarily have a different percentage interest in each pooled fund and in the master trust as whole. Moreover, many master trusts permit separate assets to be held and managed by the master trust outside of any pooled investment fund, for the benefit of one or more (but not necessarily all) participating plans.

Under many master trusts, therefore, the plan's percentage interest in the master trust as a whole does not necessarily bear any relationship to the plan's interest in each separate pooled fund and each separate asset within the master trust. Thus, in order to determine accurately the share of each item of assets, liabilities, income, expense, etc. Allocated to the plan from the master trust, it is necessary to know relevant financial information for each pooled investment fund and each separately held asset in the master trust, as well as each plan's percentage or dollar interest in each pooled investment fund and each separately held asset. Accordingly, the Department is proposing revisions which, if adopted, would provide that the bank, trust company, or similar institution maintaining the master trust shall complete such information for each participating plan.

In the proposed instructions, the term "investment account" is used to mean both pooled investment funds and separately held assets in the master trust. Each of the following would be treated as a separate investment account: (1) each pool of assets such that each plan has the same fractional interest in each asset in the pool and each plan is unable to dispose of its interest in any asset in the pool without disposing of its interest in the pool, and (2) each asset held in the master trust which is not part of such a pool of assets. Thus, every asset held in the master trust would be considered to be held in an investment account. An investment acccount, therefore, could consist of a pool of assets, such as the pooled funds typically maintained in master trusts, or of a single asset. Any asset which is "dedicated" to a single plan or to several plans (i.e., an asset held exclusively for the benefit of such plan or plans apart from any pool of investments) would itself be treated as comprising a separate investment account. In the case of a master trust in which each plan has the same percentage interest in each pooled investment fund (and in each separate asset, if any), the definition of "investment account"; would permit all of the assets in the master trust to be viewed as a single pool of assets appropriate for treatment as a single investment account.

A principal feature of the proposed reporting revisions would be that detailed financial information would be provided with respect to each investment account maintained within the master trust, as explained more fully below. By contrast with current requirements, it would not be necessary to determine the plan's allocable share of each line item of Form 5500 for assets held in the master trust.

Assets and Liabilities

The current value of a plan's interest in a master trust at the beginning and end of the plan year would be reported in item 13(c)(x) of Form 5500. The value of the plan's interest in a master trust would be the sum of the net values of the plan's interest in each master trust investment account. No other information regarding the assets held in the master trust and liabilities attributable to those assets would be reported in item 13 of the plan's Form 5500.

Detailed information on assets held in the master trust would be provided with respect to each master trust investment account in a statement in the format of item 13, showing the assets and liabilities of the investment account at the beginning and end of the most recent fiscal year of the investment account.

Income, Expenses and Changes in Net Assets

In item 14(n)(ii) of the plan's Form 5500, the net investment gain (or loss) allocated to the plan from all master trust investment accounts for the plan year would be reported. This figure would be determined by adding together all net investment gains allocated to the plan for the plan year and by subtracting from that sum any net

[2] Letters received by the Department regarding the treatment of master trusts under the regulations are available for public inspection in the Public Documents Room of Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue, N.W., Washington, D.C. 20216.

investment losses allocated to the plan for the plan year.[3]

A separate schedule would list each master investment account in which the plan has an interest and would show the net investment gain (or loss) allocated to the plan from each such master trust investment account for the plan year.

A statement prepared for each investment account would report, in the format of item 14, the income, expenses and change in net assets and net increase (decrease) in net assets of the investment account during the most recent fiscal year of the investment account.

Any expenses which are incurred by the plan in connection with the master trust but which are not subtracted from the gross income of one of the master trust investment accounts in determining the net increase (decrease) in net assets of such investment accounts would be reported in item 14(j) or (k) of the plan's Form 5500.

Fees, Commissions or Other Compensation

Item 12 of the plan's Form 5500 would include the plan's share of amounts of compensation paid during the plan year to the trustee of the master trust and to persons providing services to the master trust, if such compensation is not subtracted from the gross income of any investment account in determining the investment account's net increase (decrease) in net assets. Any amounts of compensation paid to persons providing services to an investment account which are subtracted from the gross income of the investment account in determining the net increase (decrease) in net assets of the investment account would be reported in a statement prepared for the investment account in the same format as item 12 of Form 5500.

Item 22(a) Schedules

Schedules of the information specified in item 22(a) (i.e., party in interest transactions, assets held for investment, loans and leases in default or classified as uncollectable and reportable transactions) would, if appropriate, be completed for each investment account.

Plan Holdings in Both Master Trusts and Other Funding Media

If some plan assets are held in a master trust and other plan assets are held in other funding media, all applicable lines in items 12, 13, 14, and 22(a) of Form 5500 must be completed to report information regarding the plan assets held in the other funding media. for example, if a plan invests all of its funds in master trust except cash temporarily deposited in a checking account held in a separate trust to pay administrative expenses unrelated to the master trust (such as the accountant's fee or charges for disclosing plan information to participants and beneficiaries), information regarding such cash must be shown in the annual report in addition to information regarding plan assets held in the master trust.

Proposed Regulation

The revisions to Form 5500 would be accompanied by a regulation, which is proposed in this document (29 CFR § 2520.103–1(e)), and which would require the plan administrator of a plan participating in a master trust to follow the instructions to Form 5500 regarding master trust. Corresponding revisions are proposed to § 2520.103–1(c).

Filing of Reports

Under the proposed regulation, a plan participating in a master trust, including a plan which would normally file a Form 5500–C or 5500–K,[4] would be required to file form 5500, in order to ensure uniformity of reporting among all plans participating in a single master trust. It is contemplated that the instructions to Forms 5500–C and 5500–K would be modified by adding a statement to the effect that those forms should not be used for filing the annual report for plans participating in a master trust. However, the plan administrator of a plan covering fewer than 100 participants at the beginning of the plan year is not required to engage an accountant to examine the financial statements of the plan or to include within the annual report a report of such accountant. (Since such plan is required to file Form 5500 because it participates in a master trust, the plan is not deemed to be making an election under 29 CFR 2520.103–1(d); therefore, the waiver of the accountant's examination and report, provided by § 2520.104–46, applies to the plan).

Under the proposal, the trustee of a master trust would furnish to the plan administrator of a plan participating in the master trust copies of the required statements, schedules and other information relating to the master trust investment accounts as specified in the instructions and would file these documents directly with the Department. It is the Department's opinion that the information required to be provided for each plan by the trustee of the master trust constitutes a part of a plan's annual report for purposes of satisfying a plan's disclosure obligations to participants and beneficiaries.[5] The required information would be filed with the Department no later than the earliest date on which Form 5500 must be filed for any plan participating in the master trust. The Department believes that the direct filing of master trust information in this manner would eliminate duplicative reporting and would provide financial information on such plans in a more useful form. The annual report of a plan participating in the master trust would be filed by the plan administrator in accordance with the "General Instructions" provided on Form 5500.

Arrangements Other Than Master Trusts

Under the proposals contained in this document, annual reporting along the lines described above would be limited to plans participating in master trusts. Although the Department is aware that arrangements other than master trusts may exist in which assets of more than one plan are pooled for investment purposes, it does not have an adequate factual basis for expanding the scope of the master trust proposals to cover plans participating in such arrangements. Special rules are currently provided in 29 CFR § 2520.103–3 for plans participating in common or collective trusts, in § 2520.103–4 for plans participating in insurance company pooled separate accounts meeting specified requirements, and in § 2520.103–21 and § 2520.103–43 for plans participating in certain group insurance arrangements. Furthermore, the instructions for Forms 5500 and 5500–C provide special reporting instructions, in the section entitled

[3] The net investment gain (or loss) allocated to the plan from each investment account for the plan year would be determined by subtracting the value of the plan's interest in the investment account at the beginning of the plan year from the value of the plan's interest at the end of the plan year and by adjusting that difference to eliminate the effect of any transfers of assets into or out of the investment account by the plan (i.e., by subtracting any such transfers into the investment account and by adding transfers out of the investment account).

[4] Forms 5500–C and 5500–K contain abbreviated financial statements of assets and liabilities and statements of income, expenses and changes in net assets.

[5] Section 104(b)(2) of the Act gives any plan participant or beneficiary the right to examine the plan's latest annual report at the plan administrator's principal office and such other places as may be necessary to make available all pertinent information to all participants. Further, section 104(b)(4) gives any plan participant or beneficiary the right to receive, upon his or her written request, a complete copy of the plan's latest annual report. The plan administrator may make a reasonable charge to cover the costs of furnishing such copy. (See also 29 CFR § 2520.104b–1 and § 2520.104b–30).

"Type of Filer", for a single plan of a controlled group of corporations or trades or businesses under common control, a multiemployer plan, a multiple-employer-collectively-bargained plan, and a multiple-employer plan (other).

The Department invites comments regarding appropriate reporting methods for multiple plan arrangements which are not entitled to follow any of the reporting methods or instructions mentioned in the preceding paragraph and which do not involve master trusts. Such comments should include a detailed explanation of both the form and operation of any such other multiple plan arrangement. Suggestions for special reporting methods for any other multiple plan arrangement will be considered separately from the subject proposal for plans participating in master trusts.

Drafting Information

The principal authors of these proposed revisions are Miriam Freund of the Pension and Welfare Benefit Programs and Roger Thomas of the Plan Benefits Security Division, Office of the Solicitor, Department of Labor. However, other persons in the Department of Labor and in the Internal Revenue Service participated in developing the proposed revisions, both on matters of substance and style.

Proposed Revisions of Annual Return/Reports and of Annual Reporting Regulation

1. In consideration of the matters discussed above, it is proposed to amend § 2520.103–1 of Title 29 of the Code of Federal Reglations by revising paragraph (c) and adding a new paragraph (e) to read as set forth below.

§ 2520.103–1 Contents of the annual report.

* * * * *

(c) *Contents of the annual report for plans with fewer than 100 participants.* Except as provided in paragraphs (d) and (e) of this section and in §§ 2520.104–43 and 2520.104a–6, the annual report of an employee benefit plan which covers fewer than 100 participants at the beginning of the plan year shall be Form 5500–C "Return/Report of Employee Benefit Plan (with fewer than 100 participants)" or 5500–K "Return/Report of Employee Pension Benefit Plan for Sole Proprietorships and Partnerships (with fewer than 100 participants and at least one owner-employee)", or 5500–R "Registration Statement of Employee Benefit Plan (with fewer than 100 participants)." See the section headed "What to File" in the instructions to these forms.

* * * * *

(e) *Plan which participate in a master trust.* The plan administrator of a plan which participates in a master trust shall file an annual report on Form 5500 in accordance with the specific instructions relating to master trusts on Form 5500 and instructions thereto. A master trust is a trust which is maintained by a bank, trust company, or similar institution regulated, supervised, and subject to periodic examination by a State or Federal agency, and which contains only assets of more than one plan of a single employer or more than one plan of several employers, all of which are members of a controlled group of corporations or trades or businesses under common control (as defined in section 414(b) and (c) of the Internal Revenue Code).

(2) It is proposed to amend the annual return/report (Forms 5500, 5500–C, and 5500–K) and instructions thereto in the manner described below.

I. Revisions to Form 5500

Add new sub-item 13(c)(x) "Value of Interest in Master Trust" and renumber current 13(c)(x) and 13(c)(xi) as 13(c)(xi) and 13(c)(xii) respectively.

Add new sub-item 14(n)(ii) "Net investment gain (or loss) from all master trust investment accounts". Renumber current sub-item 14(n)(ii) ("Other changes") as 14(n)(iii).

II. Revisions to Instructions for Form 5500

[Insert at the end of "A. What to File" under "General Instructions".]

Plans Participating in Master Trust(s)

A. *Definitions and General Information.*

For purposes of this form, a master trust is deemed to exist where the assets of more than one plan of a single employer or more than one plan of several employers, all of which are members of a single controlled group of corporations or trades or businesses under common control (as defined in section 414(b) and (c) of the Code) are held in trust maintained by a bank, trust company, or similar institution regulated, supervised, and subject to periodic examination by a State or Federal agency.

For purposes of this form, the assets of a master trust are considered to be held in one or more "investment accounts". A master trust investment account may contain a pool of assets or a single asset. Each pool of assets held in a master trust must be treated as a separate master trust investment account if each plan which has an interest in the pool has the same fractional interest in each asset in the pool as its fractional interest in the entire pool, and if each such plan is unable to dispose of its interest in any asset in the pool without disposing of its interest in the pool. A master trust may also contain assets which are not held in such a pool. Each such asset must also be treated as a separate master trust investment account.

Financial information must generally be provided with respect to each master trust investment account as specified in Part C, "Reporting Information Relating to Master Trusts and Master Trust Investment Accounts," below.

Each plan participating in a master trust must file Form 5500, regardless of the number of participants in the plan. If such a plan covers fewer than 100 participants at the beginning of the plan year, the accountant's examination and report described in section 103(a)(3)(A) of the Act is not required (see 29 CFR 2520.104–46).

B. *Reporting Information Relating to the Individual Plan* 1. In item 12 include the plan's share of amounts of compensation for services paid during the plan year to the master trustee and to persons providing services to the master trust if such compensation is not subtracted from the gross income of any master trust investment account in determining the net investment gain (or loss) from the investment account (see ¶B6, below). Amounts of compensation subtracted from investment account gross income in determining the net investment gain (or loss) from the investment account must be reported on separate schedules (see ¶C3, below).

2. Enter the current value of the plan's interest in the master trust at the beginning of the plan year and at the end of the plan year on line 13(c)(x). The value of the plan's interest in a master trust is the sum of the net values of the plan's interests in master trust investment accounts. The net values of such interests are obtained by multiplying the plan's percentage interest in each master trust investment account by the net assets of the investment account reported in the applicable column of the "net assets" line item of the statement of assets and liabilities filed for the investment account (see ¶C4, below). If some plan funds are held in a master trust and other plan funds are held in other funding media, complete all applicable sub-items of item 13 with regard to assets held in other funding media.

3. In sub-items 14 (d), (e), (f), (i), (j), (k), and (n)(i), do not report earnings, expenses, gains or losses, and unrealized appreciation or depreciation which were included in computing the net investment gain (or loss) from any master trust investment account. (See ¶B6, below, for explanation of net investment gain (or loss) from master trust investment account). If some plan funds are held in a master trust and other plan funds are held in other funding media, complete all applicable sub-items of item 14 to report plan earnings, expenses, gains or losses, and unrealized appreciation or depreciation relating to the other funding media.

4. In sub-item 14(j), report all administrative expenses (by specified category) paid by or charged to the plan which were not subtracted from the gross income of a master trust investment account in determining the net investment gain (or loss) from the investment account (see ¶B6, below).

5. Enter in sub-item 14(n)(ii) the net investment gain (or loss) allocated to the plan for the plan year from all master trust investment accounts. The net investment gain (or loss) allocated to the plan for the plan year from all master trust investment accounts is obtained by subtracting any net investment losses allocated to the plan from master trust investment accounts from the sum of net investment gains allocated to the plan from master trust investment accounts. The net investment gain (or loss) allocated from each master trust investment account is reported on a separate schedule (see ¶B6, below).

6. State the name of the master trust used in the master trust's filing with the Department of Labor (see Part C, below). Attach a list of each master trust investment account in which the plan has an interest. In tabular format show the plan's fractional interest, in the form of a percentage, in each investment account at the beginning of the plan year and at the end of the plan year; the total amount of transfers to the investment account, and the total amount of transfers from the investment account, by the plan during the plan year; and the net investment gain (or loss) allocated to the plan for the plan year from the investment account. The net investment gain (or loss) allocated to the plan for the plan year from the investment account is equal to:

—the current value of the plan's interest in the investment account at the end of the plan year, *minus*

—the current value of the plan's interest in the investment account at the beginning of the plan year, *plus*

—any amounts transferred out of the investment account by the plan during the plan year, *minus*

—any amounts transferred into the investment account by the plan during the plan year.

7. Do not complete sub-item 22(a) if all plan funds are held in master trusts. If some plan funds are held in master trusts and other plan funds are held in other funding media, complete sub-item 22(a) to report information relating to the other funding media. In such cases, complete item 22(a)(v) only with respect to transactions involving assets of the plan which are not held in a master trust. In determining the 3 percent figure, do not include the value of plan assets held in the master trust in the current value of the plan's assets at the beginning of the plan year. Do not report acquisitions or dispositions of interests in a master trust in sub-item 22(a)(v). (See ¶C6, below, with respect to information that must be included concerning each master trust investment account.)

C. Reporting Information Relating to Master Trusts and Master Trust Investment Accounts

For each plan participating in the master trust, the bank, trust company or similar institution maintaining the master trust shall furnish to the plan administrator and file directly with the Department of Labor the information described below. Each of the required statements and schedules should indicate the name of the plan, the sponsor's employer identification number, and the three digit plan number. The required information shall be filed with the Department of Labor by mailing it to: Master Trust, Office of Reports and Disclosure, Pension and Welfare Benefit Programs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20216. The required information must be filed with the Department no later than the earliest date on which Form 5500 must be filed for any plan participating in the master trust.

1. The name and fiscal year of the master trust and the name and address of the master trustee.

2. A list of all plans participating in the master trust, showing each plan's name and its percentage interest in each master trust investment account as of the beginning and end of the most recent fiscal year of the investment account.

3. A statement, in the same format as item 12 of Form 5500, for each master trust investment account, showing amounts of compensation paid during the most recent fiscal year of the investment account to persons providing services with respect to the investment account and subtracted from the gross income of the investment account in determining the net increase (decrease) in net assets of the investment account (see ¶C5, below).

4. A statement in the same format as item 13 of Form 5500, for each master trust investment account, showing the assets and liabilities of the investment account at the beginning and end of the most recent fiscal year of the investment account.

5. A statement in the same format as item 14 of Form 5500 for each master trust investment account, showing the income, expenses, changes in net assets, and net increase (decrease) in net assets of each such investment account during the most recent fiscal year of the investment account. In place of sub-items (a), (b), and (c) of item 14, show all transfers of assets into the investment account by participating plans. In place of sub-item (h) of item 14, show all transfers of assets out of the investment account by participating plans. Do not complete sub-item 14(n)(ii).

6. Schedules in the format set forth in the instructions to item 22 of Form 5500, of the following items with respect to each master trust investment account for the most recent fiscal year of the investment account: assets held for investment, nonexempt party in interest transactions, defaulted or uncollectable loans and leases, and 3 percent transactions involving assets in the investment account. The 3 percent figure shall be determined by comparing the current value of the transaction at transaction date with the current value of the investment account assets at the beginning of the fiscal year of the investment account.

III. Revisions to Instructions for Form 5500–C

1. [Insert at the end of the first sentence under "A. What to File" under "General Instructions":]

* * * and for each plan, regardless of the number of participants, which participants in a master trust. See "A. What to File" under "General Instructions" in the instructions for Form 5500, for detailed filing information for plans participating in master trusts. (An accountant's examination and report is not required for a plan which meets the requirements of 29 CFR § 2520.104–46 and which participates in a master trust.)

2. [Insert at end of second paragraph under "A. What to File" under "General Instructions":]

Exception: Plan participating in master trusts must file Form 5500, as noted in the preceding paragraph, rather than Form 5500–C.

IV. Revisions to Instructions for Form 5500–K

[Insert at end of first paragraph under "A. What to File" under "General Instructions":]

Exception: A plan that participates in a master trust must file Form 5500, regardless of the number of participants in the plan; Form 5500–K should not be filed for such plan. See "A. What to File" under "General Instructions" in the instructions for Form 5500, for detailed filing information for plans participating in master trusts. (An accountant's examination and report is not required for a plan which meets the requirements of 29 CFR 2520.104–46 and which participates in a master trust.)

Signed at Washington, D.C. this 23rd day of December, 1980.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 80–40554 Filed 12–24–80; 9:02 am]

BILLING CODE 4510–29–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

Surface Coal Mining and Reclamation and Enforcement Under Federal Program for Ohio

AGENCY: Office of Surface Mining Reclamation and Enforcement, Department of the Interior.

ACTION: Notice of intent to prepare Federal Program, Suspension of Ohio schedule for State program resubmission, and Notice of public comment period.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) was advised by the State of Ohio of the existence of injunctions enjoining the State from resubmitting its State regulatory program to the Department of the Interior for a period of one year. Accordingly, the Secretary of the Interior is temporarily suspending the

Ohio schedule for resubmission and is initiating action to prepare a Federal program for the regulation of surface coal exploration, mining and reclamation on non-Federal and non-Indian lands in Ohio. The Federal program will not be implemented before December 1, 1981, unless the injunctions cease to remain in effect or are no longer determined effective under Section 503(d) of the Surface Mining Control and Reclamation Act of 1977, 30 U.S.C. 1201, *et seq.* In any event, Ohio will be given the opportunity to resubmit a State program before a Federal program is implemented. If Ohio does resubmit, the program will be reviewed in accordance with the Secretary's regulations. A Federal program will be implemented only if the State fails to resubmit, or if the resubmitted program is disapproved. Public comment is also being sought on the preparation of a Federal program for Ohio and on Ohio's actions under the interim program.

DATE: Public comments must be received by OSM by 5:00 p.m., January 29, 1981.

ADDRESS: Information and comments should be sent to: Office of Surface Mining, Room 153, South Interior Building, 1951 Constitution Avenue, N.W., Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: Carl C. Close, Assistant Director, OSM, State and Federal Programs, 1951 Constitution Avenue, N.W., U.S. Department of the Interior, Washington, D.C. 20240, (202) 343–4225.

SUPPLEMENTARY INFORMATION: Under the Surface Mining Control and Reclamation Act of 1977 (the "Act"), a State which seeks to regulate surface coal mining and reclamation operations within its borders may apply to the Secretary of the Interior for approval of a State program. In order for a program to be approved, a State must develop a program that contains laws and regulations which are consistent with the Act and the regulations of the Secretary of the Interior. The Act says that once a State makes a program submission, the Secretary of the Interior has six months in which to consider the State's application. At the end of that six-month period the Secretary has to decide whether to approve, conditionally approve, approve in part and disapprove in part, or completely disapprove the State program submission. If the Secretary partially or completely disapproves the State program submission, the State, under normal conditions, has sixty days to revise and resubmit its program. The statute then gives the Secretary sixty days to consider the resubmitted program and to make a final decision. If, after the end of this ten month period, the Secretary is unable to approve or conditionally approve the State Program, he is required to promulgate a Federal program.

As announced in the October 1, 1980, Federal Register notice, 45 FR 64962, the Secretary of the Interior reviewed the State of Ohio's initial program submission and disapproved that program. Ohio had until December 1, 1980, to resubmit a revised program.

In a letter dated November 26, Charles E. Call, Chief of the Division of Reclamation, Ohio Department of Natural Resources, informed the Office of Surface Mining that the Ohio Department of Natural Resources was enjoined on November 24, 1980, by the Common Pleas Court of Franklin County, Ohio, and on November 25, 1980, by the Common Pleas Court of Belmont County, Ohio, from resubmitting to the Office of Surface Mining a State program for the regulation of surface coal mining and reclamation operations. Ohio did not resubmit a program by the December 1, 1980 deadline.

Section 503(d) of the Surface Mining Control and Reclamation Act provides:

> . . . [T]he inability of State to take any action the purpose of which is to prepare, submit or enforce a State program, or any portion thereof, because the action is enjoined by the issuance of an injunction by any court of competent jurisdiction shall not result * * * in the imposition of a Federal Program. Regulations of the surface coal mining and reclamation operations covered or to be covered by the State program subject to an injunction shall be conducted by the State pursuant to Section 502 of this Act, until such time as the injunction terminates or for one year, whichever is shorter, at which time the requirements of Section 503 and 504 shall again be fully applicable.

The Secretary has completed all the actions in the review of the Ohio State program that can be done without further participation by the State of Ohio. Because the Secretary of the Interior has received notification that the State of Ohio is enjoined from taking further formal action, the Secretary is temporarily suspending the State program approval process for Ohio as of November 24, 1980 (the date of the first injunction), which was the 54th day of the 60 days that Ohio had for resubmission.

The effect of this action is that federal enforcement of the interim program requirements, e.g., two federal inspections per year of each mine or regulated facility, will continue until the injunctions are lifted, expire, or are determined not to invoke the operation of Section 503(d). Since the Act allows the state access to its reserved portion of the Abandoned Mine Land Fund only after it has achieved regulatory primacy, Ohio's access to the Fund must be delayed. The amount currently reserved for Ohio is $15,652,069.98.

The Secretary has considered various options in rescheduling Ohio's state program approval process. First, because the 60 day resubmission period expired on December 1, 1980, and because the injunctions give Ohio more time than the 60 days normally allowed, Ohio could be required to resubmit its state program on the day the injunctions are lifted. However, an immediate deadline for resubmission after the injunctions are lifted appears abrupt and would ignore the fact period when the first injunction was issued. Second, Ohio could be given 60 days after the lifting of the injunctions to resubmit its state program. However, 60 additional days appears excessive, because (1) Ohio has already had 54 days to develop its resubmission, (2) it would be unfair to other states which only had 60 days to resubmit and (3) the operation of the injunctions has already given Ohio considerably more time than the normal 60 days to develop an acceptable program. Third, Ohio could be given the amount of time it hads remaining to resubmit its program, six days. This would take into account the time Ohio already had for resubmission, would be fair to other states involved in the process, and would be a reasonable deadline for the state to meet.

The Secretary has chosen the third option. Beginning on November 24, 1981, or, if the injunctions are lifted or determined to be ineffective before that date, then on the date when the injunctions are lifted or deemed ineffective, Ohio will have six days to resubmit an acceptable program. In any event, the deadline for Ohio's resubmission will not be later than November 30, 1981. The Secretary will make every effort to notify Ohio by letter prior to that date for resubmission in order to assist Ohio in meeting the deadline.

The legislative history of Section 503(d) indicates that its purpose is to avoid penalizing states which make good faith efforts to comply with the Act but are prevented by court action from achieving full compliance. Where, however, attendant circumstances lead the Secretary to determine that an injunction does not invoke the operation of Section 503(d), or that the State has failed to make a good faith effort to comply with the Act, the Secretary will not suspend the statutory timetable for state programs beyond the date of such

determination. The Secretary has not yet determined, at this time, whether Section 503(d) is applicable in Ohio. The Secretary is reviewing the circumstances under which the injunctions were entered and the jurisdictional competence of the state courts to hear the matter. The Secretary believes that the delay and relief available under Section 503(d) is limited to those States which are seeking in good faith to prepare and adopt a permanent surface coal mining and reclamation program. Section 503 is not meant to be used as an artifice or device to avoid the requirements of the Surface Mining Act.

Section 503(d) does not provide general authority to extend the statutory timetable established under that Act. Accordingly, the Secretary requests public comment on the issues bearing upon the applicability of Section 503(d) in Ohio. If, after review, the Secretary determines that Section 503(d) is inapplicable to Ohio under the circumstances, Ohio will have six days from the date of such determination within which to resubmit an acceptable state program. If it fails to do so, the Secretary will implement a Federal program for Ohio in accordance with Section 504 of the Act. Until a determination is made, the Secretary will presume that Section 503(d) applies, and thus will suspend the running of the resubmission period provided by Section 503(c). However, the Secretary expressly reserves that right to take appropriate action if he concludes that the circumstances surrounding the entry of the injunctions warrant doing so.

Section 503(d) also requires a State which is subject to an injunction prohibiting resubmission of a state program to regulate surface coal mining and reclamation operations pursuant to Section 502 of the Act (the interim program) until such time as the injunction terminates or until one year after the injunction is entered, whichever comes first. The Secretary construes Section 503(d) of the Act to authorize implementation of a Federal program if a State fails to implement Section 502 during the term of an injunction. Thus, while the Secretary fully endorses the intent of Congress to have the State assume regulatory primacy under the Act, he also is required to implement a Federal program in cases where that becomes necessary because of a State's failure to carry out its responsibilities under Section 502.

Consequently, the Secretary is also examining the compliance by the State of Ohio with Section 502 of the Surface Mining Control and Reclamation Act and the interim program regulations issued by the Department of the Interior related to Section 502 (42 FR 62639, December 13, 1977). Within the next three months and after receipt or public comments and completion of this preliminary analysis, the Secretary will decide what further steps are necessary and should be taken. At that time, he may conclude that there is no basis for further examination because the State of Ohio is adequately enforcing the requirements of Section 502 of the Act; alternatively, he may decide there is the need for a public hearing or additional public comment. If the Secretary ultimately determines there is a lack of compliance, he will recommence the State program review process after appropriate notice to Ohio.

One additional effect of the injunctions, if they run a full year, is to delay the permanent program in Ohio for a period of approximately eight to twelve months beyond that applicable to most other States in the country. In addition, if Ohio is ultimately unsuccessful in obtaining approval of its program, the Secretary will then have to adopt a Federal program for that State. This could cause an additional delay of six months or more if the process for adoption of the Federal program were delayed until after the injunctions are lifted.

To reduce the potential delay in the application of the permanent surface coal mining reclamation program in Ohio if a Federal program becomes necessary, the Secretary has decided to begin preparation of a Federal program for Ohio within the next three months. This action is considered necessary both to reduce the time during which the environmental objectives established by Congress are not fully achieved because a permanent program has not been implemented and to reduce the potential for competitive economic disadvantages among states because implementation of permanent programs in the different states are unlikely to be concurrent. The Secretary will not actually implement this program until Ohio either fails to meet the six day deadline to resubmit its program or resubmits but fails to obtain approval of its program.

In the meantime, the Secretary has instructed the Director of the Office of Surface Mining to make every effort during the period of the injunctions to accomplish the following: (1) work with the State toward correcting the remaining deficiencies in its proposed program to the extent the State can participate in such an effort, given the existence of the injunctions; (2) ensure that the Federal enforcement program under Section 502 is diligently pursued in order to obtain compliance with the provisions of the Act and the interim program regulations; and (3) determine whether Ohio is adequately carrying out its responsibilities under Section 502 of the Act.

A major purpose of this notice is to seek public comment on preparing a Federal program in Ohio and to receive specific suggestions for how the Secretary of the Interior ought to adopt or modify the permanent program regulations to meet the local conditions in the State of Ohio. Section 504(a) of the Act and 30 CFR 736.22(a)(1) require that each Federal program consider the nature of the topography soils, climate and biological, chemical, geological, hydrological, agronomic and other physical conditions of the State involved. For important information, the reader is referred to "General Background on the Permanent Program" and "Criteria for Promulgating Federal programs" previously published in the **Federal Register** on May 16, 1980 (45 FR 32328). That notice explains how the Secretary will consider unique conditions in a State, how existing State laws will be considered, and what standards will be used in adopting regulations. The reader should also refer to the Secretary's decision concerning the Ohio program published in the **Federal Register** on October 1, 1980. (45 FR 64962 *et seq.*)

This action of proposing the preparation of a contingent Federal program for Ohio is not significant under the criteria of Executive Order 12044 and 43 CFR Part 14 and does not require preparation of regulatory analysis, nor is this action a major Federal action significantly affecting the environment under the National Environmental Policy Act.

PUBLIC COMMENT PERIOD: The comment period announced in this notice will extend until January 30, 1981. All written comments must be received at the address given above by 5:00 p.m. on that date.

Comments on the preparation of a Federal program received after that hour will not be considered in drafting the proposed Federal program; they will be considered to the extent applicable in subsequent actions under that program.

Dated: December 18, 1980.

Joan Davenport,

Assistant Secretary, Energy and Minerals.

[FR Doc. 80-40452 Filed 12-29-80; 8:45 am]

BILLING CODE 4310-05-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 162

[OPP-250023A; PH-FRL 1715-2]

Exemption of Certain Biological Control Agents From Regulation; Notification of Secretary of Agriculture

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule Related Notice.

SUMMARY: Notice is given that the Administrator of EPA has forwarded to the Secretary of the U.S. Department of Agriculture a proposed regulation exempting certain biological control agents (generally, organisms of an order higher than microorganisms) from further regulation under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, because that are adequately regulated by other Federal agencies.

FOR FURTHER INFORMATION CONTACT: Ronald E. Ney, Jr., Hazard Evaluation Division (TS–769), Office of Pesticide Programs, 401 M St. SW., Washington, D.C. 20460, (703 577–7347).

SUPPLEMENTARY INFORMATION: Pursuant to sec. 25(a)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) (Pub. L. 92–516, 86 Stat. 973; 7 U.S.C. 136 et seq.), the Administrator of EPA sent the Secretary of Agriculture a copy of a proposed rule exempting certain biological control agents (i.e., organisms of a class higher than microorganisms) from further regulation under FIFRA. This rule is being proposed, under FIFRA sec. 25 (b)(1), which authorizes EPA to exempt from regulation under FIFRA any pesticides which are adequately regulated by other Federal agencies.

This proposed rule was submitted to the Secretary of Agriculture on November 26, 1980. If the Secretary comments in writing within 30 days after receiving the proposed regulation, the Administrator shall publish in the **Federal Register** (along with the proposed regulation) the comments of the Secretary and the response of the Administrator. If the Secretary does not comment in writing within 30 days after receiving the proposed regulation, the Administrator may sign the regulation for publication in the **Federal Register** anytime after such 30 day period.

Pursuant to FIFRA sec. 25(a)(3), a copy of the proposed regulation was forwarded on December 18, 1980, to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition and Forestry of the Senate.

This proposed regulation was also submitted to the FIFRA Scientific Advisory Panel on November 26, 1980, for its review, as required by sec. 25(d) of FIFRA. (Sec. 25, Pub.L. 92–515, 86 Stat. 973; Pub.L. 94–140, 89 Stat. 753; 7 U.S.C. 136 et seq.)

Dated: December 19,1980

Robert V. Brown,

Acting Deputy Assistant Administrator for Pesticide Programs

[FR Doc. 80–40473 Filed 12–29–80; 8:45 am]

BILLING CODE 6560–32–M

Notices

Federal Register
Vol. 45, No. 251
Tuesday, December 30, 1980

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

Feed Grain Donations for the Oglala Sioux Indian Tribe in South Dakota

Pursuant to the authority set forth in Section 407 of the Agricultural Act of 1949, as amended (7 U.S.C. 1427) and Executive Order 11336, I have determined that:

1. The chronic economic distress of the needy members of the Oglala Sioux Indian Tribe on the Pine Ridge Indian Reservation in South Dakota has been materially increased and become acute because of severe and prolonged drought substantially reducing range forage and hay production, thereby creating a serious shortage of feed and causing increased economic distress. This reservation is designated for Indian use and is utilized by members of the Oglala Sioux Indian Tribe for grazing purposes.

2. The use of feed grain or products thereof made available by the Commodity Credit Corporation for livestock feed for such needy members of the tribe will not displace or interfere with normal marketing of agricultural commodities.

3. Based on the above determinations, I hereby declare the reservation and grazing lands of the tribe to be an acute distress area and authorize the donation of feed grain owned by the Commodity Credit Corporation to livestock owners who are determined by the Bureau of Indian Affairs, Department of the Interior, to be needy members of the tribe utilizing such lands. These donations by the Commodity Credit Corporation may commence upon signature of this notice and shall be made available through May 10, 1981, or to such other time as may be stated in a notice issued by the Department of Agriculture.

Signed at Washington, D.C. on December 18, 1980.

John E. Gibbs,

Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 80-40255 Filed 12-29-80; 8:45 am]

BILLING CODE 3410-05-M

Feed Grain Donations for the Crow Creek and Lower Brule Indian Tribes in South Dakota

Pursuant to the authority set forth in Section 407 of the Agricultural Act of 1949, as amended (7 U.S.C. 1427) and Executive Order 11336, I have determined that:

1. The chronic economic distress of the needy members of the Crow Creek and Lower Brule Indian Tribes in South Dakota has been materially increased and become acute because of severe and prolonged drought substantially reducing range forage and hay production, thereby creating a serious shortage of feed and causing increased economic distress. The Indian reservations involved are designated for Indian use and are utilized by members of the Crow Creek and Lower Brule Tribes for grazing purposes.

2. The use of feed grain or products thereof made available by the Commodity Credit Corporation for livestock feed for such needy members of the tribes will not displace or interfere with normal marketing of agricultural commodities.

3. Based on the above determinations, I hereby declare the reservation and grazing lands of the tribes to be an acute distress area and authorize the donation of feed grain owned by the Commodity Credit Corporation to livestock owners who are determined by the Bureau of Indian Affairs, Department of the Interior, to be needy members of the tribes utilizing such lands. These donations by the Commodity Credit Corporation may commence upon signature of this notice and shall be made available through May 10, 1981, or to such other time as may be stated in a notice issued by the Department of Agriculture.

Signed at Washington, D.C. on December 18, 1980.

John E. Gibbs,

Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 80-40254 Filed 12-29-80; 8:45 am]

BILLING CODE 3410-05-M

Commodity Credit Corporation

Determinations Regarding the 1981-Crop Loan Rate for Upland Cotton and for Extra-Long Staple (ELS) Cotton, the Payment Rate for ELS Cotton, and the Loan Program for Seed Cotton

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Notice of determination of the 1981-crop loan rates for upland and ELS cotton, the payment rate for ELS cotton, and the loan program for seed cotton.

SUMMARY: The purpose of this notice is to set forth the basis for the determinations announced by the Secretary of Agriculture on October 31, 1980 with respect to (1) the 1981 loan rate for Strict Low Middling (SLM) one and one-sixteenth inch upland cotton (micronaire 3.5 through 4.9) at average location in the United States, (2) the 1981 loan rate and a payment rate with respect to the 1981 crop of ELS cotton, and (3) the 1981 loan program for seed cotton.

These determinations were required to be made by the Secretary in accordance with provisions of Sections 101(f) and 103(f) of the Agricultural Act of 1949, as amended, and Section 5(a) of the Commodity Credit Corporation Charter Act, as amended.

EFFECTIVE DATE: December 29, 1980.

ADDRESS: Director, Production Adjustment Division, ASCS-USDA, 3630 South Building, P.O. Box 2415, Washington, D.C. 20013

FOR FURTHER INFORMATION CONTACT: Charles V. Cunningham, Chief Program Analysis Branch, Production Adjustment Division, ASCS, P.O. Box 2415, Washington, D.C. 20013, (202) 447-7873. The Final Impact Statement describing the options considered in developing this Notice of Determinations and the impact of implementing each option is available from the above named individual.

SUPPLEMENTARY INFORMATION: This final action has been reviewed under USDA procedures established in

Secretary's Memorandum 1955 to implement Executive Order 12044 and has been classified "not significant."

The title and number of the federal assistance program that this notice applies to are: Title-Commodity Loans and Purchases; Number-10.051; as found in the Catalog of Federal Domestic Assistance.

This action will not have significant impact specifically on area and community development. Therefore, review as established by OMB Circular A–95, was not used to assure that units of local government are informed of this action.

A notice that determinations were to be made with respect to these provisions of the Agricultural Act of 1949, as amended, and the Commodity Credit Coporation Chater Act, as amended, was published in the **Federal Register** on August 29, 1980 (45 FR 57751) in accordance with 5 U.S.C. 553 and Executive Order 12044. Interested persons were given until October 28, 1980, to submit recommendations, views, and comments.

A total of nine responses were received concerning the loan rate for upland cotton or the seed cotton loan program. Five persons from Texas, two from Arkansas, and one each from Washington, D.C. and California responded.

Of the eight responses concerning the loan rate for upland cotton, two recommended a loan rate of 52.46 cents, and four others recommended levels which were outside legislative authority. Four persons stated that the loan level likely to be in effect would be insufficient when compared to the cost of producing uplan cotton.

One comment was received concerning the loan rate and payment rate for ELS cotton recommending a loan rate of 99.0 cents and a payment rate of zero.

Five persons recommended that a seed cotton loan program be instituted for the 1981 crop. No respondent opposed the program.

All comments received were duly considered were within statutory authority.

It was essential that these determinations be announced as soon as possible so that farmers could make their farming and marketing plans. Accordingly, these determinations with respect to the 1981 crops of uplan, ELS, and seed cotton were announced by the Secretary on October 31, 1980. The basis for these determinations is set forth herein.

Final Determinations

1. *Upland Cotton Loan Rate.* Based on the formula prescribed in Section 103(f) of the Agricultural Act of 1949, as amended (hereinafter referred to as the "1949 Act"), the loan rate for Strict Low Middling (SLM), one and one-sixteenth inch upland cotton (micronaire 3.5 through 4.9) at average location in the United States has been determined to be 52.46 cents per pound. This figure is calculated using the domestic spot market prices as required by Section 103(f) of the 1949 Act.

The loan rate for upland cotton must be the smaller of: (a) 85 percent of the average price (weighted by market and month) of SLM 1 1/16-inch upland cotton (micronaire 3.5 through 4.9) quoted in the designated United States spot markets during the five year period ending July 31, 1980, excluding the year with the highest and the year with the lowest average price, or (2) 90 percent of the average, for the fifteen-week period beginning July 1, 1980, of the five lowest priced growths of the growths quoted for Strict Middling (SM) 1 1/16-inch cotton C.I.F. Northern Europe (adjusted downward by the average difference during the period April 15, 1980, through October 15, 1980, between such average Northern Europe price quotation for such quality of cotton and the market quotations in the designated United States spot markets for SLM 1 1/16-inch cotton (micronaire 3.5 through 4.9)).

In no event, however, shall such loan level be less than 48 cents per pound. Further, if the level which is determined based upon the calculation of the average Northern Europe quotation results in a loan level that is less than the level which is determined based on the calculation of the average United States spot market price, the Secretary may increase the loan level to such level as the Secretary deems appropriate, but not in excess of the level which is determined based upon the calculation of the the average United States spot market price.

The spot market calculation is as follows: (1) Weighted average spot market prices for SLM 1–1/16 inch upland cotton, micronaire 3.5 through 4.9:

August 1975 through July 1976 - 55.29 cents.
August 1976 through July 1977 - 71.59 cents.
August 1977 through July 1978 - 51.15 cents.
August 1978 through July 1979 - 61.01 cents.
August 1979 through July 1980 - 68.87 cents.

(2) Average of the five years, excluding the highest and lowest years: 55.29 + 61.01 + 68.87 / 3 = 61.72 cents.

(3) Loan rate based on U.S. spot market calculation: 61.72 x 0.85 = 52.46 cents.

The Northern Europe calculation is as follows:

(1) Average Northern Europe quotation for SM 1-1/16 inch cotton July 1 through Oct. 14, 1980...	95.35
(2) Average difference between average Northern Europe quotation and the U.S. spot market average for SLM 1-1/16 inch, mic. 3.5 through 4.9 Apr. 15 through Oct. 15, 1980	-11.18
(3) Adjusted Northern Europe average	84.17
(4) 90 percent of adjusted average	75.75

Accordingly, the 1981 upland cotton loan rate is 52.46 cents per pound.

2. The loan level for 1981-crop ELS cotton is 99.0 cents per pound, and the payment rate is zero. Section 101(f) of the 1949 Act requires that price support shall be made available to cooperators for the 1968 and each subsequent crop of ELS cotton, if producers have not disapproved marketing quotas therefor, through loans at a level which is not less than 85 percent or more than 135 percent in excess of the loan level established for Strict Low Middling 1-1/16 inch upland cotton of such crop at average location in the United States (except that such loan level for ELS cotton shall in no event be less than 35 cents per pound). Section 101(f) also provides for price support payments at a rate which, together with the loan level established for such crop, shall be not less than 55 percent or more than 90 percent of the parity price for ELS cotton as of the month in which the payment rate so determined is announced. Section 401 of the 1949 Act requires that, in determining the level of support in excess of the minimum level prescribed for ELS cotton, consideration shall be given to the supply of the commodity in relation to the demand therefor, the price levels at which other commodities are being supported, the availability of funds, the perishability of the commodity, the importance of the commodity to agriculture and the national economy, the ability to dispose of stocks acquired through a price support operation, the need for offsetting temporary losses of export markets, and the ability and willingness of producers to keep supplies in line with demand.

The loan rate of 52.46 cents per pound for 1981-crop upland cotton is basis 3.5 through 4.9 micronaire. This rate must be converted to average micronaire by deducting 0.85 cents—the estimated premium included in the upland rate for 3.5 through 4.9 micronaire—before it can serve as the basis for the ELS loan rate. The possible range of the loan rate for ELS cotton is 95.48 to 121.28 cents (85 percent to 135 percent in excess of the adjusted rate for upland cotton). The parity price for ELS cotton applicable for October 1980 is $1.80 per pound. The

minimum total support is 99.0 cents per pound (55 percent of parity), and the maximum total support is $1.62 per pound (90 percent of parity).

Supplies of ELS cotton are projected to continue tight during the remainder of the 1980/81 marketing year. Stocks carried into the 1981/82 marketing year, which begins on August 1, 1981, are projected at 31,000 bales. The market price for ELS cotton is likely to be sufficient incentive for producers to increase their plantings of ELS cotton in 1981/82. Therefore, there is no need to provide a total support above the minimum level of 55 percent of parity, and there is no need to provide a direct support payment for the 1981 crop of ELS cotton.

It is determined that the loan rate for 1981-crop ELS cotton is 99.0 cents per pound. Since 99.0 cents per pound is equal to the statutory minimum of 55 percent of the October 1980 parity price for ELS cotton, no support payments are required to be made.

The loan rate of 99.0 cents per pound for 1981-crop ELS cotton would encourage the production of ELS cotton for the marketplace and minimize government expenditures for the ELS program. This level is expected to provide adequate returns to ELS producers and would not constrict export sales or domestic mill use.

3. The seed cotton loan program has been reviewed, and it has been determined that seed cotton from the 1981 crops of upland and ELS cotton will again be elegible for loans. Recourse loans are offered to producers of seed cotton pursuant to the Commodity Credit Corporation Charter Act as a means of affording interim financing to producers until their cotton is ginned in the form in which it can be marketed and eligible for regular nonrecoure loans under the upland and ELS cotton programs under the provisions of the 1949 Act, as amended.

Detailed regulations concerning the seed cotton loan program will be published later.

Signed at Washington, D.C. on December 22, 1980.

Jim Williams,

Acting Secretary of Agriculture.

[FR Doc. 80-40391 Filed 12-29-80; 8:45 am]

BILLING CODE 3410-05-M

Forest Service

National Forest System Advisory Committee; Meeting

The National Forest System Advisory Committee will meet in Washington, D.C., January 15-16, 1981. The meeting will be held in the South Agriculture Building, 12th Street and Independence Avenue, SW., Room 3840, beginning at 8 a.m.

This Committee, comprised of 12 members from a broad spectrum of geographic and interest areas, advises the Secretary of Agriculture and the Forest Service on the planning and management of the National Forests. The purpose of the meeting is to bring to completion subcommittee positions or recommendations on *energy* (biomass, transmission corridors, small hydroelectric facilities, and energy minerals), *Resources Planning Act, human resources programs* (and their use in achieving National Forest outputs), and *subjects recommended for further study* and evaluation. This will include non-Forest uses on Forest lands and information on land grant college assistance to States and Federal agencies as in the case of the Range Improvement Task Force at New Mexico State University.

Phillip L. Thornton, Acting Deputy Assistant Secretary for Natural Resources and Environment, and Kay Ceniceros, Advisory Committee chairperson, will cochair the meeting.

The meeting will be open to the public. Persons who wish to attend should notify Floyd J. Marita, Executive Secretary, USDA-Forest Service, P.O. Box 2417, Room 3021-S, Washington, D.C. 20013, telephone (202) 447-6341. Written statements may be filed with the Committee before or after the meeting.

Jerome A. Miles,

Deputy Chief.

December 22, 1980.

[FR Doc. 80-40359 Filed 12-29-80; 8:45 am]

BILLING CODE 3410-11-M

CIVIL AERONAUTICS BOARD

Alaska International Air, Inc.; Service Mail Rates Investigation

AGENCY: Civil Aeronautics Board.

ACTION: Summary of Order 80-12-107 modifying the temporary subsidy mail rate for Alaska International Air, Inc., effective November 4, 1980, retroactively.

SUMMARY: The Board adopted an order, modifying Alaska International Air's temporary mail rates as prescribed by Order 80-10-1, insofar as they relate to points in the Aleutian Islands. Instead, the final mail rates established by Order 80-5-33 for Reeve Aleutian Airways for mail service to points in the Aleutians will apply to AIA.

DATE: Since these rates have already gone through full notice and comment procedures when they were originally established for Reeve, the institution of show-cause procedures on these rates is unnecessary and they are effective on and after November 4, 1980, the date on which Alaska International Air filed its rate petition.

FOR FURTHER INFORMATION CONTACT: Peter Bonanno, Jr., Bureau of Domestic Aviation, Civil Aeronautics Board, 1825 Connecticut Ave., N.W., Washington, D.C. 20428.

The complete text of Order 80-12-107 is available from our Distribution Section, Room 516, 1825 Connecticut Ave., N.W., Washington, D.C. Persons outside the metropolitan area may send a postcard request for Order 80-12-107 to the Distribution Section, Civil Aeronautics Board, Washington, D.C. 20428.

By the Civil Aeronautics Board: December 19, 1980.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 80-40380 Filed 12-29-80; 8:45 am]

BILLING CODE 6320-01-M

[Order 80-12-94; Docket 38504]

Mississippi Valley Airlines, Inc.; Intent To Terminate Essential Air Service at Ottumwa, Iowa

Adopted by the Civil Aeronautics Board at its offices in Washington, D.C. on the 18th day of December, 1980. Application of Mississippi Valley Airlines, Inc. for compensation for losses in providing essential air transportation at Ottumwa, Iowa, under section 419(a)(3) of the Federal Aviation Act of 1958, as amended; Docket 38504.

On July 21, 1980, Mississippi Valley Airlines, Inc. (MVA) filed a notice of intent to terminate essential air service at Ottumwa, Iowa, effective August 20, 1980. By Order 80-8-108, August 20, 1980, we prohibited the carrier from suspending or reducing its servcie at Ottumwa for a 30-day period, through September 19, 1980.[1]

On October 22, 1980, MVA filed an application for compensation for losses at Ottumwa for the period August 20 through September 19, 1980, inclusive. The carrier porvided a detailed explanation of its estimated traffic, revenue, expenses, and operating statistics and sought interim compensation of $39,989.07, excluding profit, for each 30-day period of forced service. On Novmeber 17, 1980, the carrier reduced its compensation

[1] We have since extended the carrier's obligation.

request to $32,188.56 exclusive of profit, to reflect actual rather than estimated August costs, and a change from flight hours to seat miles as a basis for allocating most indirect expenses.

We have reviewed MVA's application and find that the information contained therein reasonably supports the requested compensation on an interim basis with but one exception. We are reallocating certain indirect expenses using revenue passenger miles rather than seat miles. This reduces compensation to $30,305, exclusive of profit, for each 30-day period of compulsory service. A profit element will be considered when we propose a final settlement of the carrier's claim.

Accordingly, pursuant to the Federal Aviation Act of 1958, as amended, particularly sections 102, 204, 419, and 1002(d) thereof, and the regulations promulgated in 14 CFR 302 and 304:

1. We set the interim level of compensation for losses sustained by Mississippi Valley Airlines, Inc. by virtue of its provision of essential air transportation at Ottumwa, Iowa at $120.737 for each scheduled flight completed beginning August 20, 1980, subject to a maximum compensaton of $30,305 per 30-day period;

2. This proceeding shall remain open pending entry of an order fixing the final rate of compenstaiton, and the amount of such rate of compensation may be the same as, lower than, or higher than the interim rate of compensation set here; and

3. We shall serve the order upon all parties to this proceeding.

We shall publish this order in the **Federal Register.**

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 80-40379 Filed 12-29-80; 8:45 am]

BILLING CODE 6320-01-M

DEPARTMENT OF COMMERCE

Senior Executive Service; Bonuses

Below is a listing of Senior Executive Service employees who are scheduled to receive bonuses:

Allan H. Young, Deputy Director, Bureau of Economic Analysis, $5,512—to be paid 1/12/81

Robert P. Parker, Chief, National Income and Wealth Division, Bureau of Economic Analysis, $5,512—to be paid 1/12/81

Carol S. Carson, Chief, Current Business Analysis Division, Bureau of Economic Analysis, $5,512—to be paid 1/12/81

Beatrice N. Vaccara, Director, Bureau of Industrial Economics, $5,512—to be paid 1/12/81

Katherine K. Wallman, Deputy Director for Social Statistics, Office of Federal Statistical Policy and Standards, $5,512—to be paid 1/12/81

Jo Ann Sondey-Hersh,

Executive Secretary, Economic and Statistical Affairs Performance Appraisal System.

[FR Doc. 80-40469 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-85-M

Bureau of the Census

Neighborhood Statistics Program; Application Deadline Extension

The Director of the Bureau of the Census is issuing below a statement that extends the application deadline of the 1980 census Neighborhood Statistics Program from December 31, 1980, to June 30, 1981. The final criteria for program participation and an explanation of the application procedure were announced in the November 21, 1979, issue of the **Federal Register** (Vol. 44, Number 226, pages 66862 and 66863). Expressions of interest in this program or requests for further information should be sent to the Director, Bureau of the Census, Washington, D.C. 20233.

1980 Census Neighborhood Statistics Program

Because of the great interest that has been expressed in the Neighborhood Statistics Program, the Bureau of the Census is extending the application deadline for program participation to June 30, 1981. The new deadline is the date by which all documentation described below must be submitted to the Bureau.

Any locality which is interested in the Neighborhood Statistics Program but has not yet notified the Census Bureau is urged to do so as soon as possible. Participation in the program should be initiated by a written request from either the chief elected official of the local government or an appropriate officer of a central neighborhood council or coalition that represents all neighborhoods in the locality. The request should include a description of how the neighborhoods meet the final criteria and a map showing the boundaries of all the neighborhoods. The letter requesting participation also should designate a person who will coordinate program activities in the locality and serve as contact person for the Bureau of the Census.

Dated: December 23, 1980.

Vincent P. Barabba,

Director, Bureau of the Census.

[FR Doc. 80-40540 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-07-M

Economic Development Administration

Senior Executive Service Performance Awards

As authorized by 5 USA 5384, notice is hereby given that the following senior executives in the Department of Commerce, Economic Development Administration will receive SES performance awards in the amount of $5,500 on January 25, 1981:

SES Members:

Harold W. Williams, Deputy Assistant Secretary

George T. Karras, Deputy Assistant Secretary for Economic Development Operations

John E. Corrigan, Director, Philadelphia Regional Office

Dated: December 22, 1980.

Robert T. Hall,

Assistant Secretary for Economic Development.

[FR Doc. 80-40435 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-24-M

International Trade Administration

Footwear From Republic of Korea; Preliminary Results of Administrative Review of Countervailing Duty Order and of Tentative Determination To Revoke

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice of Preliminary Results of Administrative Review of Countervailing Duty Order and of Tentative Determination to Revoke.

SUMMARY: This notice is to advise the public that, as a result of an administrative review of the countervailing duty order on footwear from the Republic of Korea, the Department of Commerce has tentatively determined to revoke such order on the grounds that net subsidies have been *de minimis* for at least two years. Interested parties are invited to comment on this decision.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: Josephine Russo, Office of Compliance, International Trade Administration, U.S. Department of Commerce, Room 1126, Washington, D.C. 20230 (202-377-4023).

SUPPLEMENTARY INFORMATION: A notice of "Final Countervailing Duty Determination," T.D. 76–13, was published in the Federal Register of January 9, 1976 (41 FR 1588–89). The notice stated that the Treasury Department has determined that exports of rubber and non-rubber footwear from the Republic of Korea were provided bounties or grants, within the meaning of section 303 of the Tariff Act of 1930 (19 U.S.C. 1303)("the Act"). Accordingly, imports into the United States of this merchandise were subject to countervailing duties. Concurrently with that determination, however, Treasury published T.D. 76–14 (41 FR 1587–88) waiving the imposition of those duties on rubber footwear under the authority of section 303(d) of the Act.

The term "rubber footwear" as used throughout this proceeding covers footwear which is either: (1) over 50 percent by weight of rubber or plastics; or (2) over 50 percent by weight of a combination of fibers with rubber or plastics, with at least 10 percent by weight of rubber or plastics. Such footwear is currently classifiable under items 700.51, 700.52, 700.53, 700.54 and 700.58 (both formerly 700.55), or 700.60, Tariff Schedules of the United States (TSUS). "Non-rubber footwear" covers all other footwear classifiable under Part I, Subpart A, of Schedule 7 of the TSUS.

The countervailable programs under the Final Determination are: (1) preferential short-term export financing, (2) special tax benefits provided to enterprises located in the Masan Free Trade Zone, (3) tax benefits resulting from the inclusion in loss accounts of reserve funds for losses accruing from overseas activities, and (4) accelerated depreciation of fixed assets utilized for export production. The Treasury Department found that Korean manufacturers or exporters of footwear received bounties or grants of 0.7 percent *ad valorem*.

On November 19, 1979, the Treasury Department received a request for revocation of the order from the Government of the Republic of Korea. In its submission, the Republic of Korea alleged that only three footwear companies received benefits from reserve funds and that, for more than a two-year period (through September 1979), reserve fund benefits were less than 0.3 percent. Four other companies were located in the Masan Free Trade Zone. Only one of these exported footwear after 1976, and it ceased exporting to the United States after May 1977. With regard to all of the programs, total benefits did not exceed 0.3 percent *ad valorem* for any company for the period January 1977 through September 1979. The Government of Korea argued that this level was *de minimus*.

On January 1, 1980, Title I of the Trade Agreements Act of 1979 (93 Stat. 150)("the TAA") went into effect. On January 2, 1980, the authority for administering the countervailing duty law was transferred from the Treasury Department to the Department of Commerce ("the Department"). Because Korea was not a "country under the Agreement" (as defined in section 701(b) of the Act), the Department revoked the waiver on February 21, 1980 for rubber footwear (45 FR 12860). On April 7, 1980, liquidation was suspended on all shipments of footwear from Korea entered, or withdrawn from warehouse, for consumption retroactive to January 1, 1980. Subsequently, the Department conducted an administrative review of the information submitted by the Korean Government. We confirmed that the benefits received by the exporting firms were no more than 0.30 percent *ad valorem* from January 1977 through December 1979.

We verified the information by examining Korean Government laws and documents; company books and records; and consulting with economic officials of the United States consulate in the Republic of Korea.

As a result of our administrative review, we preliminarily conclude that the imported merchandise has not benefitted from more than *de minimis* net subsidies for at least the two-year period specified in section 355.42, Commerce Regulationas. As further required by this section, the manufacturers and exporters have agreed in writing to an immediate suspension of liquidation and, if appropriate, reinstatement of the order if circumstances develop which indicate that the imported merchandise benefits from a net subsidy.

Therefore, the Department has tentatively detemined to revoke the countervailing duty order concerning footwear from Kora. If this order is revoked, it shall apply with respect to unliquidated entries of this merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice. Additionally, entries from January 1, 1980 to the date of publication, assuming no change in the *de minimis* rate, will be liquidated without regard to countervailing duties. The suspension of liquidation previously ordered will continue until further notice.

Interested parties may submit written comments on or before January 29, 1981, and may request disclosure and/or a hearing on or before January 14, 1981.

The Department will publish a notice of final results of administrative review after analysis of issues raised in written comments or at a hearing.

This administrative review, tentative determination to revoke, and notice publication are in accordance with section 751(a)(1), (c) of the Act (93 Stat. 175–76, 19 U.S.C. 1675(a)(1), (c)) and sections 355.41 and 355.42 of the Commerce Regulations (19 CFR 355.41, 355.42, 45 FR 4947–48).

John D. Greenwald,

Deputy Assistant Secretary for Import Administration.

December 18, 1980.

[FR Doc. 80-40365 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-25-M

Minority Business Development Agency

Financial Assistance Application Announcement

December 18, 1980.

The Minority Business Development Agency announces that it is seeking applications under its program to operate one project for a twelve month period beginning April 1, 1981. The total cost of the project will not exceed $340,000.

Funding Instrument: It is anticipated that the funding instrument, as defined by the Federal Grant and Cooperative Agreement Act of 1977, will be a grant.

Program Description: The General Business Services Program (GBS) of the Minority Business Development Agency (MBDA) provides technical assistance to minority business persons and firms for the purpose of improving their stability by increasing their management and marketing capabilities. MBDA offers competitive grants to consulting firms (either non-profit or commercial entities). These firms must be capable of providing such services as:

Preparation of business plans;
Financial packaging;
Industrial management assistance;
Personnel management services;
Marketing planning.

and a broad range of other business services excluding legal services.

Applications are invited for the following project: One grant for a management and technical assistance project to operate in the Columbia, Greenville, Spartanburg, and Charleston SMSAs in South Carolina. The project will operate at a cost not to exceed $340,000. The Project I.D. Number is 04–10–80002–01. This project will also

include supplying specialized consulting services.

Eligibility Requirements: There are no restrictions. Any profit or non-profit institution is eligible to submit an application.

Pre-application Conference: A Pre-application Conference for this project will be held on January 8, 1981 at 1:30 p.m. at the following address: U.S. Department of Commerce, Minority Business Development Agency, 1371 Peachtree Street, NE, Suite 505, Conference Room, Atlanta, Georgia 30309.

Application Materials: An application kit for this project may be requested by writing the following address: U.S. Department of Commerce, Minority Business Development Agency, 1371 Peachtree Street, NE, Suite 505, Conference Room, Atlanta, Georgia 30309.

In requesting an application kit, the applicant must specify its profit status; i.e., State or local government, federally recognized Indian tribal units, educational institutions, hospitals, or other type of profit or non-profit institution. This information is necessary to enable MBDA to include the appropriate cost principles in the application kit.

Award Process: All applications that are submitted in accordance with the instructions in the application kit will be submitted to a panel for review and ranking. Specific criteria by which applications will be evaluated is included in the application kit.

Closing Date: Applicants are encouraged to obtain an application kit as soon as possible in order to allow sufficient time to prepare and submit an application before the closing date of January 21, 1981. Applications received after this date will not be considered.

(11.800 Minority Business Development, Catalog of Federal Domestic Assistance)

Note.—This program is not subject to the requirements of OMB Circular A–95.

Dated: December 18, 1980.

Charles F. McMillan,

Regional Director.

[FR Doc. 80-40381 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-21-M

National Bureau of Standards

Federal Standard COBOL (FIPS Pub. 21–1); Proposed Interpretation

Under the provisions of Public Law 89–306 (79 Stat. 1127; 40 U.S.C. 759 (f)) and Executive Order 11717 (38 FR 12315, dated May 11, 1973), the Secretary of Commerce is authorized to establish uniform Federal automatic data processing standards. Interpretation number 7 to Federal Standard COBOL (FIPS Pub 21–1) is being recommended for Federal use. It pertains to the OCCURS clause.

This proposed interpretation is in accordance with the Interpretation Procedures for Federal Standard COBOL as contained in Federal Information Processing Standards Publication 29, dated June 30, 1974. The proposed interpretation, if adopted, will serve as an additional specification to Federal Standard COBOL, which is an adoption of the voluntary industry standard (COBOL, X3.23–1974) that has been developed by the American National Standards Institute.

The proposed interpretation contains a definition of the problem identification of the issues, recommended interpretation, supporting justification for the proposed interpretation, necessary clarifications to Federal Standard COBOL to effect the resolution, and the effective date of the interpretation.

Prior to approval of the proposed interpretation by the National Bureau of Standards, it is essential to assure that proper consideration is given to the needs and views of manufacturers, the public, and State and local governments. The purpose of this notice is to solicit such views.

Interested parties may submit comments in writing to the Standards Administration Office, Institute for Computer Sciences and Technology, National Bureau of Standards, Washington, D.C. 20234, not later than March 30, 1981. Telephone inquiries should be directed to Mable V. Vickers at (301) 921–3485.

Dated: December 22, 1980.

Ernest Ambler,

Director.

Federal Standard COBOL Interpretation No. 7—The OCCURS Clause

Definition of the problem

When a group data item, having subordinate to it an entry that specifies the OCCURS DEPENDING ON clause, is the receiving field in a statement which moves data to the item, is it permissible for contents of subordinate variable-occurrence data items whose occurrence numbers exceed the value of the data item referenced in the OCCURS DEPENDING ON clause to be changed in a predictable way as a side effect of executing the statement?

Issues

The situation of concern arises where there are occurrences of a data item which lie beyond the maximum occurrence for a table determined by the value of another data item referenced in an OCCURS DEPENDING ON clause. It is necessary to determine the extent to which an implementation is permitted to change the contents of these occurrences. In particular, the question must be answered whether or not it is allowed for the contents of such occurrences to be changed as if they were part of the table area during the execution of statements which refer to a group data item which has the variable-occurrence data item subordinate to it.

Interpretation

This interpretation applies to American National Standard COBOL, X3.23–1974, as it has been adopted as Federal Standard COBOL, FIPS Pub 21–1. The interpretation is that the contents of data items whose occurrence numbers exceed the value of the data item referenced in the OCCURS DEPENDING ON clause are not predictable and may be changed or left intact as the implementor sees fit until the value of the data item referenced in the OCCURS DEPENDING ON clause is increased. After the value of the data item referenced in the OCCURS DEPENDING ON clause is increased, the varable-occurrence data items which previously had unpredictable contents cannot be assumed to contain or not to contain any particular values until data is next moved into them.

Supporting justification

References: The following references are to American National Standard COBOL, X3.23–1974:

(a) Pages III–3 and III–4, Paragraph 2.1.4, General Rule 3.b, states: ". . . the current value of the data item referenced by data-name-1 represents the number of occurrences. This format specifies that the subject of this entry has a varable number of occurrences. . . . This does not imply that the length of the subject entry is variable, but that the number of occurrences is variable. . . . Reducing the value of the data item referenced by data-name-1 makes the contents of data items, whose occurrence number now exceed the value of the data item referenced by data-name-1 unpredictable."

(b) Page III–4, Paragraph 2.1.4, General Rule 4, states: "When a group item, having subordinate to it an entry that specifies Format 2 of the OCCURS clause, is referenced, only that part of the table area that is specified by the

value of data-name-1 will be used in the operation."

Discussion:

Consider the following excerpts from a COBOL program:

```
01  A.
    02 B PICTURE IS 9.
    02 C.
       03 D OCCURS 1 TO 9 TIMES DEPENDING ON B
          PICTURE IS X.
          .
          .
          .
PARA-1. MOVE 9 TO B.
        MOVE "ABCDEFGHI" TO C.
PARA-2. MOVE 5 TO B.
PARA-3. MOVE "123456789" TO C.
PARA-4. MOVE 9 TO B.
PARA-5. IF C = "12345FGHI"
          PERFORM INTACT
        ELSE IF C = "123456789"
          PERFORM SIDE-EFFECT.
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(a) Execution of the two statements in paragraph PARA–1 establish the size of C as nine characters, including all nine occurrences of D, and results in the contents of C being "ABCDEFGHI". Execution of the statement in PARA–2 then causes C to include only the first five occurrences of D for purposes of executing subsequent statements which refer to C. The last four occurrences of D have unpredictable content according to reference (a). The statement in PARA–3 results in "12345" being moved into the leftmost characters of C according to reference (b). The statement in PARA–4 causes C to include all nine occurrences of D for purposes of executing subsequent statement. During execution of the following IF statement, control will pass to the procedure INTACT if the last four occurrences of D have been left intact throughout the execution of the statements in PARA–2, PARA–3, and PARA–4. Control will pass to the procedure SIDE–EFFECT if the result of executing the statement in PARA–3, in apparent violation of reference (b), is "as if" all nine occurrences of D had been used as the receiving field for the movement of data. This interpretation of Federal Standard COBOL allows for control to pass to either procedure or to neither of the procedures.

(b) Reducing the value of B to five in the statement in PARA–2, according to reference (a), causes the contents of D(6), D(7), D(8), and D(9) to be unpredictable. Concurrently with executing the statement in PARA–2 which reduces the value of B or any subsequently executed statement in PARA–3 or PARA–4, the contents of D(6), D(7), D(8), and D(9) may be changed since they are unpredictable. In PARA–4 the value of B is increased to nine. After completing the execution of this statement, the contents of D(6), D(7), D(8), and D(9) must no longer be changed except by execution of statements which move data to them according to the rules for the various COBOL statements. There are no statements to reinitiate the data in D(6), D(7), D(8), and D(9) after the value of B is increased in PARA–4. Therefore, either or both of the two conditions in the following IF statements can be false. Control need not pass to either of the procedures INTACT or SIDE–EFFECT.

(c) The specifications in American National Standard COBOL, X3.23–1974, are directed both to implementors of COBOL compilers and to users who write programs for interchangeable use with various compilers. Reference (a) specifies that the contents of occurrences which lie outside the current table area are unpredictable. Reference (a) is obviously not intended to require that an implementation must introduce indeterminacy in the contents of data items outside the table area. For a given implementation, these contents may be predictable, and this does not make the compiler noncompliant with the standard. In the example presented, reference (a) is no obstacle to passing control to either of the procedures INTACT or SIDE–EFFECT.

The specification of unpredictability is directed instead to the programmer. Standard-complaint programs cannot depend for their correctness upon the contents of occurrences which lie outside the current table area either being left intact or being changed in a particular way, despite the fact that any one implementation may give consistent results.

(d) Reference (b) specifies that only the occurrences that are part of the current table area will be used in an operation referencing a group data item to which the occurrences are subordinate. If, at the time of executing the statements in PARA–5, the contents of D(6), D(7), D(8), and D(9) are "6", "7", "8", "9", respectively, control passes to the procedure SIDE–EFFECT. It appears "as if" all occurrences of D, rather than just the first five, had been used as the receiving field when the group data item C was referenced in the execution of the MOVE statement in PARA–3.

This appearance is not, however, prohibited by reference (b). Neither reference (a) nor any other specification restricts the times at which the contents of occurrences outside the current table area can be changed once they become unpredictable. If these contents are subsequently found to have any particular values, this is an accident of implementation that need not be attributed to any one operation during the execution of statements. This is true even if the values are the same as those which could result from a hypothetical aberrant execution of a statement.

Clarification of Federal Standard COBOL. None.

Effective date of interpretation.—The effective date of this interpretation shall be 30 days after the date the approved interpretation is published in the **Federal Register.**

[FR Doc. 80-40344 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-13-M

Solicitation of Comments Concerning Protocol Standards for Local Area Networks

Under the provisions of Pub. L. 89–306 (79 Stat. 1127; 40 U.S.C. 759(f)) and Executive Order 11717 (38 FR 12315, dated May 11, 1973), the Secretary of Commerce is authorized to establish uniform automatic data processing standards. The National Bureau of Standards (NBS) is considering the development of Federal Information Processing Standards (FIPS) for local area networks. These protocol standards which are being developed correspond to layers one and two of the International Organization for Standardization (ISO), *Reference Model for Open Systems Interconnection,* (document number ISO/TC97/SC16 N227), and are meant to be applicable to local area networks in the one-to-twenty million bit per second speed range, covering distances of one-to-five kilometers and supporting over one hundred fifty drops or interfaces.

NBS is requesting comments on the following items:

1. The desirability of issuing a family of such protocol standards (as opposed to a single standard) dealing with the different local area network technologies that have been developed and are being developed.

Examples include carrier sense multiple access networks and token bus access networks.

2. The desirability of the issuance, as soon as possible, of protocol standards applicable to carrier sense multiple access networks due to the relative maturity of this type of technology.

3. The desirability of specifying protocol standards which can meet user requirements and can be implemented in a cost effective manner in LSI technology.

Comments should be provided in writing by March 2, 1981 to the following address: National Bureau of Standards, Director, Institute for Computer Sciences and Technology, Administration Building, Room A200, Washington, D.C. 20234. ATTN: Comments on LAN Standards.

For additional information contact: Robert P. Blanc, Chief, Systems and Network Architecture Division, Building 225, Room B218, Washington, D.C. 20234, (301) 921–3817.

Dated: December 22, 1980.

Ernest Ambler,

Director.

[FR Doc. 80-40440 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-13-M

National Oceanic and Atmospheric Administration

Coastal Zone Management Programs

AGENCY: Office of Coastal Zone Management.

ACTION: Notice of availability of evaluation findings.

SUMMARY: Notice is hereby given of the availability of the evaluation findings for the California, Delaware and Hawaii Coastal Zone Management Programs.

Section 312 of the Coastal Zone Management Act of 1972, as amended (16 U.S.C. 1451 et seq.) requires the conduct of a continuing review of the performance of each coastal state under its federally approved coastal zone management program. All 3 states evaluated were found to be adhering to their management programs as a result of which accomplishments are occurring with respect to resource protection, management of coastal development, increased recreational access, and improved government decisionmaking.

A copy of findings made by the Acting Assistant Administrator for Coastal Zone Management for each of these states may be obtained on request from: Rosella Sussman, Evaluation Officer, Office of Coastal Zone Management, Page Building 1, 3300 Whitehaven Street, N.W., Washington, D.C. 20235 (telephone: (202) 634–4245).

Dated: December 12, 1980.

Donald W. Fowler,

Acting Assistant Administrator for Coastal Zone Management.

[FR Doc. 80-40465 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-08-M

Western Pacific Fishery Management Council's Pelagic Fishery Resources Subpanel, Spiny Lobster Subpanel and Scientific and Statistical Committee; Public Meetings

AGENCY: National Marine Fisheries Service, NOAA.

SUMMARY: The Western Pacific Fishery Management Council, established by Section 302 of the Fishery Conservation and Management Act of 1976 (Pub. L. 94–265), has established a Spiny Lobster Subpanel, a Pelagic Fishery Resources Subpanel, and a Scientific and Statistical Committee (SSC), which will meet separately. The spiny Lobster Subpanel will meet to review the final Spiny Lobster Fishery Management Plan (FMP); the Pelagic Fishery Resources Subpanel will meet to review a final draft of the billfish source document, and the SSC will meet to review the final Spiny Lobster FMP, a final draft of the billfish source document, a work plan for the bottomfish fisheries, as well as other business.

DATES: The Spiny Lobster Subpanel meeting will convene on Friday, January 23, 1981, at approximately 1:30 p.m., and will adjourn at approximately 4:30 p.m. The Pelagic Fishery Resources Subpanel meeting will convene on Monday, January 26, 1981, at approximately 9 a.m., and will adjourn at approximately 5:30 p.m. and the SSC meeting will convene on Tuesday, January 27, 1981, at approximately 9 a.m., and will adjourn on Wednesday, January 28, 1981, at approximately 3:30 p.m. These meetings are open to the public.

ADDRESS: All of the above meetings will take place at the Honolulu Laboratory, Southwest Fisheries Center, National Marine Fisheries Service, 2570 Dole Street, Honolulu, Hawaii.

FOR FURTHER INFORMATION CONTACT: Western Pacific Fishery Management Council, Room 1608, 1164 Bishop Street, Honolulu, Hawaii 96813, Telephone: (808) 523–1368.

Dated: December 23, 1980.

William H. Stevenson,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 80-40535 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-22-M

National Technical Information Service

U.S. Government-Owned Inventions; Availability for Licensing

The inventions listed below are owned by the U.S. Government and are available for domestic and, possibly, foreign licensing in accordance with the licensing policies of the agency-sponsors.

Copies of patents cited are available from the Commissioner of Patents & Trademarks, Washington, DC 20231, for $.50 each. Requests for copies of patents must include the patent number.

Copies of patent applications cited are available from the National Technical Information Service (NTIS), Springfield, Virginia 22161 for $5.00 each ($10.00 outside North American Continent). Requests for copies of patent applications must include the PAT-APPL number. Claims are deleted from patent application copies sold to avoid premature disclosure. Claims and other technical data will usually be made available to serious prospective licensees upon execution of a non-disclosure agreement.

Requests for information on the licensing of particular inventions should be directed to the addresses cited for the agency-sponsors.

Douglas J. Campion,

Program Coordinator, Office of Government Inventions and Patents, National Technical Information Service, U.S. Department of Commerce.

U.S. Department of Agriculture, Program Agreements and Patent Branch, Administrative Services Division, Federal Building, Science and Education Administration, Hyattsville, Md. 20782

Patent application 6–151,068: Control of Nematodes and Other Helminths; filed May 19, 1980

Patent application 6–156,292: Process for the Preparation of Tris[N-carbalkoxylaminomethyl) phosphine Oxides and Sulfides; filed June 4, 1980

Patent application 6–160,752: A Dry Chemical Process for Grafting Acrylic and Methyl Acrylic Ester and Amide Monomers Onto Starch-Containing Materials; filed June 18, 1980

Patent application 6–160,753: Process and Apparatus for Encapsulating Additives in Resealed Erythrocytes for Disseminating Chemicals via the Circulatory System; filed June 18, 1980

Patent application 6–160,754: Preferential Degradation of Lignin in Gramineous Materials; filed June 18, 1980

Patent application 6–163, 850: Control of Cotton Seedling Disease Pathogens with Pyrrolnitrin; filed June 27, 1980

Patent 4,209,433: Method of Bonding Particle Board and the Like Using Polyisocyanate/Phenolic Adhesive; filed December 19, 1978, patented June 24, 1980; not available NTIS

Patent 4,212,800: Inhibition of Lanthionine Formation During Alkaline Treatment of Keratinous Fibers; filed September 26, 1978, patented July 15, 1980; not available NTIS
Patent 4,214,873: Tris(N-Carbalkoxylaminomethyl-phosphine Oxides and Sulfides; filed April 30, 1979, patented July 29, 1980; not available NTIS

U.S. Department of Health and Human Services; National Institutes of Health, Chief, Patent Branch, Westwood Building, Bethesda, Md. 20205

Patent 4,201,773: 7-0-(2,6-Dideoxy-alpha-L/Lyxo-Hexopyranosyl)-Caunomycinone, Desmethoxy Daunomycinone, Adriamycinone, and Carminomycinone; filed July 26, 1978, patented May 6, 1980; not available NTIS
Patent 4,206,208: Use of 4-Carboxy-Phthalato(1.2-Diaminocyclohexane)-Platinum (II) and Alkali Metal Salts Thereof with Cyclophosphamide and 5-fluorouracil in Alleviating L1210 Murine Leukemia; filed December 22, 1978, patented June 3, 1980; not available NTIS
Patent 4,206,226: Use of 4-Carboxy-Phthalato-(1, 2-Diaminocyclohexane)-Platinum (II) and Alkali Metal Salts Thereof in Alleviating L1210 Murine Leukemia; filed July 19, 1978, patented June 3, 1980; not available NTIS
Patent 4,210,745: Procedure for the Preparation of 9-beta-D-Arabinofuranosyl-2-Fluoroadenine; filed November 20, 1978, patented July 1, 1980; not available NTIS
Patent 4,217,798: Automated Test Tube Stopper Remover; filed April 30, 1979, patented August 19, 1980; not available NTIS

U.S. Department of the Interior; Branch of Patents; 18th And C Streets, NW., Washington, D.C. 20240

Patent application 6-108,191: Electrowinning of Lead from H2SiF6 Solution; filed December 27, 1979
Patent application 6-109,361: Permeability Restoration and Lowering of Uranium Leakage From Leached Ore Beds; filed January 3, 1980
Patent application 6-116,695: Estraction of Metals from Mixtures of Oxides or Silicates; filed January 30, 1980
Patent application 6-116,697: Recovery of Lithium from Low-Grade Ores; filed January 30, 1980
Patent application 6-125,408: Process for Recovering Ni(II), Cu(II) and Co(II) from an Ammoniacal-Ammonium Sulfate Leach Liquor; filed February 28, 1980
Patent application 6-138,397: Polyimide Reverse Osmosis Membranes; filed April 8, 1980
Patent application 6-140, 380: Method for Wrought and Cast Aluminum Separation; filed April 14, 1980
Patent application 6-141,087: Leaching Gold-Silver Ores; filed April 17, 1980
Patent application 6-141,088: Leaching Gold-Silver Ores; filed April 17, 1980
Patent application 6-147,690: Method and Apparatus For the Measurement of Ionic Activities in Water With Differential Pressure Transducers; filed May 7, 1980
Patent application 6-152,211: Thorium Oxide-Containing Catalyst and Method of Preparing Same; filed May 21, 1980
Patent application 6-152,212: Selective Paging and Intercommunication System; filed May 21, 1980
Patent application 6-162,542: High Surface Area Transition Metal Catalysts and Method of Preparing Same; filed June 24, 1980
Patent 4,198,297: Removal of Trace Copper Ions From Water; filed November 23, 1976, patented April 15, 1980; not available NTIS
Patent 4,203,192: Method of Anchoring a Vibrating Wire into a Hollow Gauge Body; filed October 23, 1978, patented May 20, 1980; not available NTIS
Patent 4,208,275: Froth Flotation Using Lanolin Modifier; filed January 24, 1979, patented June 17, 1980; not available NTIS
Patent 4,208,294 Dilution Stable Water Based Magnetic Fluids; filed February 12, 1979, patented June 17, 1980; not available NTIS

U.S. Department of Energy, Assistant General Council for Patents, Washington, D.C. 20546

Patent 4,188,173: Vertical Pump with Free Floating Check Valve, Filed October 6, 1976, patented February 12, 1980; not available NTIS
Patent 4,192,714: Reactor Safety Method. Filed December 7, 1966, patented March 11, 1980; not available NTIS
Patent 4,205,278: Multiple Excitation Regenerative Amplifier Inertial Confinement System; filed January 11, 1978, patented May 27, 1980; not available NTIS

U.S. Department of the Navy Director, Navy Patent Program/Patent Council for the Navy, Office of Naval Research, Code 302, Arlington, Va. 22217

Patent application 6-156,441: Intense Ion Beam Generation with an Inverse Reflex Tetrode (IRT); filed June 4, 1980
Patent application 6-158,006: Transformer Core Clamp; filed June 9, 1980
Patent application 6-162,346: Autocorrelation Sidelobe Reduction Device for Phase-Coded Signals; filed June 23, 1980
Patent application 6-163,000: High-Agility Reflector support and Drive System; filed June 25, 1980
Patent application 6-172,848: Method and Composition for Cleaning Metal Surfaces; filed July 25, 1980
Patent 4,172,408: Liquid Propellant Gun, Breech Pressure Axial Injection; filed August 29, 1977, patented October 30, 1979; not available NTIS
Patent 4,173,002: Method of Lasing with 7-Hydroxy-Coumarin-8-Methyleneiminoblisacetic Acid and Metal Complexes Thereof; filed March 20, 1978, patented October 30, 1979; not available NTIS
Patent 4,184,018: Non-Flashing Electrolyte for use with Calcium Anode; filed February 5, 1979, patented January 15, 1980; not available NTIS
Patent 4,193,966: Carbon Dioxide Absorbent Cannister with Condensate Control; filed June 15, 1978, patented March 18, 1980; not available NTIS
Patent 4,197,510: Isochronous cyclotron; filed June 23, 1978, patented April 8, 1980; not available NTIS
Patent 4,197,517: High Speed Frequency Tunable Microwave Filter; filed November 3, 1978, patented April 8, 1980; not available NTIS
Patent 4,200,686: High Energy Density Thermal Cell; filed February 5, 1979, patented April 29, 1980; not available NTIS
Patent 4,200,753: Water-Soluble Fluorescing and Lasing Dyes; filed November 17, 1978, patented April 29, 1980; not available NTIS
Patent 4,204,659: Energy Absorber; filed April 25, 1978, patented May 27, 1980; not available NTIS
Patent 4,206,364: Device for Producing Extended Elongated Plasmas for X-Ray Lasers; filed January 16, 1979, patented June 3, 1980; not available NTIS
Patent 4,207,622: Direction-Finding Array of Crossed Dipoles; filed April 13, 1978, patented June 10, 1980; not available NTIS
Patent 4,207,625: Doppler Compensator for Heterodyne Correlation Devices; filed March 6, 1961, patented June 10, 1980; not available NTIS
Patent 4,209,767: Acousto-Optic Coupler for Glide Slope Control Systems; filed March 3, 1977, patented June 24, 1980; not available NTIS
Patent 4,210,847: Electric Wind Generator; filed December 28, 1978, patented July 1, 1980; not available NTIS
Patent 4,210,881: Millimetor Wave Microstrip Tripiexer; filed November 9, 1978, patented July 1, 1980; not available NTIS
Patent 4,211,502: Breakaway Pin Release; filed July 6, 1979, patented July 8, 1980; not available NTIS
Patent 4,213,029: Radiation Transmissive Housing Having a Heated Load Bearing Gasket; filed February 21, 1979, patented July 15, 1980; not available NTIS
Patent 4,215,291: Collective Particle Accelerator; filed February 2, 1979, patented July 29, 1980; not available NTIS

National Aeronautics and Space Administration, Assistant General Council for Patent Matters, NASA Code GP-2, Washington, D.C. 20545

Patent Application 6-161,256: Photocapacitive Image Converter; filed June 20, 1980
Patent 4,204,037: Method and Automated Apparatus for Detecting Coliform Organisms; filed April 4, 1978, patented May 20, 1980; not available NTIS
Patent 4,210,401: Visible and Infrared Polarization Ratio Spectroreflectometer; filed July 28, 1978, patented July 1, 1980; not available NTIS
Patent 4,210,474: Silicone Containing Solid Propellant; filed October 16, 1978, patented July 1, 1980; not available NTIS
Patent 4,212,199: System for Use in Conducting Wake Investigation for a Wing in Flight; filed February 28, 1979, patented July 15, 1980; not available NTIS
Patent 4,212,477: Circumferential Shaft Seal; filed March 31, 1976, patented July 15, 1980; not available NTIS
Patent 4,212,690: Heat Treat Fixture and Method of Heat Treating; filed March 23, 1979, patented July 16, 1980; not available NTIS
Patent 4,213,051: Dual Acting Slit Control Mechanism; filed September 8, 1978, patented July 15, 1980; not available NTIS

Patent 4,213,131: Scannable Beam Forming Interferometer Antenna Array System; filed May 14, 1979, patented July 15, 1980; not available NTIS

[FR Doc. 80-40468 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-04-M

National Telecommunications and Information Administration

Grant Appeals Board of the Public Telecommunications Facilities Program; Open Meeting

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice.

SUMMARY: By this notice we announce the rescheduling of a meeting of the Grant Appeals Board of the Public Telecommunications Facilities Program (PTFP).

PURPOSE: To consider the petition of Barbara Wheeler Gilbert, on behalf of the Wiconi Project of the South Dakota United Indian Association (Wiconi), seeking reconsideration of an action of the PTFP staff declining to accept for filing Wiconi's application for grant under the Public Telecommunications Financing Act of 1978, Pub. L. No. 95-567, 92 Stat. 2405, 47 U.S.C. 390, *et seq.* (1978), refusing to waive the closing date for the filing of applications and denying Wiconi's petition for extraordinary relief to become the substitute applicant for the American Indian Satellite Project.

TIME: January 15, 1981, at 10:00 a.m.

PLACE: National Telecommunications and Information Administration, 1800 G Street, N.W., Room 765, Washington, D.C.

COMMENTS: Interested parties are encouraged to submit comments on the petition for reconsideration of Ms. Gilbert. A copy of Ms. Gilbert's petition and the staff decision rejecting Wiconi's petition for extraordinary relief were published as appendices to our initial notice of this meeting. 45 F.R. 72,243 (October 31, 1980). An original and seven copies of any comments should be filed on or before January 8, 1981, with: Office of Chief Counsel, NTIA/DOC, 1800 G Street, N.W., Room 703, Washington, D.C. 20504. A certificate of service must be attached to the comments reflecting that a copy of the comments has been served on: Barbara W. Gilbert; Project Director, American Indian Satellite Project, 905 6th Street, S.W., Washington, D.C. 20024.

Additional information may be obtained from Robert Hunter, NTIA/DOC, Office of Chief Counsel, 1800 G Street, N.W., Room 703, Washington, D.C. 20504. Telephone (202) 377-1866.

(Catalog Program Number 11.550)

Gregg P. Skall,

Chief Counsel.

[FR Doc. 80-40541 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-60-M

Senior Executive Service; Bonuses

Below is a listing of Senior Executive Service employees who are scheduled to receive bonuses:

Stanley I. Cohn, Deputy Administrator for Operations, $5,512—to be paid 1/12/81
Dale N. Hatfield, Associate Administrator for Policy Analysis and Development, $8,018—to be paid 1/12/81
William F. Utlaut, Deputy Director, Institute for Telecommunication Sciences, $4,009—to be paid 1/12/81

Jo Ann Sondey-Hersh,

Executive Secretary, National Telecommunications and Information Administration Performance Appraisal System.

[FR Doc. 80-40470 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-BS-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Soliciting Public Comment on Bilateral Negotiations During 1981 With Governments of Japan, Mexico, Singapore and Sri Lanka

December 1980.

In accordance with the Committee for the Implementation of Textile Agreements' desire to solicit public comment whenever practicable on actions implementing the GATT Arrangement Regarding International Trade in Textiles (the "Multifiber Arrangement" or "MFA") and pursuant to the bilateral textile agreements, the U.S. Government anticipates holding negotiations during 1981 with the Governments of Japan, Mexico, Singapore and Sri Lanka regarding certain aspects of the agreements.

Any party wishing to comment or provide data on information regarding these agreements, or to comment on domestic production or availability of textiles and apparel affected by the agreements, is invited to submit such comments or information in ten copies to Mr. Paul O'Day, Chairman, Committee for the Implementation of Textile Agreement and Deputy Assistant Secretary of Commerce for Textiles and Apparel, International Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230. Since the exact timing of the negotiations is not yet established, comments should be submitted promptly. Comments or information submitted in response to this notice will be available for public inspection in the Office of Textiles and Apparel, Room 2808, U.S. Department of Commerce, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Further comment may be invited regarding particular comments or information received from the public which the Committee for the Implementation of Textile Agreements considers appropriate for further consideration.

The solicitation of comments regarding any aspect of the MFA or agreements entered into thereunder, or the implementation thereof, is not a waiver in any respect of the exemption contained in 5 U.S.C. 553(a)(1) and 554 (a)(4) relating to matters which constitute "a foreign affairs function of the United States."

Paul T. O'Day,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 80-40434 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-25-M

Announcing an Import Restraint Level for Certain Man-Made Fiber Textile Products From Costa Rica, Effective January 1, 1981; Correction

December 23, 1980.

In FR Doc. 80-37046, appearing at pages 79136 and 79137 in the issue for Friday, November 28, 1980, the first sentence of paragraph 2 of the letter to the Commissioner of Customs, appearing on page 79137, which established an import restraint level for certain man-made fiber textile products from Costa Rica, effective on January 1, 1981, should be corrected to read as follows:

In carrying out this directive entries of textile products in Category 649 which have been exported to the United States on and after January 1, 1980 and extending through December 31, 1980, shall, to the extent of any unfilled balances, be charged against the level of restraint established for such goods during the twelve-month period which began on January 1, 1980 and extends through December 31, 1980.

Paul T. O'Day,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 80-40537 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-25-M

Announcing Import Restraint Levels for Certain Cotton, Wool and Man-Made Fiber Textile Products From Macau, Effective on January 1, 1981; Correction

December 23, 1980.

In FR Doc. 80-38471, appearing at page 81643 in the issue for Thursday, December 11, 1980, the first sentence of paragraph 2 of the letter to the Commissioner of Customs establishing import restraint levels for certain cotton, wool and man-made fiber textile products from Macau, effective on January 1, 1981, should be corrected to read as follows:

In carrying out this directive entries of textile products in the foregoing categories which have been exported to the United States on and after January 1, 1980 and extending through December 31, 1980, shall, to the extent of any unfilled balances, be charged against the levels of restraint established for such goods during the twelve-month period which began on January 1, 1980 and extends through December 21, 1980.

Paul T. O'Day,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 80-40538 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-25-M

Announcing Import Levels for Certain Cotton, Wool and Man-Made Fiber Textile Products From the Republic of Korea, Effective on January 1, 1981

December 23, 1980

AGENCY: Committee for the Implementation of Textile Agreements.

ACTION: Establishing import levels for certain cotton, wool and man-made fiber textile products imported from the Republic of Korea, effective on January 1, 1981.

SUMMARY: The Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of December 23, 1977, as amended, between the Governments of the United States and the Republic of Korea, establishes specific ceilings for cotton, wool and man-made fiber textile products in Categories 333/334/335, 338/339, 340, 341, 347/348, 433/434, 440, 444, 445/446, 633/634/635, 638/639, 640, 641, 643, 645/646, and 659 pt., among others, during the agreement year which begins on January 1, 1981 and extends through December 31, 1981. In the letter published below, the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs, in accordance with the terms of the bilateral agreement, to prohibit entry into the United States for consumption, or withdrawal from warehouse for consumption, of textile products in the foregoing categories, produced or manufactured in the Republic of Korea and exported during the twelve-month period which begins on January 1, 1981 and extends through December 31, 1981, in excess of the designated levels. The level for Category 645/646, among others, may be adjusted later in the year as a result of consultations between the two governments.

During the twelve-month period beginning on January 1, 1981, and also pursuant to the terms of the bilateral agreement, the United States Government has decided also to control Group I (Categories 300, 301, 310–320, 330, 360–363, 369, 600–605, 610–614, 625–627, 630, 665, 666, and 669) at the group level of 141,285,894 square yards equivalent.

(A detailed description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on February 28, 1980 (45 FR 13172), as amended on April 23, 1980 (45 FR 27463), and August 12, 1980 (45 FR 53506)).

This letter and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

EFFECTIVE DATE: January 1, 1981.

FOR FURTHER INFORMATION CONTACT: William Boyd, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, Washington, D.C. 20230 (202/377-5423).

Paul T. O'Day,

Chairman, Committee for the Implementation of Textile Agreements.

United States Department of Commerce, International Trade Administration
Washington, D.C., December 23, 1980.

Committee for the Implementation of Textile Agreements

Commissioner of Customs, Department of the Treasury, *Washington, D.C.*

Dear Mr. Commissioner: Under the terms of the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as extended on December 15, 1977; pursuant to the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of December 23, 1978, as amended, between the Governments of the United States and Republic of Korea; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended by Executive Order 11951 of January 6, 1977, you are directed to prohibit, effective on January 1, 1981 and for the twelve-month period extending through December 31, 1981, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton, wool and man-made fiber textile products in the following categories, produced or manufactured in Korea, in excess of the indicated levels of restraint:

Category	12-mo. level of restraint
Group I (300, 301, 310-320, 330, 360-363, 369, 600-605, 610-614, 625-627, 630, 665, 666 and 669).	141,285,894 square yards equivalent.
333/334/335	92,475 dozen of which not more than 52,618 dozen shall be in Category 333/334 and not more than 53,728 dozen shall be in Category 335.
338/339	504,099 dozen.
340	163,226 dozen.
341	101,689 dozen.
347/348	243,328 dozen of which not more than 171,825 dozen shall be in Category 347 and not more than 132,336 dozen shall be in Category 348.
433/434	16,691 dozen of which not more than 12,136 dozen shall be in Category 433 and not more than 6,224 dozen shall be in Category 434.
440	206,059 dozen.
444	3,906 dozen.
445/446	50,413 dozen.
633/634/635	1,347,719 dozen of which not more than 170,238 dozen shall be in Category 633; not more than 784,220 dozen shall be in Category 634; and not more than 595,418 dozen shall be in Category 635.
638/639	5,367,635 dozen.
640 pt.[1]	4,320,773 dozen.
640 pt.[2]	1,598,731 dozen.
641	994,774 dozen.
643	58,903 dozen.
645/646	3,126,416 dozen.
659 pt[3]	2,134,965 pounds.

[1] In Category 640, only T.S.U.S.A. numbers 380.0455, 380.8431 and 380.8433.
[2] In Category 640, all T.S.U.S.A. numbers except those listed in footnote 1.
[3] In Category 659, only T.S.U.S.A. numbers 703.0500, 703.1000 and 703.1515.

In carrying out this directive, entries of textile products in the foregoing categories, except Category 659 pt., which have been exported to the United States on and after January 1, 1980 and extending through December 31, 1980, shall, to the extent of any unfilled balances be charged against the levels of restraint established for such goods during the twelve-month period beginning on January 1, 1980 and extending through December 31, 1980. In the event that the levels of restraint established for that period have been exhausted by previous entries, such goods shall be subject to the levels set forth in this letter. Textile products in Category 659 pt. which have been exported prior to January 1, 1981 shall not be subject to this directive.

The levels of restraint set forth above are subject to adjustment in the future pursuant to the provisions of the bilateral agreement of December 23, 1977, as amended, between the Governments of the United States and the Republic of Korea, which provide, in part, that: (1) within the aggregate and applicable group limits, specific levels of restraint may be adjusted by designated percentages; (2) these same levels may be adjusted for carryover and carryforward up to 11 percent of the applicable category limit; (3) administrative arrangements or adjustments may be made to resolve problems arising in the implementation of the agreement. Any appropriate adjustments under the provisions

of the bilateral agreement referred to above will be made to you by letter.

A detailed description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on February 28, 1980 (45 FR 13172), as amended on April 23, 1980 (45 FR 27463), and August 12, 1980 (45 FR 53506).

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The actions taken with respect to the Government of the Republic of Korea and with respect to imports of cotton, wool and man-made fiber textile products from the Republic of Korea have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, these directions to the Commissioner of Customs, which are necessary for the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the **Federal Register**.

Sincerely,

Paul T. O'Day,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 80-40539 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-25-M

Announcing Import Restraint Levels For Certain Cotton and Man-Made Fiber Textile Products From the People's Republic of China, Effective January 1, 1981; Correction

December 22, 1980.

In **Federal Register** Doc. 80-37652, appearing at page 80324 in the issue for Thursday, December 4, 1980, the first sentence of paragraph 2 of the letter to the Commissioner of Customs establishing import restraint levels for certain cotton and man-made fiber textile products from the People's Republic of China, effective on January 1, 1981, should be corrected to read as follows:

In carrying out this directive entries of textile products in the foregoing categories which have been exported to the United States on and after January 1, 1980 and extending through December 31, 1980, shall, to the extent of any unfilled balances, be charged against the levels of restraint established for such goods during the twelve-month period which began on January 1, 1980 and extends through December 31, 1980.

Paul T. O'Day,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 80-40433 Filed 12-29-80; 8:45 am]

BILLING CODE 3510-25-M

DEPARTMENT OF DEFENSE

Office of the Secretary

DOD Advisory Group on Electron Devices; Advisory Committee Meeting

The DoD Advisory Group on Electron Devices (AGED) will meet in closed session on March 9–10, 1981, at the Advisory Group on Electron Devices, 201 Varick Street, New York, New York, 10014.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of Electron Devices.

The AGED meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities, or in their laboratories. The agenda for this meeting will include programs on Radiation Hardened Devices, Microwave Tubes, Displays and Lasers. The review will include details of classified defense programs throughout.

In accordance with 5 U.S.C. App. 1 Sec. 10(d) (1976), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1976), and that accordingly, this meeting will be closed to the public.

M. S. Healy,

OSD Federal Register Liaison Officer, Washington Headquarters Services, Department of Defense.

December 22, 1980.

[FR Doc. 80-40360 Filed 12-29-80; 8:45 am]

BILLING CODE 3810-70-M

DOD Advisory Group on Electron Devices, Working Group A; Advisory Committee Meeting

Working Group A (Mainly Microwave Devices) of the DoD Advisory Group on Electronic Devices (AGED) will meet in closed session on 22 January, 1981, at the Advisory Group on Electron Devices, 201 Varick Street, New York, New York 10014.

The mission of the Advisory group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group A meeting will be limted to review of research and development programs which the military propose to inititate with industry, universities or in their laboratories. This microwave device area includes programs on developments and research related to microwave tubes, solid state microwave, electronic warfare devices, millimeter wave devices, and passive devices. The review will include classified program details throughout.

In accordance with 5 U.S.C. App. 1 Sec. 10(d) (1976), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1976), and that accordingly, this meeting will be closed to the public.

M. S. Healy,

OSD Federal Register Liaison Officer, Washington Headquarters Services, Department of Defense.

December 22, 1980.

[FR Doc. 80-40361 Filed 12-29-80; 8:45 am]

BILLING CODE 3810-70-M

DOD Advisory Group on Electron Devices, Working Group B; Advisory Committee Meeting

Working Group B (Mainly Low Power Devices) of the DoD Advisory Group on Electron Devices (AGED) will meet in closed session 17 February 1981, at the Advisory Group on Electron Devices, 201 Varick Street, New York, New York 10014.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group B meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. The low power device area includes such programs as integrated circuits, charge coupled devices and memories. The review will include classified program details throughout.

In accordance with 5 U.S.C. App. 1 Sec. 10(d) (1976), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C.

552b(c)(1) (1976), and that accordingly, this meeting will be closed to the public.

M. S. Healy,

OSD Federal Register Liaison Officer, Washington Headquarters Services, Department of Defense.

December 22, 1980.

[FR Doc. 80-40362 Filed 12-29-80; 8:45 am]

BILLING CODE 3810-70-M

DOD Advisory Group on Electron Devices, Working Group C; Advisory Committee Meeting

Working Group C (Mainly Imaging and Display) of the DOD Advisory Group on Electron Devices (AGED) will meet in closed session 21–22 January 1981, at the Naval Ocean Systems Center, 271 Catalina Blvd., San Diego, Ca. 92152, and on 26 February 1981 at the Palisades Institute for Research Services, AGED, 1925 N. Lynn Street, Arlington, Virginia 22209.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group C meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. This special device area includes such programs as infrared and night vision sensors. The review will include classified program details throughout.

In accordance with 5 U.S.C. App 1 Sec. 10(d) (1976), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1976), and that accordingly, this meeting will be closed to the public.

M. S. Healy,

OSD Federal Register Liaison Officer, Washington Headquarters Services, Department of Defense.

December 22, 1980.

[FR Doc. 80-40363 Filed 12-29-80; 8:45 am]

BILLING CODE 3810-70-M

DOD Advisory Group on Electron Devices, Working Group D; Advisory Committee Meeting

Working Group D (Mainly Laser Devices) of the DoD Advisory Group on Electronic Devices (AGED) will meet in closed session 3 and 4 February 1981, at the Palisades Institute or Research Services, Inc., 1925 North Lynn Street, Arlington, Virginia 22209.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group D meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. The laser area includes programs on developments and research related to low energy lasers for such applications as battlefield surveillance, target designation, ranging, communications, weapon guidance and data transmission. The review will include classified program details throughout.

In accordance with 5 U.S.C. App 1 Sec. 10(d) (1976), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1976), and that accordingly, this meeting will be closed to the public.

M. S. Healy,

OSD Federal Register Liaison Officer, Washington Headquarters Services, Department of Defense.

December 22, 1980.

[FR Doc. 80-40364 Filed 12-29-80; 8:45 am]

BILLING CODE 3810-70-M

DEPARTMENT OF EDUCATION

Education Appeal Board; Applications for Review Accepted for Hearing

AGENCY: Department of Education.

ACTION: Notice of Applications for Review Accepted for Hearing by Education Appeal Board.

SUMMARY: This notice lists the applications for review that were received and accepted for hearing by the Education Appeal Board between July 1, 1980, and December 8, 1980.

FOR FURTHER INFORMATION CONTACT: Dr. David S. Pollen, Chairman, Education Appeal Board, 400 Maryland Avenue, S.W. (Room 2141, FOB–6), Washington, D.C. 20202. Telephone (202) 245–7835.

SUPPLEMENTARY INFORMATION: Under sections 451 through 456 of the General Education Provisions Act (20 U.S.C. 1234), the Education Appeal Board has authority to conduct (1) audit appeal hearings, (2) withholding, termination and cease and desist hearings initiated by the Secretary of Education, and (3) other proceedings designated by the Secretary as being within the jurisdiction of the Board. For information concerning the Board and its procedures, see the Board's final regulations published in the **Federal Register** on April 3, 1980 (45 FR 22634).

This notice lists the applications for review that were received and accepted for hearing by the Education Appeal Board between July 1, 1980, and December 8, 1980.

One application for review involved programs conducted under the Vocational Education Act of 1963, as amended: *Appeal of the State of Maryland,* Docket No. 10–(65)–80.

The State appealed a final audit determination by the Assistant Secretary for Vocational and Adult Education that Federal funds authorized under the Vocational Education Act of 1963 were misspent. The audit exceptions, based on two audits by the HEW Audit Agency, involve a number of State and city programs. The contested issues include the propriety of the State's procedure for determining recipient eligibility, the failure of the State to show how a funded curriculum project would benefit disadvantaged students, and the use of Vocational Education funds for projects covered by the Vocational Rehabilitation Act. Also in dispute are expenditures for city vocational education and work study programs, and for city administrative and wage costs. Finally, the State contests the audit finding that Consumer and Homemaking funds were improperly distributed. The Department of Education requested a refund from the State in the total amount of $513,712.

One application for review involved programs conducted under Title I of the Elementary and Secondary Education Act of 1965, as amended: *Appeal of the State of Illinois,* Docket No. 9–(64)–80.

The State appealed final audit determinations that: [1] one local educational agency failed to provide services from State and local funds to schools serving Title I project areas comparable to services provided schools in non-Title I project areas; [2] one local education agency used Title I funds to supplant State and local funds by charging Title I for a portion of the salaries of three principals; [3] the State educational agency awarded excess Title I funds to local districts after the period for obligating the funds had lapsed and without determining the need for additional funds or monitoring the use of these funds; and [4] two local educational agencies overstated indirect cost rates and misapplied indirect cost rates to capital expenditures under Title I. The Department of Education requested a refund of $718,458 from the State.

Intervention

Section 78.43 of the final regulations establishing procedures for the Education Appeal Board provides that an interested person, group, or agency may, upon application to the Board Chairperson, intervene in appeals before the Education Appeal Board, including the appeals listed above.

An application to intervene must indicate to the satisfaction of the Board Chairperson or, as appropriate, the Panel Chairperson, that the potential intervenor has an interest in and information relevant to the specific issues raised in the appeal. If an application to intervene is approved, the intervenor becomes a party to the proceedings.

All these applications or questions should be addressed to Dr. David S. Pollen, Chairman, Education Appeal Board, 400 Maryland Avenue, S.W. (Room 2141, FOB–6), Washington, D.C. 20202, telephone (202) 245–7835.

(20 U.S.C. 1234)

Note.— Catalog of Federal Domestic Assistance Number not applicable.

Dated: December 15, 1980.

David S. Pollen,

Chairman, Education Appeal Board.

[FR Doc. 80-40396 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

Education Appeal Board; Summaries of Final Actions

AGENCY: Department of Education.

ACTION: Summaries of final actions of the Education Appeal Board.

SUMMARY: This notice contains summaries of two decisions of the Education Appeal Board which were adopted as the final decisions of the Department of Education between July 1, 1980, and December 8, 1980. Also included is a summary of a cease and desist order issued by the EAB and a summary of an appeal dismissed by the Board during the same period.

FOR FURTHER INFORMATION CONTACT: Dr. David S. Pollen, Chairman, Education Appeal Board, 400 Maryland Avenue, S.W. (Room 2141, FOB–6), Washington, D.C. 20202. Telephone (202) 245–7835.

SUPPLEMENTARY INFORMATION: Under sections 451 through 456 of the General Education Provisions Act (20 U.S.C. 1234), the Education Appeal Board has authority to conduct (1) audit appeal hearings, (2) withholding, termination, and cease and desist hearings initiated by the Secretary of Education, and (3) other proceedings designated by the Secretary as being within the jurisdiction of the Board. For information concerning the Board and its procedures, see the Board's final regulations published in the **Federal Register** on April 3, 1980 (45 FR 22634).

This notice summarizes two decisions of the Education Appeal Board that were adopted as the final decisions of the Department of Education between July 1, 1980, and December 8, 1980. Also included is a summary of a cease and desist order issued and a summary of an appeal dismissed by the EAB during the same period. Summaries of the Board's final actions and decisions are published on a semiannual basis in order to keep the public informed as to the Board's activities.

The summaries are prepared as a convenience to the public and are intended only to highlight the holdings of the Education Appeal Board. The summaries are not official parts of the decisions and should not be relied upon as guidance from the Department of Education or legal precedent. Copies of the full decisions of Education Appeal Board are available at the address given above on request and with payment of the full costs of reproduction.

SUMMARY OF FINAL DECISION: *Appeal of the State of Pennsylvania,* Docket No. 10–(25)–76, July 12, 1980.

The State of Pennsylvania appealed five final audit determinations made by the Deputy Commissioner for Elementary and Secondary Education involving programs conducted by local educational agencies (LEAs) under Title I of the Elementary and Secondary Education Act of 1965, as amended. The Commissioner sought a refund of $664,707.21 from the State. Three LEAs intervened in the appeal, and the State of Pennsylvania moved the Panel to join two additional LEAs as indispensable parties. The Hearing Panel denied the State's motion as it found it had no direct jurisdiction to join parties. One of the LEAs in question entered the appeal voluntarily. The other LEA objected to being joined but promised full cooperation with the State on issues related to the appeal. The Panel held, therefore, that there was no prejudice to the State by its ruling.

On additional prehearing motions filed by the State, the Panel held that the Commissioner (now the Secretary) was authorized to seek recovery of improperly spent Title I funds; that the EAB had jurisdiction to review the final audit determinations and make an initial decision advising the Commissioner (now the Secretary) whether the audit exceptions were properly taken; that the procedures of the EAB as stated in the Board's regulations and general provisions were reasonable; and that the contested amount was reduced by application of the statute of limitations.

In the final opinion, the Panel upheld four audit exceptions. The Panel found that the two LEAs improperly used Title I funds to pay the salaries of personnel whose services were not designed to meet the special educational needs of educationally deprived children. The Panel found that two other LEAs improperly used Title I funds to provide services in schools that did not have high concentrations of children from low-income families and therefore were ineligible to receive Title I funds.

The Panel also found that although one LEA used Title I funds to pay the salaries of art, music and physical education teachers and library personnnel who served all the children in the LEA's elementary schools, virtually all the children in the schools were educationally deprived and the services were designed to meet the children's special educational needs. The Panel ruled that Pennsylvania did not have to refund to the Department the $242,282.92 at issue for this exception.

On several collateral issues, the Panel ruled that Pennsylvania's interests in a properly conducted audit were sufficiently protected by the appeal process, that the date of expenditure governed the application of the statute of limitations, and that Pennsylvania and the LEAs had sufficient notice of the evidentiary hearings held in the appeal.

The Hearing Panel issued a decision on May 7, 1980, requiring Pennsylvania to refund $422,424.29 to the U.S. Department of Education. This decision was adopted as the final decision of the U.S. Department of Education on July 12, 1980.

SUMMARY OF FINAL DECISION: *Appeal of the State of West Virginia,* Docket No. 3–(33)–77, August 30, 1980.

West Virginia appealed a final audit determination, made by the Deputy Commissioner for Elementary and Secondary Education, that a local educational agency agency within the State of West Virginia improperly used Federal funds under Title I of the Elementary and Secondary Education Act of 1965, as amended, to help pay construction costs of an administrative office building in 1975. The Deputy Commissioner requested a refund from the State in the amount of $125,000.

The Hearing Panel sustained the Deputy Commissioner's position, holding that Title I funds could not be used to help pay construction costs of an administrative office building. The Panel found that the administrative offices used to house Title I personnel were not

"school facilities" nor were they essential to the success of the local educational agency's Title I program, therefore the construction costs of these offices were not allowed by the Title I statute. Further, post-construction use of the offices for Title I purposes not contemplated and described by the local educational agency in its project application could not justify the use of Title I funds for construction.

On June 20, 1980, the Hearing Panel issued a decision requiring West Virginia to refund $125,000 to the U.S. Department of Education. The Panel's decision was adopted as the final decision of the U.S. Department of Education on August 30, 1980.

SUMMARY OF CEASE AND DESIST ORDER: *Cease and Desist Hearing for the State of California and the Richmond, California Unified School District,* Docked No. 4–(59)–80 September 27, 1980.

The Richmond, California Unified School District appeared before the EAB, for itself and with the authorization of the California State Department of Education, to argue against the issuance of a cease and desist order by the Board based on a cease and desist complaint issued by the Commissioner of Education on April 4, 1980. In the cease and desist complaint the Commissioner charged that the Richmond Unified School District violated advisory council requirements under Title I of the Elementary and Secondary Education Act of 1965, as amended, as interpreted in the Interpretive Rule issued by the Office of Education on October 27, 1978, by prohibiting a husband and wife from serving concurrently on a Title I advisory council. The Commissioner also charged that the California State Department of Education failed to carry out its Title I administrative responsibilities with regard to Richmond.

On preliminary matters, the Hearing Panel ruled that the Commissioner had complied with the Board's regulations providing for the issuance of a cease and desist complaint, and that the State educational agency and local educational agency had a right to appear to present reasons why the cease and desist order should not be issued.

The Panel held that it was required to enforce the Interpretive Rule, as EAB regulations prohibited the Panel from waiving the rule or ruling on its validity. The Panel found that the Interpretive Rule was applicable to the Richmond local educational agency and that, by its admitted policy of prohibiting a husband and wife from serving concurrently on a Title I advisory council, the local agency violated the rule. Further, the Panel held that the California State Department of Education violated the Interpretive Rule by failing to enforce it according to that agency's administrative responsibilities under Title I.

The Hearing Panel issued an order on July 24, 1980, requiring the Richmond Unified School District to cease and desist from enforcing its policy, and ordering the California State Department of Education to take apparopriate administrative steps to ensure compliance with the cease and desist order by the local educational agency. The order became final on September 27, 1980.

SUMMARY OF DISMISSAL OF ACTION: *Appeal of the State of Ohio,* Docket No. 5–(41)–78, November 20, 1980.

The State of Ohio appealed a final audit determination issued by the Department of HEW's Regional Commissioner of Region V in 1976. The audit exception was based on a transfer of $1,000,000 in Federal funds from the State Library Board to the State General Fund. The Federal money was awarded to the State under the Library Services and Construction Act (LSCA). The transfer was in accordance with a State appropriations act which provided State funds for library support during a period when LSCA funds were impounded by the Federal government. The State law directed the State finance director to recover these State expenditures for the general fund once Federal monies became available. At the State finance director's request, the State Library Board transferred $1,000,000 in subsequent LSCA Federal funds to the State Emergency Purposes fund. This transfer constituted partial replacement of $3,000,000 in State appropriations expended for library support during the period of impoundment, as required by the State law. The final audit determination maintained that such a transfer was improper.

The Assistant Secretary for Educational Research and Improvement further reviewed the final determination letter and vacated it as not supported by sufficient evidence. The Assistant Secretary moved the Hearing Panel to dismiss the appeal. The State of Ohio concurred in the motion. The Hearing Panel issued on Order Dismissing the Appeal on November 20, 1980.

Note.—Catalog of Federal Domestic Assistance Number not applicable.

Dated: December 15, 1980.

David S. Pollen,

Chairman, Education Appeal Board.

[FR Doc. 80-40397 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

Grants for Research on Knowledge Use and School Improvement

AGENCY: Department of Education.

ACTION: Amendment to Application Notice.

The application notice published in the **Federal Register** on December 5, 1980 (45 FR 80575–80576) is amended by revoking the January 6, 1981 closing date for submittal of preapplications for major grants under the Grants for Research on Knowledge Use and School Improvement program. There is no longer a requirement for the submittal of preapplications for major grants under this program.

This action is taken because of administrative delays in preparing the program announcement package.

FURTHER INFORMATION: For further information, contact Mr. Rolf Lehming, Team Leader, Knowledge Use and School Improvement Studies, DIP, NIE, OERI, who is located in Room 619B, 1200 19th Street, N.W., Washington, D.C. and whose telephone number is (202) 254–6050.

(Catalog of Federal Domestic Assistance Number 84.117, Educational Research and Development: formerly 13.950)

Dated: December 22, 1980.

F. James Rutherford,

Assistant Secretary for Educational Research and Improvement.

[FR Doc. 80-40396 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

National Institute of Handicapped Research; Transmittal of Applications

AGENCY: Department of Education.

ACTION: Notice of closing date for transmittal of applications.

Applications are invited for noncompeting continuation projects under the National Institute of Handicapped Research.

Authority for this program is contained in Section 204 of the Rehabilitation Act of 1973, as amended, by Pub. L. 95–602.

Under this program awards are issued to public and private agencies and organizations, including institutions of higher education.

The purpose of the awards is planning and conducting research, demonstration and related activities which bear

directly on the development of methods, procedures, and devices to assist in the provision of vocational and other rehabilitation services to handicapped individuals, especially those with the most severe handicaps.

Closing Date for Transmittal of Applications: To be assured of consideration for funding, applications for a noncompeting continuation award should be mailed or hand delivered no later than 90 days prior to the end of the current budget period.

If the application is late, the Department of Education may lack sufficient time to review it and may decline to accept it.

Applications Delivered by Mail: An application sent by mail must be addressed to the U.S. Department of Education, Application Control Center, *Attention:* 84.133, Washington, D.C. 20202.

An applicant should show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the U.S. Secretary of Education.

If an application is sent through the U.S. Postal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmark, or

(2) A mail receipt that is not dated by the U.S. Postal Service.

An applicant should note that the U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

An applicant is encouraged to use registered or at least first class mail.

Applications Delivered by Hand: An application that is hand delivered must be taken to the U.S. Department of Education, Application Control Center, Room 5673, Regional Office Building No. 3, 7th and D Streets, S.W., Washington, D.C.

The Application Center Control will accept a hand delivered application between 8:00 a.m., and 4:30 p.m. (Washington, D.C. time) daily, except Saturday, Sundays, and Federal holidays.

Available Funds: The funding level for the National Institute of Handicapped Research is expected to be approximately $35 million for fiscal year 1981.

Application Forms: Application forms will be mailed to applicants approximately 90 days before applications are due.

Applications must be prepared and submitted in accordance with the regulations, instructions, and forms included in the program information packages. Applicants are urged not to submit information that is not requested.

Applicable Regulations: Regulations governing this program include the following:

(a) Regulations governing the National Institute of Handicapped Research; and

(b) Education Division General Administrative Regulations (EDGAR) (34 CFR, Part 75, and 77) published in the **Federal Register** on April 3, 1980 (45 FR 22494).

Note.—Program regulations governing the institute are currently undergoing revision. Prior to final publication of these regulations, the Institute will review and make grant awards solely under the provisions of EDGAR.

Further Information: For further information contact Margaret J. Giannini, M.D., F.A.A.P., Director, National Institute of Handicapped Research, 400 Maryland Avenue, S.W., (Room 3070, Switzer Building), Washington, D.C. 20202. *Telephone:* 202–245–0565.

Dated: December 22, 1980.

(Catalog of Federal Domestic No. 84.133, National Institute of Handicapped Research)

Edwin Martin,

Assistant Secretary for Special Education Services.

[FR Doc. 80-40421 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Voluntary Agreement and Plan of Action To Implement International Energy Program; Meetings

In accordance with section 252(c)(1)(A)(i) of the Energy Policy and Conservation Act (42 U.S.C 6272), notice is hereby provided of the following meetings:

I. A meeting of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) will be held on January 6, 1981, at the offices of Mobil Oil Corporation, 150 East 42nd Street, New York, New York, beginning at 9:30 a.m. The agenda for the meeting is as follows:

1. Opening remarks.
2. Review of ISAG draft report on AST–3, and of matters arising from AST–3.
3. Closing remarks and confirmation of next meeting date.

II. A meeting of the Industry Working Party (IWP) to the International Energy Agency (IEA) will be held on January 14 and 15, 1981, at the offices of Texaco Inc., 2000 Westchester Avenue, White Plains, New York, beginning at 9:30 a.m. on January 14. The agenda for the meeting is as follows:

1. Status of Standing Group on the Oil Market (SOM) and IWP activities and arrangements for future meetings.
2. Questions concerning a review of the crude and oil product import registers.

As provided in section 252(c)(1)(A)(ii) of the Energy Policy and Conservation Act, these meetings will not be open to the public.

Pursuant to section 252(c)(3) of the Energy Policy and Conservation Act, a verbatim transcript of these meetings will be made; the transcript, with such deletions as are determined to be necessary or appropriate pursuant to E.O. 12065 (43 FR 28949, July 3, 1978), E.O. 11932 (41 FR 32691, August 5, 1976) and 22 CFR 9a.1–9a.9, will be available in the Reading Room of the Department of Energy, Room 1E–190, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, between the hours of 8:00 AM and 4:00 PM weekdays, except Federal holidays.

Issued in Washington, D.C., December 22, 1980.

Craig S. Bamberger,

Assistant General Counsel, International Trade & Emergency Preparedness.

[FR Doc. 80-40477 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-01-M

Office of Energy Research

Solar Photovoltaic Energy Advisory Committee and Subcommittee of the Energy Research Advisory Board; Open Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770), notice is hereby given of the following meetings:

Name: Solar Photovoltaic Energy Advisory Committee (SPEAC) and Central Utilities Applications Pilot Plant Subcommittee (CUAPPS) of the Energy Research Advisory Board.

Date and time:
January 19, 1981—9 a.m.–4 p.m. (SPEAC)
January 20, 1981—9 a.m.–12 noon (SPEAC)
January 20, 1981—1 p.m.–4 p.m. (CUAPPS)
January 21, 1981—9 a.m.–4 p.m. (SPEAC)

Place: *January 19–20, 1981* (SPEAC and CUAPPS), Sandia Laboratory, Room B–6, Koronado Club, Kirtland Air Force Base, Albuquerque, New Mexico.

January 21, 1981 (SPEAC), Solar Power Research Institute, Building 17, Room 4A, 1617 Cole Boulevard, Golden, Colorado.

Contact: Georgia Hildreth, Director, Advisory Committee Management, Department of

Energy, Forrestal Building—Room 8G087, 1000 Independence Avenue, SW., Washington, D.C. 20585 Telephone: 202–252–5187.

Purpose of the Committee: To advise the Secretary on the scope and pace of research and development with respect to solar photovoltaic energy systems; the need for and timing of solar photovoltaic energy systems demonstration projects; the need for change in any research, development, or demonstration program established under this Act; and the economic, technological, and environmental consequences of the use of solar photovoltaic energy systems.

Tentative agenda:

January 19–20, 1981—*SPEAC*

—Review of the photovoltaic systems development activities

—Review of the photovoltaic concentrator subsystem activities

—Public Comment (10 minute rule)

January 20, 1981—*CUAPPS*

—Discussion of need for pilot plant

—Public Comment (10 minute rule)

January 21, 1981—*SPEAC*

—Review of photovoltaic research and development activities

—Public Comment (10 minute rule)

Public participation: The meetings are open to the public. Written statements may be filed with the Committee and Subcommittee either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact the Advisory Committee Management Office at the address or telephone number listed above. Requests must be received at least 5 days prior to the meetings and reasonable provision will be made to include the presentation on the agenda. The Chairperson of the Committee and Subcommittee are empowered to conduct the meetings in a fashion that will facilitate the orderly conduct of business.

Transcripts: Available for public review and copying at the Public Reading Room, Room 1E190, Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C., between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Executive summary: Available approximately 30 days following the meeting from the Advisory Committee Management Office.

Issued at Washington, D.C. on December 22, 1980.

Georgia Hildreth,

Director, Advisory Committee Management.

[FR Doc. 80-40476 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-01-M

Economic Regulatory Administration

Mandatory Oil Import Program

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) is issuing this notice in order to clarify the status of the license fees formerly imposed on imports of petroleum and petroleum products by Presidential Proclamation 3279, as amended. Although the Proclamation currently provides that no fee shall be in effect through December 31, 1980, it is silent as to the status of license fees after that date. Consequently, in the absence of any further amendment of the Proclamation by the President, a zero fee will remain in effect indefinitely. Importers must continue to observe all the other requirements imposed by the Proclamation, including the requirement that they obtain licenses prior to the importation of petroleum and petroleum products.

FOR FURTHER INFORMATION CONTACT:

Martin J. Berrigan (Office of Oil Imports), Economic Regulatory Administration, 2000 M Street NW., Room 6222, Washington, D.C. 20461, (202) 653–3443

Robert D. R. de Sugny (Office of General Counsel), Department of Energy, 1000 Independence Avenue SW., Forrestal Building, Room 6F–094, Washington, D.C. 20585, (202) 252–2900

William L. Webb (Office of Public Information), Economic Regulatory Administration, 2000 M Street NW., Room 110–B, Washington, D.C. 20461, (202) 653–3511.

SUPPLEMENTAL INFORMATION:

Proclamation 3279 was amended in 1973 in order to impose per barrel license fees of $0.21 on crude oil and $0.63 on unfinished oils and finished products. Since that time the domestic and international oil markets have experienced significant changes. Domestic markets were made subject to price and allocation controls pursuant to the Emergency Petroleum Allocation Act, while international markets have experienced large price increases and fluctuating levels of supply. In order to meet those rapidly changing conditions, the amount of the fees has been changed on several occasions and the original $0.21 and $0.63 license fees have been suspended entirely since April 1979. The suspension was extended most recently in June of this year in order to provide time for a reassessment of the need for the $0.21 and $0.63 fees (Presidential Proclamation 4766, 45 FR 41899, June 23, 1980). At that time, no provision was made for the reimposition of any particular fee. Therefore, the license fee will remain at the zero level as long as the President does not take any further action to amend Proclamation 3279.

All other requirements of Proclamation 3279, as amended, remain in effect, which means that licenses still must be obtained from the Office of Oil Imports prior to the importation of petroleum and petroleum products. Section 213.35(a)(6) of the Mandatory Oil Import Program's regulations, contained in Title 10 of the Code of Federal Regulations, provides that licenses shall remain valid for such period as a zero fee is in effect. Therefore, an otherwise valid license may continue to be used by an importer despite the fact that a December 31, 1980, expiration date may appear on the face of the license. The foregoing does not apply to licenses issued for the exchange of Canadian crude oil under section 213.28(b) of the regulations; such licenses are valid for one year from the date of issuance unless fees are reimposed or the license is completely utilized at an earlier date.

Issued in Washington, D.C., December 22, 1980.

Hazel R. Rollins,

Administrator, Economic Regulatory Administration.

[FR Doc. 80-40463 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-01-M

Mapco, Inc.; Proposed Consent Order

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of proposed consent order and opportunity for comment.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) announces a proposed Consent Order and provides an opportunity for public comment on the proposed Consent Order and on potential claims against the refunds deposited in an escrow account established pursuant to the Consent Order.

Comments by: January 29, 1981.

ADDRESS: Send comments to Alan L. Wehmeyer, Chief, Crude Products Program Management Branch, Central Enforcement District, 324 East 11th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT:

Alan L. Wehmeyer, Chief, Crude Products Program Management Branch, Central Enforcement District, 324 East 11th Street, Kansas City, Missouri 64106. Phone (816) 374–5932.

SUPPLEMENTARY INFORMATION: On December 2, 1980, the Office of Enforcement of the ERA executed a proposed Consent Order with Mapco, Inc. ("Mapco"). Under 10 CFR, 205.199J(b), a proposed Consent Order which involves a sum of $5,000 or more in the aggregate, excluding penalties and interest, becomes effective only after the

DOE has received comments with respect to the proposed Consent Order. Although the ERA has signed and tentatively accepted the proposed Consent Order, the ERA may, after consideration of the comments it receives, withdraw its acceptance and, if appropriate, attempt to negotiate an alternative Consent Order.

I. The Consent Order

Mapco, with its home office located in Tulsa, Oklahoma, is engaged in the processing and sale of natural gas liquids (NGL) and NGL products, and is subject to the Mandatory Petroleum and Allocation and Price Regulations at 10 CFR Parts 210, 211, and 212. To resolve certain civil actions which could be brought by the Office of Enforcement of the Economic Regulatory Administration as a result of its audit of Mapco, the ERA Office of Enforcement and Mapco entered into a Consent Order, the significant terms of which are as follows:

1. The Office of Enforcement has examined Mapco's books and records and reviewed all pertinent matters relating to Mapco's compliance with the DOE petroleum price regulations in effect during the period from September 1, 1973 through October 31, 1980. All civil matters pertaining to compliance with the DOE petroleum price regulations and prices charged by Mapco in sales of NGL and NGL products during the period September 1, 1973 through October 31, 1980 are resolved by this Consent Order.

2. Mapco will refund the aggregate amount of $31,500,000, which includes interest through the date on which the Consent Order becomes effective, plus further interest as specified in the Consent Order. In addition, Mapco will reduce by $15,097,160 the amount of increased product costs incurred but not recovered as of September 30, 1980, and otherwise available for recovery in sales of covered NGL products after September 30, 1980.

3. Execution of the Consent Order constitutes neither an admission by Mapco nor a finding by DOE that Mapco has violated any statutes or applicable regulations of the Cost of Living Council, the Federal Energy Office, the Federal Energy Administration or the Department of Energy.

4. The provisions of 10 CFR 205.199J, including the publication of this Notice, are applicable to the Consent Order.

II. Disposition of Refunded Overcharges

In this Consent Order, Mapco agrees to refund, in full settlement of any civil liability with respect to actions which might be brought by the Office of Enforcement, ERA, arising out of the transactions specified in I.1. above, the sum of $31,500,000 within 60 months after the Consent Order becomes effective. Refunded overcharges will be distributed as follows:

a. With respect to its sales of propane through Thermogas, Inc. (Thermogas), Mapco will, beginning on the first day of the first month after the effective date of this Consent Order and continuing until such refund is completed, implement price reductions of not more than eight cents ($.08) per gallon but not less than one cent ($.01) per gallon in its sales of propane through Thermogas, in order to accomplish a refund in the aggregate of $22,500,000.

b. With respect to its sales of NGL products through Mapco Products Company (Mapco Products), Mapco agrees to refund the sum of $9,000,000, plus interest, in the form of checks made payable to the United States Department of Energy and delivered to the Assistant Administrator for Enforcement, ERA. These funds will remain in a suitable account pending the determination of their proper disposition.

The DOE intends to distribute the refund amounts in a just and equitable manner in accordance with applicable laws and regulations. Accordingly, distribution of such refunded overcharges requires that only those "persons" (as defined at 10 CFR 205.2) who actually suffered a loss as a result of the transactions described in the Consent Order receive appropriate refunds. Because of the petroleum industry's complex marketing system, overcharges may have been passed through as higher prices to subsequent purchasers or offset through devices such as the Old Oil Allocation (Entitlements) Program, 10 CFR 211.67. In fact, the adverse effects of the overcharges may have become so diffused that it is a practical impossibility to identify specific, adversely affected persons, in which case disposition of the refunds will be made in the general public interest by an appropriate means such as payment to the Treasury of the United States pursuant to 10 CFR 205.199I(a).

III. Submission of Written Comments

A. *Potential Claimant:* Interested persons who believe that they have a claim to all or a portion of the refund amount should provide written notification to the ERA at this time. Proof of claims is not now being required. Written notification to the ERA at this time is requested primarily for the purpose of identifying valid potential claims to the refund amount. After potential claims are identified, procedures for the making of proof of claims may be established. Failure of a person to provide written notification of a potential claim within the comment period for this notice may result in the DOE irrevocably disbursing the funds to other claimants or to the general public interest.

B. *Other Comments:* The ERA invites interested persons to comment on the terms, conditions, or procedural aspects of this Consent Order. You should submit your comments or written notification of a claim within 30 days after publication of this notice to Alan L. Wehmeyer, Chief, Crude Products Program Management Branch, ERA Central Enforcement District, U.S. Department of Energy, 324 East 11th Street, Kansas City, Missouri 64106. You may obtain a free copy of the Consent Order by writing to the same address.

You should identify your comments or written notification of a claim on the outside of your envelope and on the documents you submit with the designation, "Comments on Mapco Consent Order." We will consider all comments we receive within 30 days after the publication of this notice. You should identify any information or data which is, in your opinion, confidential and submit it in accordance with the procedures in 10 CFR 205.9(f).

Issued in Kansas City, Missouri, on the 4th day of December 1980.

William D. Miller,

District Manager, Economic Regulatory Administration.

Concurrence:

Robert J. Wehrle-Einhorn,

Acting Chief Enforcement Counsel.

[FR Doc. 80-40385 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Project No. 3273]

Chittenden Falls Hydro Power, Inc., Application for Short-Form License (Minor)

December 19, 1980.

Take notice that Chittenden Falls Hydro Power, Inc. (Applicant filed on July 30, 1980, an application for license pursuant to the Federal Power Act, 16 U.S.C. 791 (a)–825 (r) for construction and operation of a water power project to be known as Chittenden Falls Hydroelectric Project No. 3273. The project would be located on Kinderhook Creek at Stockport in Columbia County, New York. Correspondence with the Applicant should be directed to: Mary

A. Eckhoff, Box 806, Melville, Long Island, New York 11747.

Project Description—The project would consist of existing project works including: (1) a reinforced concrete dam, 320 feet long and 4 feet high, set on a natural rock ledge at the top of waterfalls 27 feet high; (2) a reservoir of negligible storage at surface elevation 59.6 feet m.s.l., (3) a timber sluiceway 8 feet wide, 8 feet deep, and 69 feet long; (4) a steel penstock, 90 inches in diameter and 46 feet long; (5) a powerhouse, 50 feet long and 30 feet wide, containing a 440-HP turbine and a 178-HP turbine; (6) a tailrace channel; and new project works to include (7) two horizontally mounted replacement generators, one rated at 300 kW and one rated at 125 kW, attached to the 440 HP turbine and 178 HP turbine, respectively; and (8) other appurtenances. Applicant estimates annual generation would average 2.5 million kWh.

Purpose of Project—Project energy would be sold to Niagara Mohawk Power Corporation.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide comments pursuant to the Federal Power Act, the Fish and Wildlife Coordination Act, the Endangered Species Act, the National Historic Preservation Act, the Historical and Archeological Preservation Act, the other applicable statutes. No other formal requests for comments will be made.

Comments should be confined to substantive issues relevant to the issuance of a license. A copy of the application may be obtained directly from the Applicant. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desiring to file a competing application must submit to the Commission, on or before February 23, 1981, either the competing applicaton itself or a notice of intent to file a competing application. Submission of a timely notice of intent allows an interested person to file the competing application no later than June 23, 1981. A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c), *as amended*, 44 FR 61328 (October 25, 1979). A competing application must conform with the requirements of 18 CFR 433 (a) and (d), as amended, 44 FR 61328 (October 25, 1979).

Comments, Protests, or Petitions to Intervene—Anyone desiring to be heard or to make any protests about this application should file a petition to intervene or a protest with the Federal Energy Regulatory Commission, in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1979). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in § 1.10 for protests. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but a person who merely files a protest or comments does not become a party to the proceeding. To become a party, or to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules. Any comments, protest, or petition to intervene must be filed on or before February 23, 1981. The Commission's address is: 825 North Capitol Street, N.E., Washington, D.C. 20426. The application is on file with the Commission and is available for public inspection.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 40366 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-85-M

[Docket No. ER81-171-000]

Duke Power Co.; Supplement to Electric Power Contract

December 19, 1980.

Take notice that Duke Power Company (Duke Power) tendered for filing on December 15, 1980 a supplement to the Company's Electric Power Contract with Blue Ridge Electric Cooperative, Inc. Duke Power states that this contract is on file with the Commission and has been designated Duke Power Company Rate Schedule FERC No. 142.

Duke Power further states that the Company's contract supplement, made at the request of the customer and with agreement obtained from the customer, provides for the following new delivery point: Delivery Point No. 19 with a designated demand of 4,500 KW.

Duke Power indicates that this supplement also includes an estimate of sales and revenue for twelve months immediately preceding and for the twelve months immediately succeding the effective date. Duke Power proposes an effective date of February 18, 1981.

According to Duke Power copies of this filing were mailed to Blue Ridge Electric Cooperative, Inc. and the South Carolina Public Service Commission.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 9, 1981. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the preceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-40368 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-85-M

[Docket No. ER81-172-000]

Duke Power Co.; Supplement to Electric Power Contract

December 19, 1980.

Take notice that Duke Power Company (Duke Power) tendered for filing on december 15, 1980 a supplement to the Company's Electric Power Contract with Pee Dee Electric Membership Corporation. Duke Power states that this contract is on file with the Commission and has been designated Duke Power Company Rate Schedule FERC No. 137.

Dule Power further states that the Company's contract supplement, made at the request of the customer and with agreement obtained from the customer, provides for the following increase in designated demand: Delivery Point No. 3 from 2,000 KW to 2,100 KW.

Duke Power indicates that this supplement also includes an estimate of sales and revenue for twelve months immediately preceeding and for the twelve months immediately succeding the effective date. Duke Power proposes and effective date of November 19, 1980.

According to Duke Power copies of this filing were mailed to Pee Dee Electric Membership Corporation and the North Carolina Utilities Commission.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18) CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 9, 1981. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to

the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plum,

Secretary.

[FR Doc. 80-40367 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-85-M

[Docket No. RP81-23-000]

El Paso Natural Gas Co.; Petition for Relief

December 19, 1980.

Take notice that on December 9, 1980, El Paso Natural Gas Company ("El Paso"), a Delaware corporation, whose mailing address is Post Office Box 1492, El Paso, Texas, 79978, filed, on behalf of five (5) customers served by El Paso's interstate pipeline system,[1] pursuant to Section 1.7 of the Commission's Rules of Practice and Procedure, a petition for relief from the unauthorized overrun gas provisions set forth in El Paso's currently effective FERC Gas Tariff.

The instant petition states that El Paso's experience in administering said unauthorized overrun gas provisions has made it aware that such provisions fail to take into account the possibility that mechanical failure or human error may result in daily deliveries to El Paso's customers in excess of their daily entitlement. By reason of mechanical failure and/or human error, customers can and do inadvertently receive gas in excess of daily entitlements, thereby unnecessarily incurring daily overrun penalties. Upon request by certain of its customers for a joint review of El Paso's penalty invoices, it has been determined that five (5) of El Paso's interstate pipeline system customers have been assessed penalty charges resulting from mechanical failures or human errors, and that a request for relief therefrom is appropriate. El Paso states that in four of the five instances referred to, the error arose in a system that was installed for the purpose of more accurately controlling gas flows and thus preventing overruns. Further, in all five instances, the problem was remedied as soon as it was recognized. In El Paso's view, given the unintentional nature of the overruns, which occurred despite (and, perhaps even as a consequence of) the efforts made by the parties to keep overruns from occurring, it would be inequitable in the extreme, and serve no good purpose, to require the customers to absorb the subject overrun penalties.

The petition states further that the overrun penalties in question constitute an inequitable financial burden on each of those five customers. El Paso therefore requested that the Commission expeditiously grant the relief sought by this petition.

Any person desiring to be heard or to make any protest with reference to said petition should, on or before Jan. 6, 1981, file with the Federal Energy Regulatory Commission Washington, D.C., 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practive and Procedure (18 CFR 1.8 or 1.10) and the Regulations Under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make any protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 4 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this petition if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the authorization is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for El Paso to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-40375 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-85-M

[Project No. 1651]

Lower Valley Power and Light, Inc.; Application for Amendment of License

December 19, 1980.

Take notice that on October 14, 1980, Lower Valley Power and Light, Inc. (Licensee) filed an application pursuant to the Federal Power Act, 16 U.S.C. 791(a)—825(r), for amendment of its license for its Upper and Lower Swift Creek Project, FERC No. 1651, located on the Swift Creek, in the Bridger-Teton National Forest, Lincoln County, Wyoming. Correspondence with the Applicant should be directed to: M. Boyd A. Parker, General Manager, Lower Valley Power and Light, Inc., P.O. Box 188, Afton, Wyoming 83110, and CH2M Hill, Attention: Loren A. Baker, P.O. Box 428, Corvallis, Oregon 97330.

Applicant requests that its license be amended to authorize the following proposed changes in the project: (1) at the upper development, replace all 7,000 feet of the existing unserviceable 36-inch diameter penstock with a new 48-inch diameter concrete penstock; (2) at the lower penstock; (b) construct a new development: (a) replace the previously removed 1,200-foot long 54-inch diameter wood stave penstock with a new 2,000-long penstock; (b) construct a new powerhouse about 800 feet downstream from the existing unserviceable powerhouse; and (c) install two new turbine-generator units, one rated at 250 kW and one rated at 500 kW; and (3) at both developments, install new appurtenant electrical facilities to include switchgear, transformers, and protective devices.

Rehabilitation of the project will also include limited dredging of reservoirs, and at the lower dam, earthwork to repair eroded areas of the downstream toe of the dam, and other necessary dam embankment repairs.

The above described proposed changes in the project will increase the total installed capacity of the project from 980 kW to 1,340 kW. Annual energy production of the rehabilitated project will be 7,000,000 kWh which is equivalent to saving 11,500 barrels of oil or 3,249 tons of coal.

Anyone desiring to be heard or to make any protests about this application should file a petition to intervene or a protest with the Commission, in accordance with the requirements of its Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in 1.10 for protests. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but a person who merely files a protest or comments does not become a party to the proceeding. To become a party, or to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules. Any comments, protest, or petition to intervene must be received on or before February 9, 1981. The

[1] The five customers are: Arizona Public Service Company, ASARCO Incorporated—Hayden, Arizona, Magma Copper Company, Phelps Dodge Corporation and Southern Union Gas Company.

Commission's address is: 825 N. Capital Street, NE, Washington, D.C. 20426. The application is on file with the Commission and is available for public inspection.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 80-40369 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-85-M

[Docket No. ER81-175-000]

Missouri Utilities Co.; Proposed Change in Rates

December 19, 1980.

Please take notice that on December 15, 1980, Missouri Utilities Company, of Cape Girardeau, Missouri, pursuant to Section 205 of the Federal Power Act and Part 35 of the Commission's Regulations thereunder, tendered for filing a change in rates applicable to electric service rendered to its Southeast Missouri wholesale electric customers. These changes in rates are proposed to become effective customers. These changes in rates are proposed to become effective as of February 13, 1981. Missouri Utilities Company indicates that the proposed changes in rates are to compensate Missouri Utilities Company primarily for increased power costs and to provide an adequate return on investments relative to the effected customers.

MIssouri Utilities Company states that its current wholesale rates in Southeast Missouri are deficient by $201,680.47 annually based on sales volumes for the test year ended June 30, 1980, as set forth in the statements accompanying its Notice of Change in Rates.

Copies of the proposed rate schedules and their revenue effect have been served upon the Missouri Utilities Company's effected wholesale customers namely the Missouri Cities of Jackson, Malden and Kennett.

Any person desiring to be heard to protest said notice should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 9, 1981. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Missouri Utilities Company's proposed tariff sheets and rate filings are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-40370 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-85-M

[Project No. 3622-000]

Mitchell Energy Company, Inc.; Application for Preliminary Permit

December 19, 1980.

Take notice that Mitchell Energy Company, Inc. (Applicant) filed on October 31, 1980, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)] for the proposed Mississippi Lock & Dam No. 8 Hydroelectric Project, FERC No. 3622 to be located at the U.S. Army Corps of Engineers Mississippi Lock and Dam No. 8, a navigational aid project, on the Upper Mississippi River near Genoa, Wisconsin, Vernon County, Wisconsin. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. Mitchell L. Dong, 173 Commonwealth Avenue, Boston, Massachusetts 02116. Any person who wishes to file a response to this notice should read the entire notice and must comply with the requirements specified for the particular kind of response that person wishes to file.

Project Description—The proposed project would utilize and existing U.S. Army Corps of Engineers' lock and dam. Project No. 3622 would consist of: (1) a proposed powerhouse located below the existing dam and equipped with turbine/generator units with a total capacity of approximately 14 megawatts; (2) proposed transmission lines; and (3) appurtenant facilities. Applicant's facilities would be located on U.S. land.

The Applicant estimates that the average annual energy output would be 86,000,000 kWh.

Purpose of Project—Energy produced at the proposed project would be purchased by a local utility in the Genoa area.

Proposed Scope and Cost of Studies under Permit—Applicant has requested a 24 month permit to prepare a definitive project report, including preliminary design and economic feasibility studies, hydrological studies, environment and social studies, soil and foundation data. The cost of the aforementioned activities along with obtaining agreements with other Federal, State and local agencies is estimated to be $50,000.

Purpose of Preliminary Permit—A preliminary permit does not authorize construction. A permit, if issued, gives the Permittee, during the term of the permit, the right of priority of application for license while the Permittee undertakes the necessary studies and examinations to determine the engineering, economic, and environmental feasibility of the proposed project, the market for the power, and all other information necessary for inclusion in an application for a license.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are invited to submit comments on the described application for preliminary permit. (A copy of the application may be obtained directly from the Applicant.) Comments should be confined to substantive issues relevant to the issuance of a permit and consistent with the purpose of a permit as described in this notice. No other formal request for comments will be made. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desiring to file a competing application must submit to the Commission, on or before February 23, 1981, either the competing application itself or a notice of intent to file a competing application. Submission of a timely notice of intent allows an interested person to file the competing application no later than April 24, 1981. A notice of intent must conform with the requirements of 18 CFR 4.33(b) and (c) (1980). A competing application must conform with the requirements of 18 CFR 4.33(a) and (d) (1980).

Comments, Protests, or Petitions to Intervene—Anyone desiring to be heard or to make any protest about this application should file a petition to intervene or a protest with the Commission, in accordance with the requirements of its Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in 1.10 for protests. In determing the appropriate action to take, the Commission will consider all protests or other comments filed, but a person who merely files a protest or comments does not become a party to the proceeding. To become a party, or to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules. Any comments, protest, or petition to intervene must be filed on or before February 23, 1981.

Filing and Service of Responsive Documents—Any comments, notices of intent, competing applications, protests, or petitions to intervene must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable. Any of these filings must also state that it is made in response to this notice of application for preliminary permit for Project No. 3622.

Any comments, notices of intent, competing applications, protests, or petitions to intervene must be filed by providing the original and those copies required by the Commision's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208, 400 First St., NW., Washington, D.C. 20426. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 80-40371 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-85-M

[Project No. 3553]

Rauniker, Inc.; Application for Preliminary Permit

December 19, 1980.

Take notice that Rauniker, Inc. (Applicant) filed on October 9, 1980, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)—825(r)] for proposed Project No. 3553 to be known as the Lowell Water Power Project located on Spring River and Shoal Creek in Cherokee County, Kansas. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Richard L. Rauniker, President, Rauniker, Inc., 220 Fairway Drive, Carl Junction MO 64834. Lowell Dam is owned by the Empire District Electric Company. Any person who wishes to file a response to this notice should read the entire notice and must comply with the requirements specified for the particular kind of response that person wishes to file.

Project Description—The proposed project would be operated primarily run-of-river with limited storage capacity for peaking operation and would consist of: (1) an existing dam comprising a 1,100-foot-long spillway section, an 800-foot-long earth embankment, and a 475-foot-long, 40 feet high, concrete gravity section containing five spillway bays; (2) an 826-acre resevoir having a normal water surface elevation of 807.25 feet msl; (3) existing penstocks requiring repair; (4) a powerhouse integral with the dam's concrete gravity section requiring rehabilitation and which would contain generating units with a total rated capacity between 2,300 kw and 4,200 kw; (5) a tailrace; (6) a new transmission line; and (7) appurtenant facilities.

The Applicant estimates that the average annual energy output would be between 9,500,000 kWh and 12,000,000 kWh.

Purpose of Project—Project energy would be sold to The Empire District Electric Company.

Proposed Scope and Cost of Studies under Permit—Applicant seeks issuance of a preliminary permit for a period of three years, during which time it would prepare studies of the hydraulic, construction, economic, environmental, historic and recreational aspects of the project. Depending on the outcome of the studies, Applicant would prepare an application for an FERC license. Applicant estimates the cost of the studies under the permit would be $53,200.

Purpose of Preliminary Permit—A preliminary permit does not authorize construction. A permit, if issued, gives the Permittee, during the term of the permit, the right of priority of application for license while the Permittee undertakes the necessary studies and examinations to determine the engineering, economic, and environmental feasibility of the proposed project, the market for the power, and all other information necessary for inclusion in an application for a license.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are invited to submit comments on the described application for preliminary permit. (A copy of the application may be obtained directly from the Applicant.) Comments should be confined to substantive issues relevant to the issuance of a permit and consistent with the purpose of a permit as described in this notice. No other formal request for comments will be made. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Application—Anyone desiring to file a competing application must submit to the Commission, on or before February 23, 1981, either the competing application itself or a notice of intent to file a competing application. Submission of a timely notice of intent allows an interested person to file the competing application no later than April 24, 1981. A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c) (1980). A competing application must conform with the requirements of 18 CFR 4.33(a) and (d) (1980).

Comments, Protests, or Petitions to Intervene—Anyone desiring to be heard or to make any protests about this application should file a petition to intervene or a protest with the Commission, in accordance with the requirements of its Rules of Practice and Procedure, 18 CFR 1.8 or 1.10 (1980). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in § 1.10 for protests. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but a person who merely files a protest or comments does not become a party to the proceeding. To become a party, or to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules. Any comments, protest, or petition to intervene must be received on or before February 23, 1981.

Filing and Service of Responsive Documents—Any comments, notices of intent, competing applications, protests, or petitions to intervene must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION," "PROTEST", or "PETITION TO INTERVENE", as applicable. Any of these filings must also state that it is made in response to this notice of application for preliminary permit for Project No. 3553. Any comments, notices of intent, competing applications, protests, or petitions to intervene must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208, 400 First Street, N.W. Washington, D.C. 20426. A copy of any notice of intent, competing application, or petition to intervene must

also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 80-40372 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-85-M

[Docket No. ER81-173-000]

Vermont Electric Power Company, Inc.; Rate Schedule Filing

December 19, 1980.

Take notice that on December 15, 1980, Vermont Electric Power Company, Inc. (VELCO) tendered for filing a rate schedule containing a lease agreement between VELCO and Citizens Utilities Company dated as of August 1, 1980, and an addendum thereto.

VELCO states that the service to be rendered under this rate schedule consists of the use by Citizens of a 15/20 MVA transformer which is owned by VELCO. The purpose of the addendum is to revise Section 8 of the agreement which concerns Repairs and Replacement.

The estimated monthly charge under this agreement is $764. The basis of the charge is one-twelfth of the annual amount determined by multiplying the original cost of the facilities involved by fifteen percent. Since the revenue from these charges will be credited to the state there will be no change in VELCO's overall rate of return and no cost of service studies were prepared in connection with the derivation of the rate.

VELCO further states that as a result of unavoidable delay in resolving certain aspects of negotiations for this rate schedule, VELCO was not able to file the schedule in a timely manner. In addition, it was necessary to submit the agreement to the Vermont Public Service Board for approval. As a result of these circumstances VELCO could not comply with the notice requirements of § 35.11 since the circumstances described constitute a good cause for a waiver. Approval of this agreement was granted by the Vermont Public Service Board.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 9, 1981. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-40373 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-85-M

[Docket No. RP81-10-001]

Western Gas Interstate Co.; Motion To Place Tariff Sheets Into Effect and Proposed PGA Rate Adjustment (Revised)

December 19, 1980.

Take notice that on December 2, 1980, Western Gas Interstate Company (Western) filed (1) Western's Motion To Place Tariff Sheets Into Effect in FERC Docket No. RP81-10-001; (2) Substitute Sixteenth Revised Sheet No. 3A; and (3) Western's agreement and undertaking to comply with the terms and conditions of Section 154.67 of the Commission's Regulations. Said tariff sheet is proposed to become effective on December 2, 1980, pursuant to the Commission's "Order Accepting For Filing And Suspending Certain Tariff Sheets, Subject To Refund And Rejecting Other Tariff Sheets", issued on November 28, 1980. Western states that the proposed rate changes filed in this docket on October 31, 1980, have been modified by the concurrent filing of "Substitute Sixteenth Revised Sheet No. 3A: to its FERC Gas Tariff, Original Volume No. 1, to reflect on intervening purchased gas cost change.

Western also states that the rates filed in its "Substitute Fifteenth Revised Sheet No. 3A", reflected an increased rate of .01¢ per Mcf in Western's Rate Schedule G-N calculated on the revised rates filed by Colorado Interstate Gas Company (CIG) in Docket No. TA81-1-32 (PGA81-1)(IP81-1) dated October 22, 1980. Thus, Western's "Substitute Sixteenth Revised Sheet No. 3A" reflects those rates originally filed in this proceeding and the increased CIG rate under Rate Schedule G-N.

Western states that copies of this filing were served upon Western's transmission system customers and the interested state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 N. Capital Street NE., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before January 6, 1981. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-40374 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-85-M

ENVIRONMENTAL PROTECTION AGENCY

[OPTS—50026; TSH, FRL 1715-2]

Enviro Control, Inc.; Data Transfer to Contractor

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data transfer.

SUMMARY: EPA's contractor, Enviro Control, Inc. (ECI) is assisting EPA in reviewing information submitted by chemical manufacturers under the Toxic Substances Control Act (TSCA) on certain chemicals as part of EPA's evaluation of the ecological impact of those chemicals for purposes of proposing testing requirements under Section 4 of TSCA. Some of the information ECI will review may be claimed confidential.

DATE: The transfer of information to ECI will begin no sooner than January 14, 1981.

FOR FURTHER INFORMATION CONTACT: John B. Ritch, Jr., Director, Industry Assistance Office (TS-799), Office of Pesticides and Toxic Substances, Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460, 202/544-1404 or toll-free 800/424-9065.

SUPPLEMENTARY INFORMATION: Under Section 4(e) of TSCA, the TSCA Interagency Testing Committee (ITC) has periodically recommended lists of chemicals or categories of chemicals to EPA for priority testing under TSCA Section 4. The agency is analyzing available information, including physicochemical properties, environmental distribution, aquatic toxicity and ecological impact, on these substances in order to determine what testing, if any, to propose. Among the sources of this information are reports submitted to EPA by manufacturers in response to requests for information on the chemicals recommended for testing

by the ITC in compliance with Section 4 of TSCA. Some of the information in these reports may be claimed confidential.

ECI will assist EPA in its evaluation of the ecological impact of the chemicals or categories of chemicals under study (Contract Nos. 68–01–6147, 68–01–6149, and 68–01–6150). In doing so, it will need to review the reports submitted by industry, some of which may contain Confidential Business Information. On completion of its task, ECI will return all originals and copies of documents containing confidential information to the EPA Document Control Officer.

Pursuant to 40 CFR 2.306(j), EPA has determined that in certain instances it will be necessary for ECI to have access to Confidential Business Information to satisfactorily perform its work under these contracts. In accordance with provisions of its contracts with EPA, ECI is required to safeguard from any unauthorized disclosure the Confidential Business Information it receives from EPA. Information generated by ECI from its review of Confidential Business Information will also be treated as confidential.

ECI has been authorized under the EPA/TSCA Confidential Business Information Security Manual to have access to Confidential Business Information. A security plan for ECI has been approved. EPA has conducted the required inspection of the ECI facilities and has found them to be in compliance with the requirements of the Manual. ECI is required to treat all TSCA Confidential Business Information in accordance with the requirements of that Manual.

(Section 4 of TSCA (Pub. L. 94–469, 90 Stat. 2003, 15 U.S.C. 2601 et. seq.))

Dated: December 15, 1980.

Warren R. Muir,

Deputy Assistant Administrator for Toxic Substances.

[FR Doc. 80–40471 Filed 12–29–80; 8:45 am]

BILLING CODE 6560–31–M

[A–4–FRL 1715–1]

Standards of Performance for New Stationary Sources; National Emissions Standards for Hazardous Air Pollutants; Delegation of Authority to the State of North Carolina

AGENCY: Environmental Protection Agency.

ACTION: Informational notice.

SUMMARY: Sections 111(c) and 112(d) of the Clean Air Act permit EPA to delegate to the states the authority to implement and enforce the standards set out in 40 CFR Part 60, Standards of Performance for New Stationary Sources (NSPS) and in 40 CFR Part 61, National Emission Standards for Hazardous Air Pollutants (NESHAPS). On May 2, 1980, the State of North Carolina asked EPA to delegate to it authority for NSPS and NESHAPS promulgated between March 1976 and July 1, 1979. EPA granted the State's request on October 22, 1980. The State now has authority to implement and enforce NSPS for ferroalloy production facilities, kraft pulp mills, lime manufacturing plants, and grain elevators, and NESHAPS for vinyl chloride. Applications and reports required under these regulations should be sent to the State's Division of Environmental Management rather than to EPA Region IV.

EFFECTIVE DATE: October 22, 1980.

ADDRESSES: Applications and reports required under all NSPS and NESHAPS promulgated prior to July 1, 1979, should be addressed to the Division of Environmental Management, North Carolina Department of Natural Resources and Community Development, P.O. Box 27687, Raleigh, North Carolina 27611, rather than to EPA Region IV.

FOR FURTHER INFORMATION CONTACT: Walter Bishop of the EPA Region IV, Air Programs Branch, telephone 404/881–3043 or FTS 257–3043.

SUPPLEMENTARY INFORMATION: On November 24, 1976, EPA delegated to North Carolina authority to implement and enforce the NSPS and NESHAPS that had been promulgated through March 23, 1976 (see 41 FR 56886, December 30, 1976). On May 2, 1980, the State requested that EPA delegate to it authority for the NSPS and NESHAPS promulgated in the period between March 23, 1976, and July 1, 1979. Delegation of these standards was made by the following letter on October 22, 1980. (Copy of Rebecca Hanmer's Letter to Neil Grigg.)

Effective immediately, all applications, reports, and other correspondence required under the NSPS for ferroalloy production facilities, kraft pulp mills, lime manufacturing plants, and grain elevators, and NESHAPS for vinyl chloride should be sent to the North Carolina Divison of Environmental Management (see address above) rather than to the EPA Region IV office in Atlanta.

(Sections 111(c) and 112(d) of the Clean Air Act (42 U.S.C. 7411(c) and 7412(d))

Dated: December 15, 1980.

John A. Little,

Acting Regional Administrator.

October 22, 1980.

Dr. Neil S. Grigg,

Director, Division of Environmental Management, North Carolina Department of Natural Resources & Community Development, P.O. Box 27687, Raleigh, North Carolina

Dear Dr. Grigg: On November 24, 1976, we delegated to the State of North Carolina the authority for implementation and enforcement of the Standards of Performance for New Stationary Sources (NSPS) and the National Emission Standards for Hazardous Air Pollutants (NESHAPS) that had been promulgated by EPA as of March 23, 1976. On May 4, 1976, February 23, 1978, March 7, 1978, and August 3, 1978, EPA promulgated NSPS for ferroalloy production facilities, kraft pulp mills, lime manufacturing plants, and grain elevators, respectively; on October 21, 1976, EPA promulgated NESHAPS for vinyl chloride. In your letter of May 2, 1980, you requested that EPA delegate to the State of North Carolina the authority for implementation and enforcement of these new Federal regulations.

As stated in our letter of November 24, 1976, we have reviewed the pertinent laws of the State of North Carolina and your rules and regulations and have determined that they provide an adequate and effective procedure for implementing and enforcing the NSPS and NESHAPS in the State of North Carolina. Therefore, we hereby delegate our authority for the implementation and enforcement of the NSPS and NESHAPS to the State of North Carolina as follows:

A. Authority for all sources located or to be located in the State of North Carolina subject to the Standards of Performance for New Stationary Sources for ferroalloy production facilities, kraft pulp mills, lime manufacturing plants, and grain elevators promulgated in 40 CFR Part 60 as of the date of this letter.

B. Authority for all sources located or to be located in the State of North Carolina subject to the National Emission Standards for Hazardous Air Pollutants for vinyl chloride promulgated in 40 CFR Part 61 as of the date of this letter.

This delegation is based upon the same conditions as those stated in our letter of November 24, 1976, except that condition 5, relating to Federal facilities, has been voided by the Clean Air Act Amendments of 1977. A copy of the November 24, 1976, letter was published in the Notices section of the **Federal Register** of December 30, 1976 (41 FR 56886), along with the associated rulemaking notifying the public that certain reports and applications required from operators of new sources shall be submitted to the State of North Carolina (41 FR 56805). All those conditions except condition 5, relating to Federal facilities, are hereby incorporated into this delegation by reference. A notice announcing this delegation will be published in the **Federal Register** in the near future.

Since this delegation is effective immediately, there is no need for the State to notify EPA of its acceptance. Unless we receive from you written notice of objections

within ten days of the date on which you receive this letter, the State of North Carolina will be deemed to have accepted all of the terms of the delegation.

Sincerely yours,

Rebecca W. Hanmer,

Regional Administrator.

[FR Doc. 80-40472 Filed 12-29-80; 8:45 am]

BILLING CODE 6560-38-M

[OPTS-59039A; TSH FRL 1714-6]

Ammonium Salt of Substituted Alkyl Phosphoric Acid; Approval of Test Marketing Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On October 8, 1980, EPA received an application for a test marketing exemption (TM-80-44) from the premanufacturing notification requirements of section 5 of the Toxic Substances Control Act (TSCA). The manufacturer has claimed its identity confidential.

EPA has determined that the manufacturer's test marketing of this chemical substance will no present any unreasonable risk of injury to health or the environment. Therefore, the Agency has granted this manufacturer an exemption from the TSCA premanufacture reporting requirements for test marketing of the substance in the manner described in the application.

DATE: Interested persons may submit written comments on or before January 29, 1981.

ADDRESS: Written comments to: Document Control Officer (TS-793), Management Support Division, Office of Pesticide and Toxic Substances, Environmental Protection Agency, Rm. E-447, 401 M Street, S.W., Washington, D.C. 20460, (202-755-8050).

FOR FURTHER INFORMATION CONTACT: Kirk Maconaughey, Chemical Control Division (TS-794), Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460 (202-426-3936).

SUPPLEMENTARY INFORMATION: Under section 5 of TSCA, anyone who intends to manufacture or import a new chemical substance for commercial purposes in the United States must submit a notice to EPA before manufacture or import begins. A "new" chemical substance is one that is not on the Inventory of existing chemical substances compiled by EPA under section 8(b) of TSCA. Section 5(a)(1) requires each premanufacture notice (PMN) to be submitted in accordance with section 5(d) and any applicable requirements of section 5(b). Section 5(d)(1) defines the contents of a PMN and section 5(b) contains additional reporting requirements for certain new chemical substances.

Section 5(h), "Exemptions", contains several provisions for exemptions from some or all of the requirements of section 5. In particular, section 5(h)(1) authorizes EPA, upon application, to exempt persons from any requirement of section 5(a) or section 5(b), to permit them to manufacture or process chemical substances for test marketing purposes. To grant an exemption, the Agency must find that the test marketing activities will not present any unreasonable risk of injury to health or the environment. EPA must either approve or deny the application within 45 days of its receipt, and under section 5(h)(6) the Agency must publish a notice of its disposition in the **Federal Register.** If EPA grants a test marketing exemption, it may impose restrictions on the test marketing activities.

The application was assigned test marketing exemption number TM 80-44. Due to administrative error, EPA failed to publish in the **Federal Register** notice of receipt of the application. EPA has granted this Test Market Exemption Application and the submitter is proceeding with his test marketing activities, however interested persons will have until January 29, 1981, to submit comments on this test marketing exemption. All comments will be reviewed and evaluated by the Agency, and should new information be brought to EPA's attention the decision to grant the exemption may be modified.

The manufacturer claimed its identity, the specific chemical identity of the chemical and the specific use of the chemical as confidential business information.

The substance is described generically as ammonium salt of substituted alkyl phosphoric acid; its generic use is as a materials coating. Six thousand, six hundred pounds of the substance will be manufactured as an approximate 50 percent solution during the test marketing period not to exceed six months. EPA has established that the test marketing of TM 80-44, under the conditions set out in the application, will not present any unreasonable risk of injury to health or the environment for the reasons explained below.

While the company provided no information on the test market substance they did supply toxicity data on a very close structural analogue. The acute toxicity level for that analogue (acute oral LD_{50}) was approximately 7 grams/kilogram. The analogue was found to be minially irritating in an eye irritation study. No other adverse chronic health effects were noted for this close structural analogue. The Agency believes that the data submitted on the analogue is representative of that expected for the test market substance.

No significant worker exposure to the substance is expected. The product will be manufactured in a closed system. The reaction is instantaneous and complete. There are no by-products. The substance, a materials coating, is applied mechancially with no worker exposure. Consumer exposure to the test market substance is very limited. The substance once applied to products is complexed and then further sealed, making it unavailable for consumer uptake. Environmental release of the substance will be low and is not judged to be a concern.

Based on the facts and information obtained and reviewed, EPA grants the manufacturer a test marketing exemption for TM 80-44, effective immediately, but subject to all conditions set out in the exemption application, and in particular those enumerated below:

1. This exemption is granted solely to this manufacturer.

2. The applicant must maintain records of the date(s) of shipment(s) to the one customer specified in the application who will test market the substance, and the quantities shipped in each shipment, and must make these records available to EPA upon request.

3. Each bill of lading that accompanies a shipment of the substance during the test marketing period must state that the use of the substance is restricted to that described to EPA in the test marketing exemption application.

4. The production volume of the new substance may not exceed the quantity of 6,600 pounds described in the test market application.

5. The test marketing acitivity approved in this notice is limited to a 6 month period commencing on the date of publication of the notice in the **Federal Register.**

6. The substance will be manufactured in a closed system as specified in the application.

7. The number of workers, both manufacturers and processors' should not exceed that specified in the application and the exposure levels and duration of exposure should not exceed that specified.

8. The Agency reserves the right to rescind its decision to grant this exemption should any new information come to its attention which indicates that the substance may present an unreasonable risk of injury to human health or the environment.

Dated: December 22, 1980.

Douglas M. Costle,

Administrator.

[FR Doc. 80-40388 Filed 12-29-80; 8:45 am]

BILLING CODE 6560-31-M

[OPTS—59038A; TSH-FRL 1714-5]

Polymer of: D-Glucose; Succinic Acid; Propanoic Acid, 2-Oxo; and Galactose; Approval of Exemption Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On October 6, 1980, EPA received an exemption application for test marketing purposes from Kelco, Division of Merck and Co., Inc. The Test Marketing Exemption (TME) case number assigned to the substance was T80–43. EPA has determined that the manufacturer's test marketing of the chemical substance will not present any unreasonable risk of injury to health or the environment. Therefore, the Agency has granted the manufacturer an exemption from the TSCA premanufacture reporting requirements for test marketing in the manner described in the application. The exemption is effective immediately.

FOR FURTHER INFORMATION CONTACT: Robert W. Jones, Chemical Control Division (TS–794), Office of Toxic Substances, Environmental Protection Agency, Room E–208, Washington, DC 20460 (202–426–8815).

SUPPLEMENTARY INFORMATION: Under section 5 of TSCA anyone who intends to manufacture or import a new chemical substance for commercial purposes in the United States must submit a notice to EPA before manufacture or import begins. A "new" chemical substance is one that is not on the Inventory of existing substances compiled by EPA under section 8(b) of TSCA. Section 5(a)(1) requires each premanufacture notice (PMN) to be submitted in accordance with section 5(D) and any applicable requirements of section 5(b). Section 5(d)(1) defines the contents of a PMN and section 5(b) contains additional reporting requirements for certain new chemical substances.

Section 5(h), "Exemptions," contains several provisions for exempt from some or all of the requirements of section 5. In particular, section 5(h)(1) authorizes EPA, upon application, to exemption persons from any requirement of section 5(a) or section 5(b), to permit them to manufacture or process chemical substances for test marketing purposes. To grant an exemption, the Agency must find that the test marketing activities will not present an unreasonable risk of injury to health or the environment. EPA must either approve or deny the application within 45 days of receipt, and under section 5(h)(6) the Agency must publish a notice of its disposition in the **Federal Register**. If EPA grants a test marketing exemption, it may impose restrictions on the test marketing activities.

On October 6, 1980, EPA received an application from Kelco, Division of Merck and Co. Inc., for an exemption from the requirements of section 5(a) and 5(b) of TSCA, to manufacture a copolymer of D-glucose; succinic acid; propanoic acid, 2-oxo; galactose for test marketing purposes.

A **Federal Register** notice published on November 10, 1980 (45 FR 74563) announced receipt of the exemption application and summarized information submitted by Kelco. The **Federal Register** notice requested comments on the appropriateness of granting the exemption. However, the Agency received no public comments concerning the application. Review of the TME application raised little or no concern with regard to health and environmental effects from the TME substance.

Considering both the toxicity and exposure, the Agency has determined that the manufacture, production, and use of this substance, in the manner described in the test market application, will not present any unreasonable risk to the people who come into contact with it during manufacture, processing, or use. There are no environmental concerns with the release or disposal of this substance. Thus, the Agency has decided to grant a test market exemption to Kelco, Division of Merck Co. Inc., for the limited manufacture of the substance as described in the test marketing exemption application.

At least 90 days prior to manufacturing the substance listed in the application for commercial purposes other than test marketing or in small quantities solely for research and development activities, the manufacturer must submit a premanufacture notice (PMN) as required under section 5(a) of TSCA. This exemption is granted solely to the applicant of TME T80–43 with the following povisions.

1. That the company not exceed the production amounts specified on the test market application;

2. That worker exposure not exceed the levels specified;

3. That the company only use the TME substance for the purpose described in the test market application and in other contacts between EPA and the submitter;

4. That the company maintain records of customers to whom the test market substance has been given or sold and that these records may be inspected by EPA;

5. That each shipment contains a statement informing the recipient that the substance shipped may only be used for the purpose allowed in the exemption;

6. The Agency reserves the right to rescind its decision to grant this exemption should any new information come to its attention which indicates that the substance may present an unreasonable risk of injury to human health or the environment.

Section 5(h)(6) of TSCA requires EPA to approve or deny a test marketing exemption within 45 days of its receipt by the Agency. The 45-day period for this exemption application expired on November 20, 1980. EPA regrets the delay in approving this application. However, simultaneously with the processing of test marketing exemption applications, EPA is Charged by TSCA with the task of examining a much larger number of premanufacture notices. The health and environmental implications associated with these notices are generally more significant and widespread than those associated with a test marketing exemption application, requiring EPA to preferentially allocate its very limited resources to the examination of the notices. In the near future EPA will communicate a set of informal guidelines to regulated industry that will help EPA make Test Marketing Exemption Application decisions in a more timely manner.

Dated: December 22, 1980.

Douglas M. Costle,

Administrator.

[FR Doc. 80-40387 Filed 12-29-80; 8:45 am]

BILLING CODE 6560-31-M

[A-10-FRL 1715-3]

Issuance of Clean Air Act Program Grant; State of Oregon

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Grant Award.

SUMMARY: The U.S. Environmental Protection Agency, Region 10 (EPA) announces award of a grant to the State of Oregon to assist the Oregon Department of Environmental Quality in the funding of its air pollution control program for Federal fiscal year 1981.

ADDRESSES: The relevant material may be examined during normal business hours at the following locations:
Central Docket Section (10A–80–23), West Tower Lobby, Gallery I, Environmental Protection Agency, Waterside Mall, 401 M Street S.W., Washington, D.C. 20460.
Air Programs Branch, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT:
Richard R. Thiel, P.E., Chief, Air Programs Branch M/S 629, Environmental Protection Agency, 1200 Sixth Avenue, Seattle, Washington 98101.

SUPPLEMENTARY INFORMATION:

Background Information

For several years, EPA has provided financial assistance to the State of Oregon to aid the Department of Environmental Quality (DEQ) in administration of its air pollution control program. This assistance has been provided through a grant under Section 105 of the Clean Air Act [42 U.S.C. 7405(b)].

Section 105 of the Clean Air Act prevents award of such grants where the recipient agency's:

> Expenditures of non-Federal funds for other than noncurrent expenditures for air pollution control programs will be less than its expenditures were for such programs during the preceding fiscal year, unless the Administrator, after notice and opportunity for public hearing, determines that a reduction in expenditures is attributable to a nonselective reduction in expenditures in the programs of all executive branch agencies of the applicable unit of Government.[1]

The Oregon DEQ has budgeted 24 percent (24%) fewer dollars from its general fund for the air program in 1981. DEQ has provided EPA with information indicating that (1) the programs of all agencies of the executive branch of State government have also been scheduled for a reduction in expenditures (although the percentage reductions vary somewhat from agency to agency) and (2) the air pollution control program and DEQ have not been selectively targeted by the State for a disproportionate reduction in funding.

Request for Comments—Opportunity for Hearing

On October 23, 1980 (45 FR 70313), EPA published in the Federal Register a request for public comment on the intent to award a grant and also provided an opportunity to request a public hearing. The same notification also appeared in the public notice section of the *Oregonian Journal* on October 24, 1980 (page A24).

The notice established November 24, 1980 for a tentative public hearing on this matter. The hearing was to be cancelled if no request for a hearing was received. No request for such a hearing was received. However, at the appointed time and place, an EPA representative was present to receive public comments had anyone appeared.

Response to Comments

Three written comments were received during the comment period. The Washington Department of Ecology, the State's air agency, expressed full support of EPA's intended action to award the grant.

Comments were also received from the State of New Hampshire's Air Resources Commission and the State of Maine's Department of Environmental Protection. Both recognized that Section 105 of the Clean Air Act allows States to reduce the State funding for air programs if EPA determines the budget reduction is a "nonselective reduction in expenditures in programs of all executive branches of the applicable unit of government," but felt the reduction would set an unfortunate national precedent. Due to the extensive documentation provided by Oregon, indicating that this cut was not selective, EPA believes no unfortunate national precedent will be set.

Evaluation of Oregon's Reduction in Expenditures

A considerable amount of documentation was submitted by the State of Oregon to substantiate that the cut was not selective. Based upon this documentation, it appears that the Oregon reduction was in the State's general fund and was applied to all executive branches of government using the same criteria. Variations in the level of funding cuts among the various State agencies were also due to other factors, such as the need to maintain essential services and to minimize personnel layoffs. Based on the documentation submitted, EPA could find no evidence that the State's air program was deliberately chosen for a disproportionately large reduction. The briefing memorandum supporting this decision and documentation from Oregon supporting the determination are available on request from Laurie M. Kral at the address listed above as well as at the document locations listed.

Intended Action

Finding that the procedural requirements have been met and that Oregon's 1980 statewide budget cuts are nonselective, Region 10 has awarded a grant to the State of Oregon to assist the Oregon Department of Environmental Quality in the funding of its air pollution control program for the Federal fiscal year 1981.

Dated: December 18, 1980.

L. Edwin Coate,

Acting Regional Administrator.

[FR Doc. 80–40502 Filed 12–29–80; 8:45 am]

BILLING CODE 6560–38–M

[1] Authority to award Section 105 grant awards was delegated to the Regional Administrators on January 28, 1976. [EPA Delegations Manual, Chapter 7, Item 1.]

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

Request for Comments on the Feasibility and Usefulness of Requiring Depository Institutions Which Make Small Business Loans To Compile and Publicly Disclose Information Regarding Such Loans.

AGENCY: Federal Financial Institutions Examination Council.

ACTION: Notice of request for comments.

SUMMARY: The Federal Financial Institutions Examination Council (Council), which is composed of representatives of the Board of Governors of the Federal Reserve System, Federal Deposit Insurance Corporation, Federal Home Loan Bank Board, National Credit Union Administration and Office of the Comptroller of the Currency, is required by Section 311(d) of the Housing and Community Development Act of 1980 (Pub. L. 96–399) to conduct a study to assess the feasibility and usefulness of requiring depository institutions which make small business loans to compile and publicly disclose information regarding such loans. The results of this study are to be reported to the House and Senate Banking Committees not later than March 1, 1981.

As part of its study, the Council requests comment from the public—including small businesses, financial institutions, community organizations, trade associations and the academic community—on the general feasibility and usefulness of public disclosure of small business loan activity and on various issues related to method of disclosure should such a requirement be deemed appropriate.

DATE: Comments must be received on or before February 17, 1981.

ADDRESS: Comments should be sent to David K. Schweitzer, Deputy Executive Secretary, Federal Financial Institutions

Examination Council, Eighth Floor, 490, L'Enfant Plaza SW, Washington, DC, 20219.

FOR FURTHER INFORMATION CONTACT: David K. Schweitzer, Deputy Executive Secretary, Federal Financial Institutions Examination Council, (202) 287–4206.

SUPPLEMENTARY INFORMATION: The Congressional call for this study on small business loan disclosures appears to have originated from a concern in some communities that lenders are giving insufficient attention to the credit needs of small business, especially those located in low- and moderate-income neighborhoods. It has been suggested that small business lending patterns in a community can be identified most effectively by requiring public disclosure of the small business lending activities of local depository institutions, just as public disclosure of mortgage lending data under the Home Mortgage Disclosure Act (HMDA) is seen by many as useful in identifying mortgage lending patterns.

Although the mandatory disclosure of small business lending activity might be judged both feasible and useful in an absolute sense, the Council requests that all comments be directed to the relative value of such disclosures in terms of real costs and benefits. Depository institutions should consider carefully the additional demands such a disclosure requirement would place on their business operations, and potential users of the data should describe clearly the benefits the proposed disclosures would provide to them.

For purposes of the issues raised below, the term "depository institution" means any commercial bank, savings bank, savings and loan association, credit union, or similar institution (including any majority-owned subsidiaries) the deposits or accounts of which are insured by an agency of the federal government or which is regulated by any agency of the federal government. The definition of "small business loan" is open for comment under Issue A2. In general, however, "business loans" may be considered to include all credit extended to any natural person, business, or organization, which is not considered "consumer credit" under Federal Reserve Regulation Z, Truth in Lending (TIL), and is exempted from TIL disclosure requirements on the basis of 12 CFR 226.3(a).[1]

ISSUES: A. Specific Issues. 1. Definition of "Small Business." If disclosure of small business lending activity were to be required, the term "small business" would have to be defined. Possible definitions could be based upon the complex eligibility standards established by the small Business Administration (SBA) for use in its various programs, simplified variations of the SBA standards (e.g., abbreviated Standard Industrial Classification, asset size, and employee count), or a single criterion such as number of employees at the borrowing firm. Comment is requested on the advantages and disadvantages of various approaches to defining "small business" and specifically on the feasibility of using number of employees as the determinant. Comments should include discussion of whether the borrower characteristics needed for a particular definition are currently recorded by financial institutions; and, if not, whether the information is readily available from borrowers and the anticipated expense of modifying recordkeeping systems to collect it. If SBA guidelines were used to define the size of a business, information such as sales, asset size, employment, etc., would have to be recorded on a consolidated basis where the borrowing business was a subsidiary or division of a larger commercial enterprise. What effect would imposing this procedure have on the lender's ability to collect required information and on the utility of the resulting data to community users? Alternatively, would disclosures based on unconsolidated information relating only to the local borrower (e.g., the subsidiary) have any value?

2. Definition of "Small Business Loan." The Council seeks comment on whether all credit granted to a borrower meeting the definition of "small business" should be considered a small business loan for disclosure purposes. Where the lender has more than one department approving various types of credit to small businesses, what difficulties, if any, could be encountered in attempting to consolidate loan data from multiple departments? Should a line of credit be counted as one loan for the total amount at the time it is established, or should each draw against that line be counted as a separate loan? Are there other unique commercial credit arrangements that could complicate disclosures?

3. Loan Data. HMDA requires mortgage loan data to be compiled in terms of number of loans and total dollar amounts (of original principle originated or purchased). Considering that commercial loans are less homogeneous in character than residential mortgages, comment is sought on the appropriate loan data disclosures for small business loans. Comment is specifically requested on the feasibility and usefulness of separating disclosures on the basis of such criteria as (a) purpose of loan, (b) term of loan, or (c) conventional versus government guaranteed. The Council also requests comment on whether disclosures should be broken down by the borrower's type of industry. For example, what added costs and benefits would result if loans were separated on the basis of the nine basic industry groups identified by U.S. Standard Industrial Classification numbers?

4. Data Aggregation and Itemization. HMDA requires that institutions with offices in standard metropolitan statistical areas (SMSA's) disclose mortgage loan data aggregated by SMSA and that, within SMSA's, data be itemized by census tract. HMDA also provides that reporting institutions record aggregated data on lending outside of the SMSA without itemization. The Council requests comment on whether similar requirements would be feasible and useful for disclosures of loans to small businesses. What kind of geographic information is routinely recorded on commercial loan applications? If a borrower operates at multiple locations, what additional information would have to be recorded to allow identification of the business location receiving primary benefit of the credit extended? What additional costs would be incurred in this process? If no single location receives the primary benefit, how should such a loan be identified geographically for disclosure purposes?

Specific comment on the feasibility and usefulness of compiling and disclosing small business loan data in non-SMSA (e.g., rural) areas is also requested.

5. Exemptions. Section 309 of HMDA (and Section 203.3(a)(1) of Regulation C–12 CFR 203) specifically exempts depository institutions with less than $10 million in assets from mortgage loan disclosure requirements. The Council solicits comment on whether a similar exemption would be appropriate with regard to any requirement for small business loan disclosures. Views on the role of small institutions in providing credit to small businesses and on what effect exclusion of small institution loan data would have on the usefulness of disclosures would be helpful.

[1] Regulation Z (12 CFR 226) Section 226.2(p) states in part " 'consumer credit' means credit offered or extended to a natural person . . . primarily for personal, family, household or agricultural purposes." The exemption in Section 226.3(a) covers "extentions of credit to organizations, including governments, or for business or commercial purposes, other than agricultural purposes."

B. Summary Issues. 1. General Feasibility. In addition to the foregoing specific issues the Council requests comment, especially from depository institutions, on the overall increase in cost of operations that would result from required small business loan disclosures. Would such costs be variable or fixed, one time or recurring, related to the size of the institution, etc.? In addition, the Council requests comment on whether past cost/benefit experience under HMDA is relevant to the recording and disclosure of small business loans. What unique characteristics of business lending might pose special problems not found with disclosures of mortgage lending activity? How can such problems be overcome and at what cost? Commentors are requested to substantiate their conclusions on this issue by describing in detail the factors considered.

2. General Usefulness. Potential users of disclosures of small business loan activity are assumed to be primarily the same groups currently using HMDA data (i.e., community action groups, local and state government agencies, private and government researchers, the federal financial regulatory agencies, etc.) plus the business community itself. The Council requests comment from all categories of potential users on what specific needs or problems currently exist which they expect to be satisfied or resolved by requiring depository institutions to compile and publicly disclose information regarding loans to small businesses. The Council considers it important for potential users to substantiate both that information is needed and that public disclosure of small business lending by depository institutions would be the most effective means of obtaining it.

Any person or organization wishing to comment on the issues outlined above may do so by filing a written submission with the Council. See DATE and ADDRESS at the beginning of this Notice. All submissions will become part of the record and will be available for public review.

Dated: December 22, 1980.

Robert J. Lawrence,

Executive Secretary, Federal Financial Institutions Examination Council.

Marie Ciblin,

Office of the Comptroller of the Currency, Communications Division.

[FR Doc. 80-40457 Filed 12-29-80; 8:45 am]

BILLING CODE 6722-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Assistant Secretary for Health

National Center for Health Care Technology; Scientific Evaluation of Medical Technology

The National Center for Health Care Technology (Center) announces that it is beginning a scientific evaluation of the clinical safety and effectiveness of the Bentonite flocculation test, DNA antibody test, mycoplasma complement fixation test, Kunkel test, and joint scans used in the diagnosis and treatment of rheumatoid arthritis. Based on this evaluation, a recommendation will be formulated to assist the Health Care Financing Administration (HCFA) in establishing Medicare coverage policy. Any person or group wishing to provide the Center with information relevant to this evaluation should do so in writing no later than March 2, 1981. To enable the Center's staff to give appropriate consideration to any literature references or analyses of clinical data, a written summary no longer than 10 pages should be attached to any such material submitted.

Written material should be submitted to: National Center for Health Care Technology, Room 17A-29, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Stephen P. Heyse, M.D., M.P.H., Health Science Analyst, National Center for Health Care Technology, Room 17A-29, Parklawn Building, Rockville, Maryland 20857, (301) 443-4990.

Dated: December 22, 1980.

Wayne C. Richey, Jr.,

Acting Executive Secretary, Office of Health Research, Statistics, and Technology.

[FR Doc. 80-40536 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-85-M

Food and Drug Administration

[FDA-225-81-3000]

Medical Treatment Standards for Methadone Treatment Programs; Memorandum of Understanding With National Institute on Drug Abuse

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration has executed a memorandum of understanding (MOU) with the National Institute on Drug Abuse. The purpose of the MOU is to describe the cooperative relationship and procedures to be followed by both the National Institute on Drug Abuse and the Food and Drug Administration in implementing the jointly published Narcotic Addict Treatment regulations. The MOU will help reduce the likelihood of inconsistent interpretations of the regulations.

EFFECTIVE DATE: November 20, 1980.

FOR FURTHER INFORMATION CONTACT: Edwin V. Dutra, Jr., Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: The Comprehensive Drug Abuse Prevention and Control Act of 1970 (CDAP&C Act) as amended, assigned to the Secretary of Health and Human Services (HHS) a number of responsibilities regarding the treatment of narcotic addicts. The Secretary delegated these responsibilities to the Director, National Institute on Drug Abuse (NIDA) and the Commissioner, Food and Drug Administration (FDA) (see 37 FR 27646, December 19, 1972; 38 FR 27315, October 2, 1973; and 21 CFR 5.1). Because of the unavoidable overlap in certain of these delegated responsibilities, FDA and NIDA have agreed to enter into this memorandum of understanding (MOU). This MOU will help reduce the likelihood of inconsistent interpretations of the jointly published regulations on narcotic addict treatment (see 45 FR 62694; September 19, 1980).

Under the notice published in the **Federal Register** of October 3, 1974 (39 FR 35697) stating that future memoranda of understanding and agreements between FDA and others would be published in the **Federal Register**, the following memorandum of understanding is issued:

Memorandum of Understanding Between the National Institute on Drug Abuse and the Food and Drug Administration

I. Purposes

The purposes of this MOU are: (a) to describe the cooperative relationship and procedures to be followed by the National Institute on Drug Abuse (NIDA) and the Food and Drug Administration (FDA) in implementing the jointly published narcotic addict treatment regulations; (b) to establish a mechanism that ensures a systematic and timely input from NIDA to FDA about decisions on the operation of narcotic treatment programs under those regulations; and (c) to reduce the likelihood of inconsistent interpretations of those regulations. This agreement does not affect FDA's authority to make and issue all final decisions under the regulations.

II. Background

In 1974 the Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970

(CDAP&C Act), was amended by the Narcotic Addict Treatment Act (NATA). The NATA was intended primarily to establish the basis for more control of narcotic addict treatment programs by the Drug Enforcement Administration (DEA) and the Department of Health and Human Services (HHS) to prevent diversion of narcotic drugs, and to ensure proper treatment of narcotic addicts. The NATA amended the CSA to provide for registration (through DEA) of practitioners conducting narcotic treatment programs. The fundamental purpose of the NATA, according to its legislative history, is to increase the Government's control over methadone and other narcotic drugs used in the treatment of narcotic addicts. This additional control would both ensure proper treatment and prevent diversion. The legislative history of the NATA further states that it is intended to complement the DEA and HHS controls in force at the time of enactment and to establish the basis for additional joint regulation of treatment programs by these two agencies.

The NATA, among other things, gives the Secretary of HHS authority to establish treatment standards for practitioners who use narcotic drugs for either maintenance or detoxification treatment of persons dependent upon narcotic drugs. Practitioners providing this treatment obtain a special registration which must be renewed annually from the Attorney General (through DEA) and, as a condition of registration, must comply with standards established by the Secretary. Under the NATA (21 U.S.C. 823(g)), the Secretary must (a) determine if an applicant/practitioner is qualified, and (b) determine if the applicant/practitioner will comply with the standards about the quantities of narcotic drugs which may be provided for unsupervised use by persons in such treatment and then report this determination to DEA. As noted above, HHS responsibilities under the NATA are carried out by FDA and NIDA.

In 1975 the Commissioner of Food and Drugs and the Director, National Institute on Drug Abuse agreed to jointly publish revisions to the methadone regulations. Accordingly, in 1977 they proposed a revision of the treatment standards. The final revised treatment standards were recently published in the Federal Register on Friday, September 19, 1980 (45 FR 62694). This revision of the methadone regulations includes the Secretary's treatment standards under the NATA.

III. Substance of Agreement

A. FDA agrees to the following terms:

1. FDA will continue to inspect and monitor narcotic addict treatment programs for compliance with the jointly published treatment standards.

2. Before issuing a letter of noncompliance to a narcotic addict treatment program, FDA will provide NIDA with a draft copy of the letter, send to NIDA the supporting information upon which the action is based, and obtain NIDA's written recommendation as to whether the letter should issue.

3. Before notifying the DEA not to certify a treatment program under the jointly published standards, FDA will provide NIDA with a draft copy of the notice, send to NIDA the supporting information upon which the action is based, and obtain NIDA's written recommendation as to whether the notice should issue.

4. Before granting or denying an exemption under section (d)(12) of the jointly published treatment standards, FDA will notify NIDA of the request for an exemption, send to NIDA the information supporting the request, and obtain NIDA's written recommendation as to whether to grant or deny the request. However, if the request involves a medical emergency or an exception for a specific patient, the notification may be made orally by telephone or in person.

5. FDA will notify NIDA in writing before taking action which is contrary to NIDA's recommendations under items 2, 3, and 4 above.

6. FDA will make the final determination in matters which relate to safety and effectiveness of drugs or to the approval of new drugs to be used in the treatment of narcotic addicts.

B. NIDA agrees to the following terms:

1. Within seven (7) days of receipt of the information from FDA described in items 2 and 3 above, NIDA will give FDA its written recommendation and, in the event of disagreement with a proposed FDA action, state the reason(s) for disagreement including, when appropriate, a recommended alternative action.

2. Within ten (10) days of receipt of the information from FDA described in item 4 above, NIDA will give FDA its written recommendation.

3. In the event of disagreement with a proposed FDA action, NIDA will state the reasons for disagreement including, when appropriate, a recommended alternative action. However, if the request involves a medical emergency or an exception for a specific patient, the recommendation may be made orally by telephone or in person.

C. NIDA and FDA agree to the following terms:

1. Jointly publish any future revisions of the methadone treatment regulations;

2. Consult each other before issuing interpretations and opinions under the treatment standards which would have broad policy implications; and

3. Consult each other on the need to update, develop, or revise the regulations and policy affecting narcotic addict treatment.

IV. Name and Address of Participants

A. National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, MD 20857.

B. Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

V. Liaison Officers

A. Liaison Officer for NIDA: Mr. Nathan M. Kight, National Institute On Drug Abuse, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4877.

B. Liaison Officer for FDA: Mr. Edwin V. Dutra, Jr., Food and Drug Administration (HFD–30), 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

VI. Period of Memorandum of Understanding

This agreement becomes effective when signed by both parties and remains in effect until it is terminated. This agreement may be terminated by either agency upon 90 days' advance written notice to the other.

VII. Revisions

Revisions to this agreement may be made by mutual consent of the agencies.

Approved and accepted for the Food and Drug Administration:
By: Mark Novitch for Jere E. Goyan.
Title: Commissioner of Food and Drugs.
Date: November 20, 1980.

Approved and accepted for the National Institute on Drug Abuse:
By: William Pollin,
Title: Director, National Institute on Drug Abuse.
Date: October 30, 1980.

Effective date. This memorandum of understanding becomes effective November 20, 1980.

Dated: December 22, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-40508 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

Health Services Administration

Filing of Annual Reports of Federal Advisory Committees

Notice is hereby given that pursuant to section 13 of Pub. L. 92–463, the Annual Reports for the following Health Services Administration Federal Advisory Committees have been filed with the Library of Congress:

National Advisory Council on the National Health Service Corps

National Advisory Council on Migrant Health

Maternal and Child Health Research Grants Review Committee.

Copies are available to the public for inspection at the Library of Congress, Newspaper and Current Periodical Reading Room, Room 1026, Thomas Jefferson Building, Second Street and Independence Avenue, S.E. Washington, D.C. or weekdays between 9:00 a.m. and 4:30 p.m. at the Department of Health and Human Services, Department Library, North Building, Room 1436, 300 Independence Avenue, S.W., Washington, D.C. 20201, Telephone (202) 245–6791.

Copies may be obtained from the following committee contacts:

National Advisory Council on the National Health Service Corps—Mr. Billy Sandlin, Bureau of Health Personnel Development and Service, Room 6–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–4434.

National Advisory Council on Migrant Health—Mr. Jaime L. Manzano,

Bureau of Community Health Services, Room 7A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–1153.

Maternal and Child Health Research Grants Review Committee—Gontran Lamberty, Dr. P. H., Bureau of Community Health Services, Room 7–15, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–2190.

Dated: December 17, 1980.

William H. Aspden, Jr.,

Associate Administrator for Management.

[FR Doc. 80-40448 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-84-M

Office of Human Development Services

White House Conference on Aging; Technical Committee on Creating an Age-Integrated Society: Implications for the Family; Meeting

The White House Conference on Aging Technical Committee was established to provide scientific and technical advice and recommendations to the National Advisory Committee of the 1981 White House Conference on Aging and to the Executive Director of the 1981 White House Conference on Aging in developing issues to be considered and to produce technical documents to be used by the Conference.

Notice is hereby given pursuant to the Federal Advisory Committee Act, (Public Law 92–463, 5 U.S.C. App. 1, sec. 10, 1976) that the Technical Committee on Creating an Age-Integrated Society: Implications for the Family will hold their next meeting Wednesday, January 14, 1981, from 9:00 a.m. until 5:00 p.m. at the Andrus Gerontology Center, University of Southern California, Los Angeles, California 90007.

The purpose of the meeting will be to: (1) complete review of technical paper by committee (Chapters I, II, III were reviewed on 12/12/80) and (2) to review Chapters IV and V on Policy and Recommendations, and the chapter on Ethnic Families.

Further information on the Technical Committee meeting may be obtained from Mr. Jerome R. Waldie, Executive Director, White House Conference on Aging, Room 4059, 330 Independence Avenue, S.W., Washington, D.C. 20201, telephone (202) 245–1914. Technical Committee meetings are open for public observation.

Dated: December 22, 1980.

Mamie Welborne,

HDS Committee Management Officer.

[FR Doc. 80-40481 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-92-M

White House Conference on Aging; Technical Committee on Creating an Age-Integrated Society: Implications for Education; Meeting

The White House Conference on Aging Technical Committee was established to provide scientific and technical advice and recommendations to the National Advisory Committee of the 1981 White House Conference on Aging and to the Executive Director of the 1981 White House Conference on Aging in developing issues to be considered and to produce technical documents to be used by the Conference.

Notice is hereby given pursuant to the Federal Advisory Committee Act, (Public Law 92–463, 5 U.S.C. App. 1, sec. 10, 1976) that the Technical Committee on Creating an Age-Integrated Soceity: Implications for Education will hold their next meeting Monday, January 19, 1981 and Tuesday, January 20, 1981 from 9 a.m. until 5 p.m. each day. The meeting will be held at the Institute of Gerontology at the University of Michigan, 520 E. Liberty Street, Ann Arbor, Michigan 48108.

The purpose of the meeting will be to review draft of committee report for revisions and finalization.

Further information on the Technical Committee meeting may be obtained from Mr. Jerome R. Waldie, Executive Director, White House Conference on Aging, Room 4059, 330 Independence Avenue, SW., Washington, D.C. 20201, telephone (202) 245–1914. Technical Committee meetings are open for public observation.

Dated: December 22, 1980.

Mamie Welborne,

HDS Committee Management Officer.

[FR Doc. 80-40482 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-92-M

White House Conference on Aging: Technical Committee on Creating an Age-Integrated Society: Implications for Societal Institutions; Meeting

The White House Conference on Aging Technical Committee was established to provide scientific and technical advice and recommendations to the National Committee of the 1981 White House Conference on Aging and to the Executive Director of the 1981 White House Conference on Aging in developing issues to be considered and to produce technical documents to be used by the Conference.

Notice is hereby given pursuant to the Federal Advisory Committee Act, (Public Law 92–463, 5 U.S.C. App. 1, sec. 10, 1976) that the Technical Committee on Creating an Age-Integrated Society—Implications for Societal Institutions will convene its fourth meeting on Friday, January 16, 1981 and Saturday, January 17, 1981 from 9:30 am until 5:30 pm each day. The meeting will be held in Room 403–425A at the Hubert H. Humphrey Bldg., 200 Independence Avenue, S.W., Washington, D.C. 20201.

The purpose of the meeting will be to review segments of the draft final report and to make plans for the completion of the committee's report.

Further information on the Technical Committee meeting may be obtained from Mr. Jerome R. Waldie, Executive Director, White House Conference on Aging, Room 4059, 330 Independence Avenue, S.W., Washington, D.C. 20201, telephone (202) 245–1914. Technical Committee meetings are open for public observation.

Dated: December 22, 1980.

Mamie Welborne,

HDS Committee Management Officer.

[FR Doc. 80-40483 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-92-M

White House Conference on Aging; Technical Committee on the Family, Social Services and Other Support Systems; Meeting

The White House Conference on Aging Technical Committee was established to provide scientific and technical advice and recommendations to the National Advisory Committee of the 1981 White House Conference on Aging and to the Executive Director of the 1981 White House Conference on Aging in developing issues to be considered and to produce technical documents to be used by the Conference.

Notice is hereby given pursuant to the Federal Advisory Committee Act, (Public Law 92–463, 5 U.S.C. App. 1, sec. 10, 1976) that the Technical Committee on the Family, Social Services and Other Support Systems will convene its final meeting on Thursday, January 15, 1981 from 9:00 am until 5:00 pm in Room 5542 at HHS-North Bldg., 330 Independence Avenue, S.W., Washington, D.C. 20201.

The purpose of the meeting will be to review the final draft of the policy paper and to approve the recommendations.

Further information on the Technical Committee meeting may be obtained from Mr. Jerome R. Waldie, Executive Director, White House Conference on Aging, Room 4059, 330 Independence Avenue, S.W., Washington, D.C. 20201, telephone (202) 245–1914. Technical Committee meetings are open for public observation.

Dated: December 22, 1980.

Mamie Welborne,

HDS Committee Management Officer.

[FR Doc. 80-40484 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-92-M

White House Conference on Aging; Technical Committee on Health Maintenance and Health Promotion; Meeting

The White House Conference on Aging Technical Committee was established to provide scientific and technical advice and recommendations to the National Advisory Committee of the 1981 White House Conference on Aging and to the Executive Director of the 1981 White House Conference on Aging in developing issues to be considered and to produce technical documents to be used by the Conference.

Notice is hereby given pursuant to the Federal Advisory Committee Act, (Public Law 92–463, 5 U.S.C. App. 1, sec. 10, 1976) that the Technical Committee on Health Maintenance and Health Promotion will hold their meeting on Thursday, January 15, 1981 and Friday, January 16, 1981 from 9:00 am to 5:00 pm each day in the Hawaii Room, 28th floor, of the General Services Administration Building, 525 Market Street, San Francisco, California.

The purpose of the meeting will be to review the final draft of the Technical Committee's report to the Conference and to make policy recommendations to be contained in the report.

Further information on the Technical Committee meeting may be obtained from Mr. Jerome R. Waldie, Executive Director, White House Conference on Aging, Room 4059, 330 Independence Avenue, S.W., Washington, D.C. 20201, telephone (202) 245–1914. Technical Committee meetings are open for public observation.

Dated: December 22, 1980.

Mamie Welborne,

HDS Committee Management Officer.

[FR Doc. 80-40485 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-92-M

White House Conference on Aging; Technical Committee on Physical and Social Environment and Quality of Life; Meeting

The White House Conference on Aging Technical Committee was established to provide scientific and technical advice and recommentations to the National Advisory Committee of the 1981 White House Conference on Aging and to the Executive Director of the 1981 White House Conference on Aging in developing issues to be considered and to produce technical documents to be used by the Conference.

Notice is hereby given pursuant to the Federal Advisory Committee Act, (Public Law 92–463, 5 U.S.C. App. 1, sec. 10, 1976) that the Technical Committee on Physical and Social Environment and Quality of Life will hold their next meeting on Tuesday, January 6, 1981 from 9:30 am to 5:00 pm and Wednesday, January 7, 1981 from 8:30 am until 4:30 pm at the St. Louis Area Agency on Aging, St. Louis, Missouri.

The purpose of the meeting will be to review segments of draft final report and make plans for completion of the report.

Further information on the Technical Committee meeting may be obtained from Mr. Jerome R. Waldie, Executive Director, White House Conference on Aging, Room 4059, 330 Independence Avenue, S.W., Washington, D.C. 20201, telephone (202) 245–1914. Technical Committee meetings are open for public observation.

Dated: December 22, 1980.

Mamie Welborne,

HDS Committee Management Officer.

[FR Doc. 80-40486 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-92-M

White House Conference on Aging; Technical Committee on Research on Aging; Meeting

The White House Conference on Aging Technical Committee was established to provide scientific and technical advice and recommendations to the National Advisory Committee of the 1981 White House Conference on Aging and to the Executive Director of the 1981 White House Conference on Aging in developing issues to be considered and to produce technical documents to be used by the Conference.

Notice is hereby given pursuant to the Federal Advisory Committee Act (Public Law 92–463, 5 U.S.C. App. 1, sec. 10, 1976) that the Technical Committee on Research on Aging will hold their next meeting on Monday, January 12, 1981 and Tuesday, January 13, 1981 from 9:00 am to 5:00 pm each day. The meeting will be held at the Federal Building, Room 13216 (13th Floor), 450 Golden Gate Avenue, San Francisco, California.

The purpose of the meeting will be to finalize draft of Technical Paper, the Recommendations, and the Executive Summary.

Further information on the Technical Committee meeting may be obtained from Mr. Jerome R. Waldie, Executive Director, White House Conference on Aging, Room 4059, 330 Independence Avenue, SW., Washington, D.C. 20201, telephone (202) 245–1914. Technical Committee meetings are open for public observation.

Dated: December 22, 1980.

Mamie Welborne,

HDS Committee Management Officer.

[FR Doc. 80-40487 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-92-M

National Institutes of Health

Cinnamyl Anthranilate; for Possible Carcinogenicity; Availability

Cinnamyl anthranilate (CAS 87–29–6) has been tested for cancer-causing activity with rats and mice in the Bioassay Program of the national Toxicology Program. A report is available to the public.

Summary: A bioassay of cinnamyl anthranilate (a synthetic flavoring agent) for possible carcinogenicity was conducted by administering the test chemcial in food to F344 rats and B6C3F1 mice.

It was concluded that under the conditions of this bioassay cinnamyl anthranilate was carcinogenic for male and female B6C3F1 mice, including increased incidences of hepatocellular carcinomas or adenomas. The test chemcial was also carcinogenic for male F344 rats, inducing low incidences of acinar-cell carcinomas or adenomas of the pancreas and adenocarcinomas or adenomas of the renal cortex. Cinnamyl anthranilate was not carcinogenic for female F344 rats.

Single copies of the report, Bioassay of Cinnamyl anthranilate for Possible Carcinogenicity (T.R. 196), are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21,

National Institutes of Health, Bethesda, Maryland 20205.

Donald S. Fredrickson,

Director, National Institutes of Health.

(Catalogue of Federal Domestic Assistance Program Number 13.393, Cancer Cause and Prevention Research)

[FR Doc. 80-39421 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-08-M

DEPARTMENT OF THE INTERIOR

Heritage Conservation and Recreation Service

National Register of Historic Places; Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the Heritage Conservation and Recreation Service before December 19, 1980. Pursuant to § 1202.13 of 36 CFR Part 1201, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, Heritage Conservation and Recreation Service, U.S. Department of the Interior, Washington, DC 20243. Written comments should be submitted by January 14, 1981.

Ronald M. Greenberg,

Acting Chief, National Register Division.

ARIZONA

Maricopa County

Tempe, *Frankenberg House*, 129 W. University Dr.

CALIFORNIA

Alameda County

Berkeley, *U.S. Post Office*, 2000 Milvia St.

Los Angeles County

Los Angeles, *U.S. Post Office and Courthouse*, 312 N. Spring St.

Santa Barbara County

Santa Barbara, *Santa Barbara County Courthouse*, 1100 Anacapa St.

Sierra County

Nevada City vicinity, *Foote's Crossing Road*, Tahoe National Forest (also in Nevada County)

Sierra City, *Kentucky Mine*, CA 49

COLORADO

Gunnison County

Pitkin vicinity, *Alpine Tunnel Historic District*

Jefferson County

Morrison vicinity, *Peterson House (Ticen House)*, E of Morrison on Morrison Rd.

GEORGIA

Heard County

Franklin, *Heard County Jail*, Court Sq. and Shady Lane

NEW HAMPSHIRE

Coos County

Bretton Woods vicinity, *Fabyan Guard Station*, NW of Bretton Woods on Cherry Mountain Rd.

OHIO

Lucas County

Neapolis vicinity, *Providence Site (33-Lu-150)*, S of Neapolis in Providence Metropolitan Park

Montgomery County

Trotwood, *Trotwood Railroad Station and Depot*, 2 W. Main St.

Adair County

Westville vicinity, *Alberty Chapel Cemetery*, SE of Westville

Creek County

Drumright, *Washington School*, 214 W. Federal St.

Garfield County

Enid, *Government Springs*, 4th St. and East Pk.

Okmulgee County

Henryetta vicinity, *Wilson School*, NW of Henryetta

OREGON

Umatilla County

Umatilla vicinity, *Umatilla (35 UM 1)*, N of Umatilla

UTAH

Salt Lake County

Salt Lake City, *Utah State Fair Grounds*, 10th W. and N. Temple Sts.

WISCONSIN

Belleville, *Library Park*, Bounded by vine, Main, Park and Pearl Sts.

Walworth County

Delavan vicinity, *Mile Long Site*, S of Delavan (boundary decrease)

[FR Doc. 80-40510 Filed 12-29-80; 8:45 am]

BILLING CODE 4310-03-M

Bureau of Land Management

Federal-Private Cooperative Coal Leasing Proposal

AGENCY: Bureau of Land Management, Interior.

ACTION: Request for public comment on the Federal-private cooperative coal leasing proposal.

SUMMARY: Under the Mineral Leasing Act of 1920, as amended, the Secretary of the Interior is responsible for managing a program for the competitive leasing of Federal coal. In addition, he is to ensure that Federal coal is leased at its fair market value. Considerations for ensuring receipt of fair market value were studied by a Department of the Interior task force that concluded its efforts in the spring of 1980.

One of the recommendations of the Fair Market Value Task Force on Federal coal leases was to enhance Federal coal sale competition by working cooperatively with private coal owners to jointly market coal from potential logical mining units comprised of both Federal and private coal. A cooperative leasing procedure would be of significant benefit to the systematic development of private-Federal mixed ownership coal, especially checkerboard coal. Acting on the task force's recommendation, a working group within the Department has designed a proposed method for cooperative leasing which it hopes to apply in the October 1981 lease sale in the Green River-Hams Fork Federal Coal Region in northwest Colorado and southwest Wyoming. This method and its benefits, costs, and potential problems are described in the enclosed appendix. The two suitable tracts for cooperative leasing, Red Rim and China Butte, are juxtaposed with the lands owned by Rocky Mountain Energy Company. Rocky Mountain Energy Company and the Department have already conducted preliminary discussions concerning the possibility of cooperative leasing on these tracts.

The public is invited to comment on the validity of this specific cooperative leasing proposal, as well as the concept of cooperative leasing itself; to suggest modifications to the proposed methods; or to suggest other means to accomplish the same ends. The next step in the process, following analysis of comments, will be to enter into formal negotiations with Rocky Mountain Energy Company over cooperative leasing.

DATES: Written comments will be received on or before January 29, 1981.

ADDRESS: Send comments to Director (160), Bureau of Land Management, 18th & C Streets, N.W. Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: Ryan Dudley, Office of Coal Management, Bureau of Land Management, (202) 343-4537.

Dated: December 22, 1980.

Ed Hastey,

Associate Director, Bureau of Land Management.

Appendix—Federal-Private Cooperative Coal Leasing Proposal

1. Introduction

This country has vast reserves of coal. Its coal deposits are widely distributed and vary greatly in quality and value. Much of this coal is privately owned and with a few notable exceptions, namely certain concentrated railroad holdings, private ownership is widely dispersed. The States also own significant reserves. However, the most significant single owner of U.S. coal reserves is the United States Government and most of these reserves are located in the West.

The "checkerboard" pattern of ownership occurs in some of the richest coal fields in the West, such as the Green River Basin in Wyoming. This pattern may have a significant effect on the development of U.S. coal and competition for Federal coal leases. Checkerboarding occurs where alternate sections of land are owned by the United States and a private landowner or corporation, most often a railroad company or its affiliate. Coal deposits in many areas of these checkerboard regions underlie a number of sections of land owned by the government and private parties, making efficient development of the deposit as a single economic unit difficult. Unless these coal deposits are controlled through lease or ownership by a single operator, the coal deposit may be mined piecemeal in a manner that is neither efficient nor economical. When a coal deposit underlies unleased Federal lands and adjoining privately owned land, the competitive interest in the unleased Federal coal may also be diminished because prospective Federal lessees may be uncertain of their ability to arrive at satisfactory contractual agreements with the adjoining private owner or owners. Also, the time needed to bring a Federal lease into production in a checkerboard area may be significantly lengthened by the extra time needed for land assembly. In short, the checkerboard pattern of ownership may constitute a significant impediment to efficient mining of coal in the checkerboard, may reduce the value of any Federal lease to a potential bidder, and may reduce competition as well. The total effect may be inefficient mining of the coal, a loss in the Department's effectiveness in meeting leasing targets, and a significant reduction in Federal leasing revenues.

II. The Concept of Cooperative Leasing

The most serious problems created by checkerboarding may be overcome if it is possible to obtain and package all the rights that are necessary for efficient mining of a potential logical mining unit prior to the sale so that the entire package can be put up for bid. Competition could then assure that the public receives a fair return from the sale of the Federal coal. Efficient development of the coal resources would also be promoted, many costly uncertainties would be eliminated, and, if the packaging can be done cheaply, there may be significant savings in transaction costs. Therefore, it is important to explore the possibility of packaging Federal and private rights, which we shall refer to as "cooperative leasing," prior to leasing Federal deposits. If cooperative leasing is adopted, the winning bidder for a Federal lease will have the opportunity to acquire all the public and private property rights that are required for efficient mining. If packaging takes place prior to auction, it eliminates the most serious problems presented by a checkerboard. There are a number of important practical and theoretical questions associated with the concept of cooperative leasing. For example, one question is what legal or procedural means should be used to effect the cooperation? This is important because different procedures have very different implications for risk bearing, capital requirements, and the need for revenue sharing rules, etc. A second question is which party should initiate the cooperative agreement: the government, one of the private parties owning rights that would be included in the package, or a third party acting as a broker? A third question is whether a workable and fair rule for sharing revenues can be defined and implemented. The list of possible questions regarding the hows and wherefores of cooperative leasing is a long one. The department believes these questions can best be answered by the experience gained through attempting to conduct a cooperative lease sale. The following discussion outlines the procedure the Department might follow for such a trial run.

III. Current Proposal for Cooperative Leasing

Even though several Department studies have been done relating to the question of cooperative leasing, a great many technical issues still need resolution for it to become a reality. Up until now, no single preferred method has been developed by, or presented to, the Department. This proposal came about as a result of the Secretary's commitment that the Department make every attempt to find a feasible way to include one "unitized" tract in the first Green River-Hams Fork regional lease sale in 1981.

As a result of this commitment, a task group set up under the guidance of the Office of Coal Leasing, Planning and Coordination has selected a workable method from among all the prior proposals. The task force has rejected, as far as this first attempt is concerned, all methods of cooperative leasing which do not meet certain, basic criteria. These criteria include the following:

1. The proposal must provide for *pre-sale* packaging of Federal and private coal. This has no applicable precedents in Federal mineral leasing. The unitization procedures common to oil and gas are *post-sale* procedures and do not solve the problems in holding a competitive sale in a checkerboard area.

2. Any lease terms affecting the value of the lease must be the same in both the public and private leases.

3. The Department has no legal authority for compulsory pre-sale packaging of Federal and private tracts; nor is it clear that such authority would be purely beneficial. Consequently, we must rely upon a voluntary agreement between the Department and willing private coal owners.

4. The proposal must be in accord with all current laws and regulations governing Federal coal leasing.

5. A potential additional criterion would provide that the private cooperator could not participate in the sale as a bidder.

With these criteria in mind, the task group sifted through the numerous theoretical proposals advanced by earlier studies. The proposal presented here is one that appeared to be both feasible and relatively simple to execute. No doubt other methods also exist which meet the criteria. The task group and the Office of Coal Leasing are anxious to receive any and all such proposals for consideration. If other methods turn out to be clearly more workable, they will be adopted. At this time, however, the need is to bring the cooperative leasing concept out of the realm of theory and into a single, concrete, and workable proposal.

A. Leasing with checkerboard ownership.—In this proposal, we focus on specific procedures for cooperative leasing in the one case of most widespread importance, namely, checkerboard ownership. Here the government and a private owner own alternate sections of land and face each

other in a two-party bargaining situation.

In the case of a potential logical mining unit (LMU) composed of Federal coal and private coal controlled by one party, the policy objectives should be to form the potential LMU at minimum cost to society and to develop procedures that allow the public to recieve a fair share of the LMU rents. Transaction costs of assembly in checkerboard potential LMU may be high both for the Department and for its future lessees. For this reason, bidders other than the private owner or a party that had already reached an understanding with the private owner might ordinarily be discouraged from bidding on the unconcolidated tract.

The bilateral situation requires that the government have the pre-sale cooperation of the private owner in order to reach agreement that his property will be put up as part of a potential logical mining unit and sold at the same time as the Federal property for specified terms. The winning bidder would thereby acquire at one sale a tract of land that can be approved and operated as an LMU without costly effort on his part.

As part of this agreement, the government and the private owner must agree on a rule by which they will split the revenues from the LMU. Because of the efficiencies of scale, the LMU will be worth substantially more than the worth of either party's tracts individually. To encourage private sector cooperation, the government should attempt to devise a sharing rule that would split the gains from forming an LMU in a way roughly proportional to each party's interests in that unit.

While the initial costs of bargaining between the government and the private owner might be substantial, once the basis for an agreement has been reached within a coal field where checkerboarding occurs, costs would be reduced for future bargaining to form additional public-private LMUs. In other words, once the basis of agreement has been established, it would likely extend without major changes to all properties and all potential LMUs in the checkerboard region. Therefore, the potential exists for a savings in the future costs associated with attempting to assemble preliminary LMUs.

In practice, the simplest way to administer cooperative leasing in the checkerboard case might be to have the private owner and the government agree on a sharing rule and then have the private owner lease to the government with written permission to sublease. Then, the entire potential logical mining unit could be offered by the government on a competitive basis with the revenues from the lease being divided according to the preagreed sharing rule. This arrangement, however, might require legislation giving the Department of the Interior authority to lease privately owned land. An alternative arrangement would be to have competitors bid separately on the total mining unit as two individual mining units in a simultaneous sale. Here an agreement would be needed whereby the winning bidder must lease the government's land and the private land separately, but at or above a price determined by the prespecified sharing rule and the level of the winning bid for the total potential LMU. Simultaneous auctions appear too cumbersome, however. The method proposed in the following section is to conduct a single auction for the Federal coal land. The private owner would not assign any rights to the Federal Government, but would, instead, agree to offer his coal lease to the successful bidder on the Federal tract upon terms which he and the Federal Government would agree upon. For the present, sales would proceed through the variable bonus/fixed royalty bidding system. Whether deferred bonuses would be used has been decided.

B. *Federal-private cooperative coal leasing proposal.*—The task force has labeled its proposal for pre-sale coal lease packaging "Federal-Private Cooperative Coal Leasing." The intent of this proposal is to provide an opportunity for any interested party, to obtain at the same time separate leases for both Federal and private coal necessary for an efficient mining operation in a checkerboard area. The sale of the Federal coal lease will be conducted in the usual and customary manner with the winning bidder obtaining the Federal lease. By means of a pre-sale cooperative leasing agreement, the winning bidder for Federal coal would be given the opportunity also to buy the private coal.

To accomplish this, the Department would enter into a presale cooperative agreement with the private coal owner. The agreement would provide that the private coal owner would sell a private coal lease at the same time as the Federal sale to the winning bidder in the Federal sale. The agreement would also contain a key provision to fix the share of the total bonus going to the private coal owner and the amount going to the Federal Government. This allows each bidder to calculate the total amount to be spent for the entire mining unit, both Federal and private coal.

The factor referred to will be called the "Federal-Private Bid Ratio." This is simply a pre-sale announced fixed ratio between the bid on the Federal lease and the selling price on the private lease which each bidder for the Federal lease is required to adhere to. This ratio will be set by agreement between the Department and the private coal owner and will be based upon economic evaluations of the tracts and arrived at through bilateral negotiations. The minimum acceptable bid for the Federal lease and its concomitant private selling price would also be set at this ratio.

Any increase in the bid for the Federal lease above the minimum will also require raising the selling price for the private lease in order to keep the ratio constant. Thus, the high bidder in the Federal sale will always be paying a "fair" price to the private cola holder also. Of course, this system requires that royalties, rentals, and any other financial consideration be equal before the sale.

c. *Proposed agreement.*—In order to further clarify the proposed pre-sale packaging procedure, the following is the task force's outline of the terms which it believes might be included in a cooperative leasing agreement.

1. The parties agree that it would be mutually advantageous to hold coordinated sales of coal leases covering deposits of Federal and X Company coal.

2. The Department and X Company shall delineate a tract, called the combined tract, which shall not exceed 25,000 acres in size. The combined tract shall be an area of land in which the coal resources can be developed in an efficient, economical, and orderly unit with due regard to conservation of the coal reserves and other resources.

The combined tract shall be delineated from all of the following Federal lands (called the "Federal tract"): [To be described]

The combined tract shall also include all or portions of the following lands owned by X Company (called the X Company tract): [to be described]

All of the lands included in the combined tract shall be contiguous. (An alternative is for the parties to agree to a combined tract constituting a potential logical mining unit prior to entering into the agreement. The agreement would then simply recite a land description of the combined tract.)

3. The X Company shall supply to the Department all available geologic information, including drill logs and isopachous maps, which the Department needs to determine the amount and quality of the coal reserves on the X Company tracts. This information must

then be available to the public without condition. The Department shall also provide like information to X Company, except where the disclosure of such information would violate the Department's confidentiality agreements or the laws respecting the nondisclosure of proprietary information. In such cases, the Department will first request the holder of the proprietary data to release it or, failing that, notify X Company of the existence of such data.

4. The Department will conduct an economic evaluation of that portion of the combined tract which embraces the Federal lands in accordance with the regulations in 43 CFR Subpart 3422. Minimum bonus bids in the Federal tract shall not be less than $25 per acre. Royalties in the lease for the Federal and private tract shall be 12 1/2 percent for a surface mine and 8 percent for an underground mine.

The Department shall, at the same time it evaluates the Federal tract, conduct an economic evaluation of the combined tract and of the X Company tract in accordance with accepted Departmental procedures. The economic evaluation shall be based on the information made available to the Department by X Company as well as other relevant data. The Department and X Company shall use the Department's evaluation of the combined tract and other relevant information to arrive at a mutually acceptable minimum bid and Federal-private bid ratio for the X Company tract. All terms of both sales would be published for comment simultaneously with the request for comment on fair market value of the Federal tract.

5. The Department will hold a lease sale for the Federal tract in October 1981.

The lease sale procedures in 43 CFR Subpart 3422 shall be followed. The Department shall not issue a lease on the Federal tract to any bidder who does not meet the leaseholder qualifications of the Mineral Leasing Act, 30 U.S.C. 181, *et seq.*, or the regulations under 34 CFR Part 3400.

The Department shall issue a lease on the Federal tract to the highest qualified bidder, who has 45 days to conclude a sale agreement with X Company at an amount determined by the bid ratio.

X Company would agree to offer the X Company tract to the highest qualified bidder on the Federal tract. The terms for the sale of the X Company tract (including the bid ratio) shall be published simultaneously with the sale notices of the Federal tract required by 43 CFR 3422.2 together with X Company's agreement to lease to anyone satisfying these terms.

X Company shall not accept any offer that does not conform to the fixed ratio between the bid on the Federal lease and the bid on the private lease which was agreed to by the Department and X Company. The sale notices for the X Company shall specify this ratio.

D. *Post-sale Procedures.*—Once the leases have been issued, the lessee should petition to have the private coal included in the LMU containing the Federal lease at approximately the same time that a mine plan is submitted. The Department is examining two methods of royalty payment distribution for such a consolidated LMU. Under the first alternative, royalties would be received by the Department on an as-mined basis. Distinct and obvious differences in the timing of royalties to the private and public owners could be compensated for in setting the bonus ratio. As a second alternative, the Department is considering whether a proration approach would be feasible. Under such a distribution method, royalties would be paid to the parties in accordance with a sharing formula based on the relative ownership of the coal deposits within the LMU.

E. *Conclusion.*—An approach that potentially allows the systematic cooperative leasing of Federal checkerboard areas has been described. The Department will proceed to implement this procedure barring significant adverse comment and will make changes as appropriate. This approach is based on solving problems as they occur rather than trying to anticipate all possible complexities and resolving them in advance. At the conclusion of the Green River-Hams Fork cooperative leasing sale, the Department will assess the benefits and costs of this method, its general level of workability, and future potential gains or losses to determine a final course of action on cooperative leasing.

[FR Doc. 80-40337 Filed 12-29-80; 8:45 am]

BILLING CODE 4310-84-M

Arizona; Public Land, Wilderness Intensive Inventory Final Decision Protest Period Extension Date; Correction

In FR Doc. 80-38282 appearing on page 81264, Column 2, in the issue of Wednesday, December 10, 1980, in the third paragraph, seventh line, change date from December 22, 1980 to December 30, 1980.

Tom Allen,

Associate State Director.

December 17, 1980.

[FR Doc. 80-40464 Filed 12-29-80; 8:45 am]

BILLING CODE 4310-84-M

Office of the Secretary

Oil Shale Environmental Advisory Panel; Meeting

Notice is hereby given in accordance with Pub. L. 92-463 that a meeting of the Oil Shale Environmental Advisory Panel will be held on January 13, 1981, at the Cosmopolitan Hotel, 1780 Broadway, Denver, Colorado. The meeting will begin at 8:30 a.m. on Tuesday, January 13, in the Century Room and conclude by 5:00 p.m.

The Panel was established to assist the Department of the Interior in the performance of its functions in connection with the supervision of oil shale leases issued under the Prototype Oil Shale Leasing Program.

The purpose of this meeting is to review a Draft of the Revised Detailed Development Plan prepared by Rio Blanco Oil Shale Company for Oil Shale Lease Tract C-a in Rio Blanco County, Colorado, to receive progress reports from Interior officials, and to consider any other matters which have come before the Panel. The Panel will also receive a status report on Interior's plans for additional oil shale leasing.

The meeting is open to the public. It is expected that space will permit at least 100 persons to attend the meeting in addition to the panel members. Interested persons may make brief presentations to the Panel on Tuesday afternoon, January 13, or file written statements with the Chairman. Requests to speak to the Panel should be made to Mr. Henry O. Ash, Chariman, Office of the Oil Shale Environmental Advisory Panel, Department of the Interior, Room 690, Building 67, Denver Federal Center, Denver, Colorado 80225, telephone (303) 234-3275.

Further information concerning this meeting may be obtained from Mr. Ash's office. Minutes of the meeting will be available for public inspection 30 days after the meeting at the panel office.

Dated: December 23, 1980.

James W. Curlin,

Acting Assistant Secretary of the Interior.

[FR Doc. 80-40449 Filed 12-29-80; 8:45 am]

BILLING CODE 4310-10-M

INTERNATIONAL COMMUNICATION AGENCY

United States Advisory Commission on Public Diplomacy

The U.S. Advisory Commission on Public Diplomacy will meet on January 14, 1981 in Room 600—1750 Pennsylvania Ave., NW., Washington, D.C. from 9:15 a.m. to 4 p.m. The topic of discussion will be: Past Activities and Future Programs for the Commission.

Because space is limited please call Elizabeth Fahl, (202) 724–9243, if you are interested in attending the meeting.

Jane S. Grymes,

Management Analyst, Management Analysis/Regulations Staff, Associate Directorate for Management, International Communication Agency.

[FR Doc. 80-40441 Filed 12-29-80; 8:45 am]

BILLING CODE 8230-01-M

DEPARTMENT OF JUSTICE

Antitrust Division

Proposed Final Judgment in United States v. B.F. Goodrich Co. and Competitive Impact Statement Thereon

Notice is hereby given pursuant to the Antitrust Procedures and Panalties Act, 15, U.S.C. Sections 16(b)–(h), that a proposed final judgment and a competitive impact statement as set out below have been filed with the United States Disrict Court for the Northern District of California in Civil No. C–78–1785–WAI, *United States v. B.F. Goodrich Company.* The Complaint in this case alleged that B.F. Goodrich conspired to fix, raise, maintain and stabilize the retail and wholesale prices of passenger tires in the western United States in violation of Section 1 of the Sherman Act.

The proposed judgment prohibts B.F. Goodrich from having any agreement or understanding with any tire dealer to fix, raise, maintain or stabilize prices, discounts, or mark-ups for B.F. Goodrich tires. The defendant is also enjoined from entering into agreements or understandings with tire dealers which prohibit either tire dealers or B.F. Goodrich from advertising the price of tires. B.F. Goodrich Company is also forbidden from soliciting or encouraging any complaints by tire dealers concerning prices, disounts, or price-related advertisements regarding B.F. Goodrich tires, as well as from acting on any such complaints.

The judgment requires B.F. Goodrich to mail out copies of the judgment to its present dealers, and to take internal measures to insure compliance with the judgment and the antitrust laws.

Public comment is invited within the statutory 60-day comment period. Such comments and responses thereto will be published in the **Federal Register** and file with the Court. Comments should be directed to Anthony E. Desmond, Chief, San Francisco Field Office, Antitrust Division, Department of Justice 450 Golden Gate Avenue, Box 36046, San Francisco, California 94102.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

Bernard H. Meyers, Glenda R. Jermanovich, Shauna I. Marshall; Department of Justice, Antitrust Division, 450 Golden Gate Avenue, Room 16216C, Box 36046, San Francisco, CA 94102, Telephone: 415/556–6300

United States District Court for the Northern District of California

Civil No. C–78–1785 WAI

Stipulation

Filed: December 15, 1980

United States of America, Plaintiff, v. *B.F. Goodrich Company,* Defendant.

It is stipulated by and between the plaintiff, the United States of America, and the defendant, B.F. Goodrich Company, by their respective attorneys, that:

1. A Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of either party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act [15 U.S.C. § 16] and without further notice to any party or other proceedings, provided that plaintiff has not withdrawn its consent, which it may do at any time before the entry of the proposed Final Judgment by serving notice thereof on defendant and by filing said notice with the Court.

2. In the event plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatever and the making of this Stipulation shall be without prejudice to plaintiff and defendant in this or any other proceeding.

Dated: December 15, 1980.

For the plaintiff:

Sanford M. Litvack, *Assistant Attorney General Antitrust Division;* Joseph H. Widmar; Anthony E. Desmond, *Attorneys, Department of Justice;* Bernard H. Meyers; Glenda R. Jermanovich; Shauna I. Marshall, *Attorneys, Department of Justice.*

For defendant B.F. Goodrich Company: Jones, Day, Reavis & Pogue, Attorneys for Defendant B.F. Goodrich Company; By Gerald W. Palmer, Esq., and Harold G. Munter, Esq., Corporate Counsel, The B.F. Goodrich Company; Harold G. Munter, Esq.

United States District Court, Northern District of California

Civ. No. C–78–1785–WAI

Final Judgment

Filed: December 15, 1980.

United States of America, Plaintiff, v. *B.F. Goodrich Company,* Defendant.

Plaintiff, the United States of America, having filed its Complaint herein on August 8, 1978, and defendant, The B.F. Goodrich Company, having answered the Complaint and having appeared by its counsel, and both parties by their respective attorneys having consented to the making and entry of this Final Judgment without trial or adjudication of any issue of fact or law herein, and without this Final Judgment constituting evidence against or an admission by any party consenting hereto with respect to any such issue:

Now, therefore, before the taking of any testimony and without trial or adjudication of any issue of fact or law herein, and upon consent of the parties hereto, it is hereby

Ordered, adjudged and decreed, as follows:

I

This Court has jurisdiction over the subject matter of this action and of the parties hereto. The Complaint states claims upon which relief may be granted against the defendant under Section 1 of the Sherman Act (15 U.S.C. § 1).

II

As used in this Final Judgment:

(A) "Defendant" means defendant The B.F. Goodrich Company;

(B) "Person" means any individual, partnership, corporation, association, firm or any other business or legal entity;

(C) "Tires" means tires used on automobiles, recreational vehicles and/or light trucks, except for those tires actually delivered to and installed by original equipment manufacturers on new vehicles;

(D) "Dealer" or "tire dealer" shall mean any person who is in the business of selling tires; and

(E) "B.F. Goodrich brand tires" means tires on which appear the name "B.F. Goodrich," "BFG," "Goodrich," or the B.F. Goodrich pentagonal, or any other tires sold through the BFG Brand Replacement Sales organization, or successors thereto.

III

(A) This Final Judgment applies to the defendant and to each of its officers, directors, agents, employees, domestic subsidiaries, successors and assigns, and to all other persons in active concert or participation with any of them who shall have received actual notice of this Final Judgment by personal service or otherwise; provided, however, that nothing contained herein shall apply to any transaction solely between defendant and its officers, directors, employees, domestic subsidiaries, or any of them when acting in such capacity.

(B) The Defendant shall require, as a condition of the sale or other disposition of all, or substantially all, of the assets of the B.F. Goodrich Tire Group (formerly, the B.F. Goodrich Tire Division), or that subdivision of defendant (by whatever name that subdivision is known) responsible for producing and distributing B.F. Goodrich brand tires, that the acquiring party agree to be bound by the provisions of this Final Judgment. The acquiring party shall file with the Court, and serve upon the Plaintiff, its consent to be bound by this Final Judgment.

(C) This Final Judgment shall apply throughout the United States.

IV

Defendant is enjoined and restrained from:

(A) entering into, adhering to, maintaining, or enforcing any contract, agreement, combination or mutual understanding with any tire dealer:

(1) to fix, raise, maintain or stabilize the price, discount, markup or margin of profit at which B.F. Goodrich brand tires are sold, or offered for sale; and/or

(2) by which said dealer or defendant is not to advertise the price of B.F. Goodrich brand tires;

(B) encouraging or soliciting any complaints by any tire dealer regarding the pricing, discounting or price-related advertising of B.F. Goodrich brand tires by any other tire dealer; or

(C) taking any coercive or joint action with respect to any tire dealer because of any complaint or other communication by any other tire dealer or wholly-owned B.F. Goodrich tire outlet regarding the pricing, discounting or price-related advertising of B.F. Goodrich brand tires.

V

Defendant is enjoined and restrained from:

(A) suggesting or requiring that any tire dealer establish, adopt, advertise or adhere to any fixed, suggested or specified price, discount, markup or margin of profit on the sale of any B.F. Goodrich brand tires; provided, however, that nothing in this provision shall prohibit the defendant from unilaterally suggesting resale prices, discounts, markups or margins of profit for the sale of B.F. Goodrich brand tires on the conditions (a) that any such oral suggestion shall include a statement in substance that each dealer, and the defendant as well, is free to sell at whatever prices, discounts, markups or margins of profit such dealer or the defendant may unilaterally choose; (b) that any such written suggestion shall include a statement on each page of any such writing in substance that each dealer, and the defendant as well, is free to sell at whatever prices, discounts, markups or margins of profit such dealer or defendant may unilaterally choose; and (c) that no less frequently than once each year defendant notify its dealers that notwithstanding any such suggestion, each dealer, and the defendant as well, is free to sell at whatever prices, discounts, markups or margins of profit each may unilaterally choose;

(B) suggesting or requiring that any tire dealer not offer the tire dealer's own guarantee on any B.F. Goodrich brand tire; or

(C) coercing or attempting to coerce any tire dealer to change its price or terms for the sale of B.F. Goodrich brand tires.

VI

Nothing in this Final Judgment shall prohibit defendant from:

(A) Proposing to any B.F. Goodrich dealer or prospective B.F. Goodrich dealer that it join in any joint advertisement to promote the sale of B.F. Goodrich brand tires, or agreeing with any such dealer to participate in any such joint advertisement or publishing or causing to be published any such joint advertisement; provided, however, that any such actual or proposed joint advertisement shall include a statement to the effect that any advertised prices are those offered by defendant and are not necessarily those offered by participating B.F. Goodrich dealers;

(B) Engaging in negotiations or communications with any person for the purpose of a proposed or actual bona fide sale by defendant of B.F. Goodrich brand tires; or

(C) formulating or submitting with any B.F. Goodrich dealer a bona fide joint bid or quotation, made in writing and in response to a formal invitation, for the sale of B.F. Goodrich brand tires to any public or private entity where performance of any contract entered into as a result of that bid or quotation is to be carried out, in whole or in part, through the sale or delivery of B.F. Goodrich brand tires by one or more B.F. Goodrich dealers.

VII

Defendant is ordered and directed:

(A) within 60 days after entry of this Final Judgment to provide a copy of this Final Judgment to

(1) each of defendant's officers and directors with responsibility for selling, pricing or advertising B.F. Goodrich brand tires;

(2) each of defendant's employees with responsibility for selling, pricing, or advertising B.F. Goodrich brand tires to dealers; and

(3) each of defendant's employees having managerial responsibility for selling, pricing or advertising B.F. Goodrich brand tires from B.F. Goodrich retail outlets; and to obtain and retain for 10 years documents sufficient to show receipt thereof;

(B) for a period of 10 years from the date of entry of this Final Judgment, to provide a copy of this Final Judgment to each of its future officers, directors and employees in the positions described in Paragraph A above and to obtain and retain for 10 years documents sufficient to show receipt thereof;

(C) to file with this Court and serve upon the plaintiff within 90 days after the date of entry of this Final Judgment an affidavit as to the fact and manner of compliance with subsections A and D of this Section VII;

(D) within 60 days after entry of this Final Judgment to provide a copy of this Final Judgment to all of defendant's present dealers, and within the ensuing four years, to provide a copy of this Final Judgment to each new franchised dealer;

(E) during the period in which this Final Judgment is in effect, to advise each of its officers and employees in positions described in paragraph (A) above of its and their obligations under this Final Judgment. Defendant shall maintain a program to insure compliance with this Final Judgment, which program shall include at a minimum the following with respect to each of such persons:

(1) the annual distribution to them of this Final Judgment;

(2) the annual submission to them of a written directive setting forth the defendant's antitrust compliance program, with such directive to include (a) an admonition that non-compliance with such program and this Final Judgment will result in appropriate disciplinary action determined by the defendant and which may include dismissal, and (b) advice that the defendant's legal staff is available at all reasonable times to confer with such persons regarding any compliance questions or problems;

(3) the imposition of an annual requirement that each of them sign and submit to the defendant a certificate in substantially the following form:

The undersigned hereby acknowledges that he/she (1) has received a copy of the Final Judgment and a written directive setting forth the Company policy regarding compliance with the antitrust laws and with such Final Judgment, (2) has read and understands such Final Judgment and directive, (3) has been advised and understands that non-compliance with such policy and Final Judgment will result in appropriate disciplinary measures determined by the Company and which may include dismissal, and (4) has been advised and understands that non-compliance with the Final Judgment may also result in conviction for contempt of court and imprisonment and/or fine; and

(4) the holding of one or more meetings with them to review the terms of this Final Judgment and the obligations it imposes, with such meetings to be arranged and conducted so that each of them attends at least one such meeting with approximately each twelve-month period.

VIII

For the purpose of determining or securing compliance with this Final Judgment, and subject to any legally recognized privilege, from time to time:

(A) duly authorized representatives of the Department of Justice shall, upon written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to defendant made to its principal office, be permitted:

(1) access during the office hours of defendant to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and other records and documents, in the possession or under the control of defendant, which may have counsel present, relating to any matters contained in this Final Judgment; and

(2) subject to the reasonable convenience of defendant and without restraint or interference from it, to interview officers, directors, agents, partners, members or employees of defendant, who may have counsel present, regarding any such matters;

(B) defendant, upon the written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division, shall submit such reports in writing, under oath if requested, with respect to any of the matters contained in this Final Judgment as may from time to time be requested.

No information or documents obtained by the means provided in this Section VIII shall be divulged by any representative of the Department of Justice to any person other than a duly authorized representative of the Executive Branch of the United States, except in the course of legal proceedings to which

the United States is a party, or for the purpose of securing compliance with this Final Judgment, or as otherwise permitted by law;

(C) if at the time information or documents are furnished by the defendant to plaintiff, the defendant represents and identifies in writing the material in any such information or documents to which a claim for protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and the defendant marks each pertinent page of such material, "Subject to Claim of Protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure," then ten (10) days' notice shall be given by plaintiff to the defendant prior to divulging such material in any legal proceeding (other than a grand jury proceeding) to which the defendant is not a party.

IX

Jurisdiction is retained by this Court for the purpose of enabling either of the parties to this Final Judgment to apply to this Court at any time for such further orders or directions as may be necessary or appropriate for the construction or carrying out of this Final Judgment, for the modification of any of the provisions hereof, for the enforcement of compliance therewith, and for the punishment of violation thereof.

X

The provisions of this Final Judgment shall be in effect for a period of not longer than ten (10) years from the date of entry of this Final Judgment.

XI

Entry of this Final Judgment is in the public interest.

Dated: ———————.

———————,

United States District Judge.

Bernard H. Meyers, Glenda R. Jermanovich, Shauna I. Marshall, Antitrust Division, U.S. Department of Justice, 450 Golden Gate Avenue, Box 36046, San Francisco, CA 94102, Telephone: 415/556-6300.

United States District Court, Northern District of California

Civ. No. C-78-1785-WAI

Competitive Impact Statement

Filed: December 15, 1980.

United States of America, Plaintiff, v. B.F. Goodrich Company, Defendant.

Pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act [15 U.S.C. § 16(b)] the United States hereby submits this Competitive Impact Statement relating to the proposed Consent Judgment submitted for entry in this civil antitrust proceeding.

I. Nature of Proceeding

On August 8, 1978 the United States Department of Justice filed a civil complaint against the B.F. Goodrich Company pursuant to Section 4 of the Sherman Act [15 U.S.C. § 4], alleging a conspiracy to fix, raise, maintain and stabilize the retail and wholesale prices of B.F. Goodrich tires sold in the western United States. The Complaint asks the Court to find that the defendant has violated Section 1 of the Sherman Act [15 U.S.C. § 1] and further requests the Court to enjoin the continuance of the conspiracy.

Entry by the Court of the proposed Consent Judgment will terminate this action. The Court will retain jurisdiction over this matter for such further proceedings as may be required to interpret, modify or enforce the proposed judgment or to punish violations thereof.

II. Description of Practices Involved in the Alleged Violation

The defendant, the B.F. Goodrich Company, manufactures tires and sells them to, among others, independent wholesalers and retailers. B.F. Goodrich also sells tires to the public through its company-owned stores and leased department operations. Because of this distribution system, B.F. Goodrich and independent wholesale distributors are actual or potential competitors for the sale of B.F. Goodrich tires to independent retailers. Similarly, by selling B.F. Goodrich tires to the public through its company-owned stores and leased department operations, B.F. Goodrich competes with independent retailers for the sale of B.F. Goodrich tires to the public.

The Complaint in the case alleges that beginning at least as early as 1972 and continuing through at least the date of the commencement of the suit (August, 1978) the defendant met and communicated with independent wholesalers and retailers in order to fix, raise, maintain and stabilize retail and wholesale prices of B.F. Goodrich tires. The Complaint further alleged that 1) the prices of B.F. Goodrich brand passenger tires have been fixed, raised, maintained and stabilized at artificial and non-competitive levels; 2) purchasers of B.F. Goodrich tires have been deprived of the benefits of free and open competition in the marketing of B.F. Goodrich tires; and 3) competition between and among B.F. Goodrich and the conspirators in the sale of B.F. Goodrich tires has been reduced and restrained.

III. Explanation of the Proposed Consent Judgment

The United States and defendant, the B.F. Goodrich Company, have agreed, in a stipulation, that the consent judgment may be entered by the Court at any time after compliance with the Antitrust Procedures and Penalties Act. The proposed judgment provides that there has been no admission by either party with respect to any issue of fact or law. Under the provisions of Section 2(e) of the Antitrust Procedures and Penalties Act, entry of the consent judgment by the Court is conditioned upon a determination of the Court that the proposed judgment is in the public interest.

A. *Prohibited Conduct*

The proposed judgment will prohibit the defendant for a period of 10 years from the date of the Final Judgment from entering into or adhering to any agreement, combination or mutual understanding with any tire dealer to fix, raise, maintain or stabilize the price, discount, mark-up or margin of profit at which B.F. Goodrich tires are sold. The defendant is also enjoined from entering into any agreement or understanding with tire dealers which prohibits either tire dealers or B.F. Goodrich from advertising the price of B.F. Goodrich tires. B.F. Goodrich is also forbidden from encouraging or soliciting any complaints by any tire dealer with respect to the pricing, discounting or price-related advertising of any other tire dealer (including B.F. Goodrich's own outlets). Nor may B.F. Goodrich take any coercive or joint action against any tire dealer due to any complaint or any communication from any other tire dealer (including B.F. Goodrich's own outlets).

B.F. Goodrich may only suggest resale prices to tire dealers under the conditions that in so doing it state to each dealer that the prices are only being suggested by B.F. Goodrich and that B.F. Goodrich and each dealer are free to sell at whatever price, discount, markup or margin of profit they may unilaterally choose. B.F. Goodrich is also prohibited from suggesting or requiring that any tire dealer not offer the dealer's own guarantee on B.F. Goodrich tires, and from coercing or attempting to coerce any tire dealer to change its prices or terms for the sale of B.F. Goodrich tires. The proposed judgment covers all B.F. Goodrich tires used on passenger cars, recreational vehicles, or light trucks. It does not apply to B.F. Goodrich Brand tires sold to and actually used by original equipment manufacturers. The proposed judgment also covers B.F. Goodrich tires bearing the name B.F. Goodrich (or variations thereof), and tires sold through the B.F. Goodrich Brand Replacement Sales organization (or successors thereto). Although the complaint only alleged violations in the six western states, the proposed judgment applies throughout the United States.

The proposed judgment applies to the defendant, its officers, directors, employees, agents, successors and assigns. Before the defendant may sell all or substantially all of its Tire Group assets, the acquiring party must agree to be bound by the judgment.

B. *Other Provisions*

The defendant is ordered for a period of 10 years to distribute a copy of the judgment to each of its employees, officers and directors with responsibility for the selling, pricing and advertising of B.F. Goodrich tires at the wholesale or retail level. The defendant must also provide a copy of the judgment to all of its present dealers, and for a period of 4 years, to each new franchised dealer. The defendant must distribute the initial copy to employees, directors, officers and dealers within 60 days after entry of the final judgment. An affidavit stating the manner of compliance must be filed by defendant within 90 days after entry of the judgment.

In addition to the annual distribution of the judgment, B.F. Goodrich must conduct a compliance program. The program shall require the defendant to take affirmative steps, including the holding of annual meetings, to advise each of the officers and other employees with any responsibility for the selling, pricing and advertising of B.F. Goodrich tires of their obligations under the judgment.

The United States Department of Justice is given access under the proposed judgment to the files and records of B.F. Goodrich, to examine such records for compliance or non-compliance with the judgment. The

Department is also granted access to interview employees of the defendant to determine whether the defendant is complying with the judgment.

C. *Effect of the Proposed Judgment on Competition*

The relief encompassed in the proposed consent judgment is designed to prevent a recurrence of any of the activities alleged in the complaint. The prohibitory language of the judgment should ensure that wholesale and retail prices of B.F. Goodrich tires shall be arrived at independently by both the defendant and individual tire dealers. The judgment contains sufficient record-keeping requirements and access to defendant's records to allow the Department to adequately monitor defendant's activities in the future.

Accordingly, it is the opinion of the Department of Justice that the proposed judgment is fully adequate to prevent future antitrust violations by the defendant. It is also the view of the Department that disposition of the case without additional litigation is appropriate in view of the fact that the proposed judgment includes the form and scope of relief equal to that which might be obtained after a full airing of the issues.

IV. Alternatives to the Proposed Consent Judgment

The alternative to the proposed Final Judgment considered by the Antitrust Division was a full trial on the merits and on relief. The Division considers the proposed Judgment to be of sufficient scope and effectiveness to make a trial unnecessary, since it provides appropriate relief against the violations alleged in the Complaint.

In line with the Antitrust Division's policy in existence at the time the case was filed, the Government originally sought a perpetual decree. Thereafter, the Division's policy in this regard changed to insistence on a term of 10 years, the term specified in the decree.

V. Remedies Available to Potential Private Plaintiffs

Section 4 of the Clayton Act [15 U.S.C. § 15] provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages such person has suffered, as well as costs and reasonable attorneys' fees. Following the filing of the Government's Complaint in this action, several lawsuits were brought on behalf of various classes of persons allegedly injured as a result of the violation of the antitrust laws alleged in the Government's suit. These lawsuits are now in the discovery phase and are pending before this Court. (*In Re B.F. Goodrich Antitrust Litigation*, MDL–386 including: *State of California* v. *B.F. Goodrich Co.*, Civil No. C–78–2263; *State of Arizona* v. *B.F. Goodrich Co.*, Civil No. 79–1841; *State of Colorado* v. *B.F. Goodrich*, Civil No. C–80–0252). These plaintiffs and any potential plaintiff will retain the same rights to seek monetary and equitable remedies that they would have had if the proposed judgment had not been entered. However, pursuant to Section 5(a) of the Clayton Act [15 U.S.C. § 16(a)], this judgment has no *prima facie* effect in the lawsuits which have been brought or may be brought against defendant B. F. Goodrich.

VI. Procedures Available for Modification of the Proposed Judgment

The proposed consent judgment is subject to a stipulation by and between the United States and the defendant which provides that the United States may withdraw its consent to the proposed judgment at any time before the Court has found that entry of the proposed judgment is in the public interest. By its terms, the proposed consent judgment provides for the Court's retention of jurisdiction of this action in order, among other reasons, to permit either of the parties thereto to apply to the Court for such orders as may be necessary or appropriate for the modification of the Final Judgment.

As provided by Section 2(b) of the Antitrust Procedures and Penalties Act, any persons wishing to comment on the proposed consent judgment may, for the sixty (60) day period prior to the effective date of the judgment, submit written comments to: Anthony E. Desmond, Chief, San Francisco Field Office, Antitrust Division, U.S. Department of Justice, 450 Golden Gate Avenue, Box 36046, San Francisco, CA 94102.

The comments, and the responses thereto, will be filed with the Court and published in the **Federal Register**. The Department of Justice will evaluate all such comments and determine whether there are any reasons for withdrawal of its consent to the judgment.

VII. Determinative Documents

Since there are no materials or documents which were determinative in formulating a proposal for the consent judgment, none are being filed by the plaintiff pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act.

Glenda R. Jermanovich,

Shauna I. Marshall,

Attorneys, Department of Justice.

[FR Doc. 80–40466 Filed 12–29–80; 8:45 am]

BILLING CODE 4410–01–M

Proposed Final Judgment in United States v. Hercules Incorporated and Competitive Impact Statement Thereon

Notice is hereby given pursuant to the Antitrust Procedures and penalties Act, 15 U.S.C. § 16(b)-(h), that on December 16, 1980, a proposed Final Judgment and a Competitive Impact Statement ("CIS") as set out below have been filed with the United States District Court for the District of New Jersey in *United States* v. *Hercules Incorporated*, Civil Action No. 80–136. The Complaint in this case alleges that Hercules violated the Sherman Act by monopolizing the U.S. industrial nitrocellulose market through exchanging price information with foreign competitors.

The proposed Judgment enjoins the defendant from engaging in or renewing any of the alleged illegal conduct and requires the defendant to refrain from exchanging price information with its competitors.

The CIS describes the terms of the Judgment and the background of the action and concludes that the proposed Judgment provides appropriate relief against the violation alleged in the Complaint.

Public comment is invited within the statutory 60-day comment period. Such comments, and response thereto, will be published in the *Federal Register* and filed with the Court. Comments should be directed to Kevin R. Sullivan, attorney, Foreign Commerce Section, Antitrust Division, Department of Justice, Washington, D.C. 20530.

Joseph H. Widmar,

Director of Operations.

United States District Court, District of New Jersey

Hon. Dickinson R. Debevoise

Civil Action No. 80–136

Filed: December 16, 1980.
Entered: ————.

United States of America, Plaintiff, v. *Hercules Incorporated*, Defendant.

Stipulation

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. A Final Judgment in the form attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16), and without further notice to any party or other proceedings, provided that plaintiff has not withdrawn its consent, which it may do at any time before the entry of the proposed Final Judgment by serving notice thereof on defendant and by filing that notice with the Court.

2. In the event plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatever and the making of this Stipulation shall be without prejudice to any party in this or any other proceding. Dates: December 16, 1980

For the plaintiff:

Sanford M. Litvak, *assistant Attorney General*; Joseph H. Widmar, *Director of Operations*; Charles F. B. McAleer, *Special Assistent for Judgment Negotiations*; Charles S. Stark; Kevin R. Sullivan; Jane C. Luxton; James J. Egan.

For the defendant:

Carpenter, Bennett & Morrissey, By: Thomas L. Morrissey, *A Member of the Firm*; Foley, Lardner, Hollabaugh & Jacobs, By: Ephraim Jacobs, *A Member of the Firm.*

United States District Court, District of New Jersey

Hon. Dickinson R. Debevoise
Civil Action No. 80–136

Final Judgment

Filed: December 16, 1980.

United States of America, Plaintiff, v. *Hercules Incorporated*, Defendant.

Plaintiff, United States of America, having filed its complaint herein on January 11, 1980, and plaintiff and defendant, Hercules Incorporated ("Hercules"), by their respective

attorneys, having consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law herein and without this Final Judgment's constituting any evidence against or an admission by any party with respect to any such issue;

Now, therefore, before the taking of any testimony and without trial or adjudication of any issue of fact or law herein and upon consent of the parties hereto, it is hereby,

Ordered, adjudged, and decreed as follows:

I

This Court has jurisdiction of the subject matter of this action and of the parties consenting hereto. The complaint states a claim upon which relief may be granted against the defendant under Section 2 of the Sherman Act (15 U.S.C. § 2).

II

As used in this Final Judgment, the term:

(A) "Person" means any individual, corporation, partnership, firm, association, or other business or legal entity;

(B) "Industrial nitrocellulose" means a dry white amorphous synthetic chemical produced by the chemical action of nitric acid on cellulose. Commonly made from the cellulose found in wood pulp or cotton linters, industrial nitrocellulose is classified by its uses and has a nitrogen content between 10.8 percent and 12.2 percent;

(C) "Nitrocellulose producer" means those persons engaged in the business of manufacturing nitrocellulose;

(D) "Distributor" means (so long as they serve in that capacity) any person in the U.S. who has been publicly designated as an agent or distributor, or whose designation as such is otherwise made known to the defendant by the producer, distributor, or agent;

(E) "Subsidiary" shall mean a company of which the parent owns more than 50% of capital stock; and

(F) "Affiliate" shall mean an entity of which the defendant has more than 50% non-stock ownership interest or has less than 50% interest and exercises or has the right to exercise control.

III

This Final Judgment applies to the defendant, Hercules, and to its officers, directors, agents, employees, subsidiaries, affiliates, successors, and assigns, and to all other persons in active concert or participation with any of them who shall have received actual notice of this Final Judgment by personal service or otherwise.

IV

Subject to the exceptions provided in Articles V and VI herein, defendant Hercules is enjoined and restrained from:

(A) Furnishing to or requesting from any other industrial nitrocellulose producer, or distributor in the U.S. for such producer:

1. information concerning the prices, terms or other conditions of sale which any industrial nitrocellulose producer intends to charge or is considering submitting to any actual or prospective purchaser of industrial nitrocellulose; provided that this prohibition shall not apply to information disseminated in the form of a press release or public announcement, or to written notification to all or to a class of customers or prospective customers; and

2. information concerning industrial nitrocellulose production capacity, excess production capacity, or production available for export; provided that this prohibition shall not apply to information disseminated in the form of a press release or public announcement, or to written notification to all or to a class of customers or prospective customers; and

(B) Acting as a distributor or agent in the United States for industrial nitrocellulose produced by any other industrial nitrocellulose producer.

V

Nothing in this Final Judgment shall be applicable to any communications with any other industrial nitrocellulose producer, or distributor in the United States for such producer, concerning price, other terms and conditions of sale, or production available for sale, in connection with a bona fide potential purchase or sale of industrial nitrocellulose between Hercules and such other industrial nitrocellulose producer, or distributor in the United States for such producer. The parties agree that, while it is not possible to anticipate all bona fide situations that might lead to buyer-seller relations between producers in the purchase or sale of industrial nitrocellulose, usually such relations are the result of: temporary inability of a producer to meet the demands of a growing market; shortage or cessation of supply capabilities; interruption of manufacturing or distribution capabilities because of explosion, fire, accident, strike or other work stoppage; and the desire or need of a producer to obtain a type or grade of industrial nitrocellulose it does not manufacture.

VI

Nothing in this Final Judgment shall be applicable to the furnishing or requesting of information described in Article IV hereof in connection with a possible acquisition, sale or licensing of assets, business or stock, or a joint venture; provided that in such circumstances, defendant is ordered and directed, prior to the furnishing or requesting of such information, to advise plaintiff of the nature of the transaction and of the information to be furnished or requested.

VII

Defendant is ordered and directed to:

(A) Furnish a copy of this Final Judgment to each of its officers, directors, sales and service managers concerned with the production or sale of industrial nitrocellulose within thirty (30) days of entry of this Final Judgment;

(B) Furnish a copy of this Final Judgment to each successor to those persons described in Paragraph VII (A) hereof within sixty (60) days after each such successor is employed;

(C) Attach to each a copy of this Final Judgment furnished pursuant to Subparagraph VII (A) and (B) hereof a statement advising each person of his or her obligations; such statement shall include (1) an instruction that non-compliance with this Final Judgment will result in appropriate disciplinary action determined by the defendant which may include dismissal, and (2) advice that the defendant's legal advisers are available at all reasonable times to confer with such persons regarding any compliance question or problem;

(D) File with this Court and serve upon the plaintiff within ninety (90) days after the date of entry of this Final Judgment and annually thereafter on the anniversary of this Final Judgment an affidavit as to the fact and mammer of its compliance with Paragraph VII hereof; and

(E) Serve upon the plaintiff annually on the anniversary of this Final Judgment the following information concerning bona fide purchases and sales of industrial nitrocellulose between Hercules and any other industrial nitrocellulose producer pursuant to Article V hereof: indentity of purchaser and seller; amount of industrial nitrocellulose purchased or sold; and price of nitrocellulose purchased or sold. If Hercules is the purchaser, the information so furnished shall include a statement of the reasons for such purchase.

VIII

For the purpose of detemining or securing compliance with this Final Judgment, and subject to any legally recognized privilege, from time to time:

(A) Duly authorized representatives of the Department of Justice shall, upon written request of the Attorney General or of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to defendant made to its principal office, be permitted:

(1) Access during regular office hours of defendant to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of defendant, who may have counsel present; and

(2) Subject to the reasonable convenience of defendant and without restraint or interference from it, to interview officers, employees, and agents of defendants, who may have counsel present;

(B) Upon the written request of the Attorney General or of the Assistant Attorney General in charge of the Antitrust Division made to defendant's principal office, defendant shall submit such written reports, under oath if requested, with respect to any of the matters contained in this Final Judgment as may be requested;

(C) No information or documents obtained in the means provided in this Section VIII shall be divulged by an representative of the Department of Justice to any person other than a duly authorized representative of the Executive Branch of the United States, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law; and

(D) If at the time information or documents are furnished by defendant to plaintiff by the means provided in this Section VIII, and defendant at the time represents and identifies in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and said defendant marks each pertinent page of such material, "Subject to

claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure," then ten (10) days notice shall be given by plaintiff to defendant prior to divulging such material in any legal proceedings (other than a grand jury proceeding) to which defendant is not a party.

IX

Jurisdiction is retained by this Court for the purpose of enabling any of the parties to this Final Judgment to apply to this Court at any time for such further orders or directions as may be necessary or appropriate for the construction or the carrying out of this Final Judgment, for the modification of any of the provisions hereof, for the enforcement of compliance herewith, or for the punishment of violation hereof.

X

Defendant shall require, as a condition of the sale or disposition of all, or substantially all, of the assets used by it in its industrial nitrocellulose business, that the acquiring party agree to be bound by the provisions of this Final Judgment, and that such agreement be filed with the Court.

XI

The term of this Final Judgment shall be ten (10) years from the date of entry.

XII

Entry of this Final Judgment is in the public interest.

Dated: _____

_____

United States District Judge.

United States District Court, District of New Jersey

Civil Action No.

Filed: December 16, 1980.

United States of America, plaintiff, v. *Hercules Incorporated*, Defendant.

Competitive Impact Statement

Pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act ("APPA"), 15 U.S.C. §§ 16(b)–(h), the United States of America submits this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I

The Nature and Purpose of the Proceeding

On January 11, 1980, the Department of Justice filed a civil antitrust complaint under Section 4 of the Sherman Act (15 U.S.C. § 4), alleging that the defendant violated Section 2 of the Sherman Act (15 U.S.C. § 2). The Complaint alleged that the defendant has attempted to monopolize and has monopolized the production and sale of industrial nitrocellulose in the United States.

The Complaint sought equitable relief to prevent continuing violations of the Sherman Act by Hercules, Inc. ("Hercules"), which have had the effect of restraining actual and potential competition in the production and sale of industrial nitrocellulose in the United States.

II

Description of the Practices Giving Rise to the Alleged Violation of the Antitrust Laws

Industrial nitrocellulose is used in combination with other chemicals as a bonding agent in various coatings. Applied in solutions, industrial nitrocellulose forms hard, smooth finishes known for their short drying time and attractive appearance. Industrial nitrocellulose is widely used in wood finishes, lacquers, paints, primers, textile and paper coatings, book bindings, printing inks, cellophane film, coatings and fingernail polishes.

Before July 1977, Hercules and E. I. duPont de Nemours and Company, Inc. ("duPont") produced and sold all of the industrial nitrocellulose used in the United States. In 1977 approximately 64 million pounds of industrial nitrocellulose were sold in the United States. Hercules' sales accounted for approximately 65 percent of 1977 U.S. sales, and duPont's sales accounted for approximately 35 percent of the U.S. total.

On July 19, 1977, duPont announced its decision to discontinue the production and sale of industrial nitrocellulose at the end of 1977. This decision left Hercules as the sole domestic nitrocellulose producer.

Shortly after the duPont announcement, foreign industrial nitrocellulose producers, especially those based in Europe, began to consider selling this product in the United States in competition with Hercules. For its part, Hercules did not have sufficient capacity to supply the entire U.S. demand, and was considering expanding its production.

Hercules' first effort, before it decided whether to expand, was to seek to ensure sufficient supplies of industrial nitrocellulose at reasonable prices for the short term. Hercules proposed to European producers that it act as the importer for all European producers interested in selling industrial nitrocellulose in the United States. After that effort was abandoned, Hercules continued to have meetings and other communications with foreign producers, the purpose and effect of which were to control the price of industrial nitrocellulose in the United States. During those communications, present prices and future price intentions were exchanged. In the last quarter of 1977 and throughout 1978, the dry weight price of substantially all the industrial nitrocellulose sold by Hercules, Societe Nationale des Poudres et Explosifs ("SNPE"), and Wolff Walsrode A.G. ("Wolff") was stabilized, exclusive of drum and duty costs.

In 1978, Hercules' sales accounted for more than 75 percent of the industrial nitrocellulose sold in the United States. The balance purchased in the United States in 1978 was produced and sold by foregin manufacturers in Europe and Japan. In that year, Hercules announced a plan to expand its industrial nitrocellulose plant capacity by 30 million pounds, by mid-1980, enough to enable Hercules to more than satisfy the entire American demand for industrial nitrocellulose.

The Complaint alleges that Hercules' actions have had the following effects, among others: (a) the defendant has monopolized and continues to monopolize the industrial nitrocellulose market in the United States; (b) actual and potential competition in the production and sale of industrial nitrocellulose in the United States has been restrained; and (c) purchasers of industrial nitrocellulose have been denied the benefits of a free and competitive market.

III

A. Explanation of the Proposed Final Judgment

The United States and the defendant have stipulated that the Court may enter the proposed Final Judgment after compliance with the APPA, 15 U.S.C. § 16(b)–(h). The proposed Final Judgment provides that its entry does not constitute any evidence against or an admisson by any party with respect to any issue of fact or law. Under the provisions of Section 2(e) of the APPA, the proposed Final Judgment may not be entered until the Court determines that entry is in the public interest.

1. Prohibited Conduct

Paragraph IV(A) of the proposed Final Judgment prohibits the defendant from furnishing to or requesting from any other nitrocellulose producer, or the distributor in the United States for such producer, information concerning the prices, terms, or other conditions of sale which any nitrocellulose producer intends to charge, or is considering submitting to any actual or prospective purchaser of industrial nitrocellulose, and from furnishing to or requesting from such producer and distributor for such producer, any information concerning industrial nitrocellulose production capacity, excess production capacity, or production available for export. This Paragraph does allow price and capacity information to be disseminated to the public in the form of a press release, public announcement, or written notification to all or to a class of customers.

Paragraph IV(B) enjoins Herrcules from acting as a distributor or agent for industrial nitrocellulose produced by any other nitrocellulose producers.

Paragraph V provides that nothing in the proposed Final Judgment shall be applicable to any discussions of price or other terms and conditions of sale offered by Hercules to any other nitrocellulose producer or offered by any other nitrocellulose producer to Hercules in connection with a *bona fide* purchase or sale of industrial nitrocellulose between Hercules and such other nitrocellulose producer. *Bona fide* situations include those which are the result of temporary inability of a producer to meet the demand of a growing market, shortage or cessation of supply capabilities, interruption of manufacturing or distribution capabilities because of explosion, fire, accident, strike, or other work stoppage; or because of the desire or need of a producer to obtain a type of industrial nitrocellulose it does not manufacture.

Paragraph VI provides that the Final Judgment is not applicable to information furnished or requested in connection with a possible acquisition, sale or licensing situation, provided that Hercules is required to advise the Government of the nature of

any such transaction before furnishing or requesting such information.

2. Affirmative Obligations

The proposed Final Judgment (Paragraph VII) requires that the defendant furnish a copy of the Final Judgment to each of its officers, directors, sales managers, and to each successor of those persons within thirty (30) days after each successor is employed, together with a statement advising each person of his or her obligations under the Final Judgment, of the possible disciplinary actions for non-compliance, and of the availability of advice from the company's legal advisers. Paragraph VI also requires the defendant to serve on the plaintiff within ninety (90) days after entry of the Final Judgment, and annually therafter, an affidavit as to the fact and manner of its compliance with Paragraph VII. Paragraph VII requires the defendant to serve plaintiff with certain information concerning *bona fide* purchases and sales of industrial nitrocellulose, including the identity of the purchaser and the seller, the amount of industrial nitrocellulose involved, the price, and, if Hercules is the purchaser, a statement of the reason for the purchase.

Section VIII of the Final Judgment will provide the Justice Department with access, upon reasonable notice, to Hercules' records and personnel in order to determine Hercules' compliance with the Judgment. Paragraph X will require any purchaser of all or substantially all the assets used by Hercules in its nitrocellulose business to enter an agreement to be bound by the provisions of the Final Judgment, and to file that agreement with the Court.

3. Scope of the Proposed Judgment

The proposed Final Judgment will remain in effect for a period of ten (10) years from the date of entry. It applies to the defendant Hercules and to all other persons in active concert or participation with any of them who shall have received actual notice of the Final Judgment by personal service or otherwise.

4. Effect of the Proposed Judgment on Competition

The relief in the proposed Final Judgment is designed to prevent any recurrence of the activities alleged in the Complaint. The prohibitive language of the Judgment is designed to ensure that Hercules will act independently in determining prices, terms and conditions at which it will sell or offer to sell industrial nitrocellulose. It will also prevent Hercules from controlling the price or distribution in the United States of foreign-produced industrial nitrocellulose. The affirmative obligations are designed to ensure that Hercules' employees are aware of their obligations under the decree in order to avoid a repetition of the kinds of behavior that occurred.

The Department of Justice believes that the proposed Final Judgment contains adequate provisions to prevent further violations by the defendant of the type of activities upon which the Complaint is based. The Department believes that disposition of the lawsuit without further litigation is appropriate because the proposed Judgment provides all the relief which the United States sought in its Complaint, and the additional expense of litigation would not result in additional public benefit.

IV

Procedures Available to Potential Private Litigants

Section 4 of the Clayton Act (15 U.S.C. § 15) provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages suffered, as well as costs and reasonable attorneys fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of such actions. Under the provisions of Section 5(a) of the Clayton Act (15 U.S.C. § 16(a)), the Judgment has no *prima facie* effect in any subsequent lawsuits that may be brought against this defendant.

V

Procedures Available for Modification of the Proposed Judgment

As provided by the Antitrust Procedures and Penalties Act, any person believing that the proposed Final Judgment should be modified may submit written comments to Kevin R. Sullivan, Antitrust Division, United States Department of Justice, Washington, D.C. 20530 within the 60-day period provided by the Act. These comments, and the Department's responses, will be filed with the Court and published in the Federal Register. All comments will be given due consideration by the Department of Justice, which remains free to withdraw its consent to the proposed Judgment at any time prior to entry. The Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for its modification, interpretation or enforcement.

VI

Alternatives to the Proposed Final Judgment

The Department considers the substantive language of the Judgment to be of sufficient scope and effectiveness to make litigation on relief unnecessary, as the Judgment provides all relief which reasonably could have been expected after trial.

The Division considered, but did not propose, relief which would include divestiture of part of Hercules' industrial nitrocellulose production capacity. This possibility was not prayed for in the Complaint and was not requestd from the defendant because it did not seem warranted by the facts, and because Hercules' single plant production capacity could not practicably be divided.

VII

Determinative Materials and Documents

No materials or documents were considered determinative by the United States in formulating the proposed Final Judgment. Therefore, none are being filed pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(h).

Kevin R. Sullivan,

Attorney, United States Department of Justice.

Jane C. Luxton,

Attorney, United States Department of Justice.

[FR Doc. 80-40467 Filed 12-29-80; 8:45 am]

BILLING CODE 4410-01-M

Drug Enforcement Administration

Quotas for Controlled Substances in Schedules I and II

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of Established 1981 Aggregate Production Quotas.

SUMMARY: This notice estalishes 1981 aggregate production quotas for tetrahydrocannabinols, a Schedule I substance, and dextropropoxyphene and pethidine intermediate-A, Schedule II substances, as required under the Controlled Substances Act of 1970.

EFFECTIVE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: Section 306 of the Controlled substances Act (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for all controlled substances in Schedules I and II each year. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration in accordance with § 0.100 of Title 28 of the Code of Federal Regulations.

On November 7, 1980, a notice of the proposed 1981 aggregate production quotas for tetrahydrocannabinols, dextropropoxyphene, and pethidine intermediate-A was published in the Federal Register (45 FR 74092). All interested parties were invited to comment on or object to these proposed aggregate production quotas on or before December 7, 1980.

One comment was received from Eli Lilly and Company of Indianapolis, Indiana, concerning dextropropoxyphene. Lilly has expressed concern that the proposed 1981 aggregate production quota for this substance will be insufficient to meet total U.S. medical needs. Because of the uncertainty attendant to the control of dextropropoxyphene in Schedule II, Lilly has requested that comments be continued to be considered by DEA after the issuance of the 1981 manufacturing

quotas to the companies who have applied for them. DEA will take into consideration any such comments received after the issuance of these quotas. However, unless extraordinary events require otherwise, full consideration of them will be deferred until early 1981, when the quotas for all Schedule II substances are reviewed and, where necessary, revised. No other comments and no requests for a hearing relative to any of the substances involved were received. In accordance with § 1303.11(c) of Title 21 of the Code of Federal Regulations, the Administrator of the Drug Enforcement Administration has determined that no hearing relative to the above mentioned comment is necessary at this time.

Therefore, under the authority vested in the Attorney General by Section 306 of the Controlled Substances Act of 1970 (21 U.S.C. 826), and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations, the Administrator of the Drug Enforcement Administration hereby orders that the 1981 aggregate production quotas for dextropropoxyphene and pethidine intermediate-A, expressed as anhydrous base, and tetrahydrocannabinols be established as follows:

Controlled substance	1981 aggregate production quota (grams)
Tetrahydrocannabinols (Schedule I)	20,000
Dextropropoxyphene (Schedule II)	44,798,000
Pethidine Intermediate-A (Schedule II)	6,877,000

DEA will review the above established quotas early in 1981 to take into consideration actual 1980 sales and actual December 31, 1980 inventories, as well as other information which might be available to DEA at that time.

Dated: December 22, 1980.

Peter B. Bensinger,

Administrator, Drug Enforcement Administration.

[FR Doc. 80-40488 Filed 12-29-80; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 80-31]

Dennis Stephen Oddo, D.D.S.; Revocation of Registrations

On October 7, 1980, the Administrator of the Drug Enforcement Administration [DEA] issued to Dennis Stephen Oddo, D.D.S. [Respondent], Orders to Show Cause as to why DEA Certificates of Registration AO8138605, issued to the Respondent at Silver Spring, Maryland, and AO8266733, issued to the Respondent at Brooklyn, New York, should not be revoked for reasons stated in the Orders to Show Cause. The Respondent, through counsel, has waived a hearing on the issues raised by the Orders to Show Cause.

The Administrator has considered the investigative file and the record of these proceedings and, pursuant to the provisions of Title 21, Code of Federal Regulations, Sections 1301.54(e) and 1316.67, hereby publishes his final order, based upon the findings of fact and conclusions of law hereinafter set forth.

The Administrator finds that on September 22, 1980, in the Circuit Court of Montgomery County, State of Maryland, in Docket No. 23766, the Respondent was convicted, in 43 counts, of violating Section 286(a)(1), Article 27, Annotated Code of Maryland, each of such counts being a felony offense relating to controlled substances. There are, therefore, lawful or statutory grounds for the revocation of the Respondent's registrations under Title 21, United States Code, Section 824(a)(2).

The Administrator further finds that by order of the Board of Dental Examiners of the State of Maryland, effective January 4, 1980, the Respondent's license to practice dentistry was suspended, thereby terminating his authority to prescribe, dispense or otherwise handle controlled substances in the course of professional practice in that State. The Administrator, therefore, concludes that there is an additional statutory basis for the revocation of the DEA registration issued to the Respondent in the State of Maryland. 21 U.S.C. 824(a)(3).

Having concluded that there are statutory grounds for the revocation of the Respondent's DEA registrations, and having been presented no legal or factual reasons for any other determination, it is the Administrator's decision that DEA Certificates of Registration AO8138605 and AO8266733, previously issued to Dennis Stephen Oddo, D.D.S., should be revoked, effective immediately. Accordingly, pursuant to the authority granted to the Attorney General by 21 U.S.C. 824, and redelegated to the Administrator of the Drug Enforcement Administration by 28 CFR § 0.100, the Administrator hereby orders that the Respondent's DEA registrations be, and they hereby are, revoked, effective immediately.

Dated: December 22, 1980.

Peter B. Bensinger,

Administrator, Drug Enforcement Administration.

[FR Doc. 80-40452 Filed 12-29-80; 8:45 am]

BILLING CODE 4410-09-M

[Docket No. 80-11]

Gold Drugs, Inc.; Permission To Retain DEA Registration

On April 15, 1980, the Administrator of the Drug Enforcement Administration [DEA] directed to Gold Drugs, Inc. [Respondent] of Hartford, Connecticut, an Order to Show Cause proposing to revoke Respondent's DEA Certificate of Registration [AG6333252] and to deny Respondent's pending application for renewal of that registration for reason that Everett Goldberg, president of Gold Drugs, Inc., had been convicted of felony offenses relating to controlled substances. The Respondent, through Counsel, requested a hearing on the issues raised by the Order to Show Cause.

Following the completion of prehearing procedures, the hearing in this matter was held in Washington, D.C. on June 11, 1980. Administrative Law Judge Francis L. Young presided. On October 2, 1980, Judge Young issued his opinion and recommended ruling, findings of fact, conclusions of law and decision. No exceptions were filed and on October 30, 1980, pursuant to 21 CFR 1316.65, he transmitted the record of these proceedings to the Administrator. The record contains, *inter alia*, the Administrative Law Judge's report or opinion, the hearing transcript, the Administrative Law Judge's orders and rulings, all exhibits which had been placed in the record, and the papers filed by the respective parties.

The Administrator has considered this record in its entirety and, pursuant to 21 CFR § 1316.67, hereby issues his final order in this matter, based upon findings of fact and conclusions of law as hereinafter set forth.

The Administrative Law Judge's report has been extremely helpful in this matter. Judge Young has carefully identified the issues and has clearly, thoroughly and fairly summarized the evidence in this case. The Administrator hereby adopts the recommended findings of fact and conclusions of law in their entirety.

The Administrator finds that Mr. Goldberg was responsible for the diversion of large quantities of Schedule II controlled substances. He knowingly filled fraudulent prescriptions for drugs such as Dilaudid, Quaalude, Percodan and various amphetamine preparations.

He charged as mush as five times the legitimate price for these prescriptions. In at least one instance, Mr. Goldberg "doctored" a prescription for his own use and on several occasions, he himself authored prescriptions in order to maintain the appearance of accountability in his dispensing records. These illegal activities began within weeks of the date on which Mr. Goldberg opened his pharmacy for business. It was a time period during which Mr. Goldberg was beset by financial, physical, psychological and family problems. These activities resulted in Mr. Goldberg's arrest and, ultimately, his guilty plea to five felony counts charging violations of the Connecticut controlled substance laws. Mr. Goldberg is now on probation and has paid a $2,500.00 fine.

In early January 1978, the Connecticut Pharmacy Commission suspended Mr. Goldberg's license as a registered pharmacist. The suspension is effective until January 20, 1982. The Pharmacy Commission has permitted Mr. Goldberg to continue the operation of the Respondent pharmacy through the employment of another pharmacist who acts as the pharmacist-manager and who is responsible for the lawful operation of the pharmacy business. Since the date of his suspension by the Connecticut authorities, Mr. Goldberg has restricted his activities to the retail merchandising aspect of the business—he does not work as a pharmacist.

The Administrator concludes, as did the Administrative Law Judge, that there is a lawful statutory basis pursuant to 221 U.S.C 824(a)(2) for the revocation of the Respondent's DEA registration and for the denial of its pending application by reason of the conviction of its president of felony offenses relating to controlled substances. The conviction of an owner or officer of a corporate registrant is sufficient ground for the revocation of the corporation's DEA registration. *In the Matter of Lynnfield Drug, Inc.*, Docket No. 76–6, 42 FR 8435 (1977); *Arenstein* v. *California State Board*, 71 Cal. Rptr. 357, 265 Cal. App. 179 (1968).

The illicit activities and felony conviction of Mr. Goldberg notwithstanding, the Administrative Law Judge felt that the circumstances which has led to Mr. Goldberg's violations has been eliminated, that the threat of further diversion by Mr. Goldberg was remote, and that, therefore, the pharmacy should be permitted to retain its DEA registration.

The Administrator reaches the same conclusion, but for different reasons than those discussed by the Administrative Law Judge. The Administrator does not believe that a pharmacist who has abused the trust placed in members of his professions and who has diverted controlled substances to individuals whom he knew were disposing of them in the illicit market should be entrusted with the responsibility for maintaining controlled substances within the closed system of distribution envisaged by the Controlled Substances Act. The action of the Connecticut Pharmacy Commission, suspending Mr. Goldberg's license and requiring him to hire a pharamacist-manager, has provided an opportunity to observe that the pharmacy can be run, lawfully and regularly, through the agency of this other pharmacist. The pharamacist-manager is responsible for the ordering, dispensing and security of the Respondent's controlled substances. He must see that dispensing records are accurately kept, that a true accountability is maintained, and that controlled substances are dispensed only pursuant to lawfully issued prescriptions in usual course of the pharmacy's professional activity. The continued employment of an independent registered pharmacist-manger is a much surer way to protect the public than to speculate that Mr. Goldberg is unlikely to again violate the law.

Accordingly, it is the Administrator's decision, pursuant to the discretion vested in him by 21 U.S.C. 824 and 28 CFR § 0.100, not to revoke the Respondent's DEA registration or to deny its pending application for renewal of such registration. This decision is conditioned, however, upon the maintenance of the *status quo* with respect to the employment of a pharmacist-manager other than Mr. Goldberg. In the event that this condition is violated, or if there is any further diversion of controlled substances from the Respondent pharmacy, the Administrator will not hesitate to order the immediate revocation of the Respondent's registration, based upon its president's conviction.

After Mr. Goldberg's license to practice pharmacy has been restored by the Connecticut authorities, and once there has been an adequate period of time in which to observe Mr. Goldberg, working as a pharmacist in conjunction with the pharmacist-manager, the Administrator will consider an application to vacate the condition imposed by this order.

Dated: December 22, 1980.

Peter B. Bensinger,

Administrator, Drug Enforcement Administration.

[FR Doc. 80–40543 Filed 12–29–80; 8:45 am]

BILLING CODE 4410–09–M

[Docket No. 80–28]

Marshall S. Tuck, M.D.; Revocation of Registration

On August 22, 1980, the Administrator of the Drug Enforcement Administration [DEA] issued to Marshall S. Tuck, M.D. [Respondent], an Order to Show Cause proposing to revoke the Respondent's DEA Certificate of Registration, AT1479939, for reason that the Respondent was not licensed to practice medicine in the State of Arizona and was not, therefore, authorized to prescribe, dispense, administer or otherwise handle controlled substances under the laws of that State. Simultaneously, citing his finding of imminent danger to the public health and safety, the Administrator ordered the immediate suspension of the Respondent's registration pending a final determination in these proceedings.

In a two-sentence letter dated September 23, 1980, the Respondent, *pro se*, requested a hearing on the issues raised by the Order to Show Cause.

By Order dated October 3, 1980, the Administrative Law Judge noted that the only ground stated in the Order to Show Cause in support of the proposed revocation seemed to present only an issue of law and granted Government counsel an opportunity to file a motion for summary judgment. The order also provided that the Respondent was to have an opportunity to file a response or opposing motion. Government counsel filed a Motion for Summary Disposition on October 20, 1980. No response has been received from the Respondent and the period of time provided him for the filing of same has expired.

The Government's motion was supported by a certification of the Associate Executive Director of the Arizona State Board of Medical Examiners attesting to the fact that as of October 7, 1980, the Respondent was not licensed, either as a physician or a physician's assistant, in the State of Arizona. The Respondent is not, therefore, a practitioner authorized to dispense or conduct research with controlled substances under the laws of Arizona. Accordingly, DEA is without statutory authority to register the Respondent in Arizona and must terminate his registration. 21 U.S.C. 823(f).

In administrative proceedings in which the Order to Show Cause alleges lack of state authorization to handle controlled substances, this agency has consistently held that, absent a showing that such state authorization in fact exists, the DEA is without statutory authority to issue or maintain a registration. In such cases, if a hearing is requested, the proceedings may be terminated summarily, that is, without an evidentiary hearing, once it is determined or established, on the record, that the prerequisite state authority is lacking. See, *James Waymon Mitchell*, Dk. 79–16, 44 FR 71466 (1979); *Alfred Tennyson Smurthwaite*, Dk. 77–29, 43 FR 11873 (1978); *John W. Whitenight, D. O.*, Dk. 77–30, 43 FR 28259 (1978); and *David Sachs, M.D.*, Dk. 77–2, 42 FR 29112 (1977).

It is settled law that when no fact question is involved or the facts are agreed, a plenary, adversary administrative proceeding involving evidence, cross examination of witnesses, and the like, is not obligatory—even though a pertinent statute prescribes a hearing. In such situations, the rational is that Congress does not intend for administrative agencies to perform meaningless tasks. *United States* v. *Consolidated Mines and Smelting Co., Ltd.*, 455 F. 2d 432, 453 (9th Cir. 1971).

In this case, Government counsel has provided documentary evidence establishing that the Respondent is not licensed to practice medicine in the State of Arizona and that he is not, therefore, authorized to administer, dispense, prescribe or otherwise handle controlled substances under the laws of that State. The Administrative Law Judge has recommended that the Respondent's registration be revoked. The Administrator, after considering the record of this matter, concurs, in all respects, with the recommendations of the Administrative Law Judge.

Accordingly, pursuant to the authority granted to the Attorney General by 21 U.S.C. 824, and redelegated to the Administrator of the Drug Enforcement Administration by 28 CFR § 0.100, the Administrator hereby orders that DEA Certificate of Registration AT1479939, previously issued to Marshall S. Tuck, M.D., be, and it hereby is, revoked, effective immediately.

Dated: December 22, 1980.

Peter B. Bensinger,

Administrator, Drug Enforcement Administration.

[FR Doc. 80-40544 Filed 12-29-80; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF LABOR

Employment and Training Administration

Labor Surplus Area Classifications Under Executive Orders 12073 and 10582; Additions to Annual List of Labor Surplus Areas

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The purpose of this notice is to announce a determination by the Department to add 12 areas to the list of labor surplus areas effective December 1, 1980.

FOR FURTHER INFORMATION CONTACT: James W. Higgins, Assistant Chief, Division of Labor Market Information, 601 D Street NW., Washington, D.C. 20213 (202–376–6263).

SUPPLEMENTARY INFORMATION: The areas described below have been classified by the Assistant Secretary for Employment and Training as labor surplus areas for purposes of Executive Orders 12073 and 10582 pursuant to 20 CFR 654.5(c) and added to the "Listing of Eligible Labor Surplus Areas" for June 1, 1980, through May 31, 1981, effective December 1, 1980.

Executive Order 12073 requires executive agencies to emphasize procurement set-asides in labor surplus areas. The Secretary of Labor is responsible under this Order for classifying and designating areas which are labor surplus areas. Under Executive Order 10582, executive agencies may reject bids or offers of foreign materials in favor of the lowest offer by a domestic supplier, provided that the domestic supplier undertakes to produce substantially all of the materials in areas of substantial unemployment, as defined by the Secretary of Labor. Areas of substantial unemployment are defined by Department of Labor regulations as labor surplus areas at 20 CFR 654.13.

The Department's labor surplus area classification procedures are set forth at 20 CFR Part 654, Subpart A. The regulations require that the Assistant Secretary for Employment and Training classify labor surplus areas and publish the labor surplus areas together with corresponding geographic descriptions. Accordingly, the following additions to the list of labor surplus areas are published for the use of all Federal departments and agencies in directing procurement activity.

Additions to List of Eligible Labor Surplus Areas Under Executive Orders 12073 and 10582—June 1, 1980 through May 31, 1981

Labor Surplus Area and Geographic Description

Alabama:
Morgan County—Morgan County
North Carolina:
Person County—Person County
Ohio:
Ashtabula County—Ashtabula County
Crawford County—Crawford County
Defiance County—Defiance County
Balance of Lucas County—Lucas County less Toledo City
Paulding County—Paulding County
Shelby County—Shelby County
Toledo City—Toledo City
Williams County—Williams County
Wyandot County—Wyandot County
Pennsylvania
Balance of Montgomery County—Montgomery County less Abington Township and Lower Merion Township

Signed at Washington, D.C. the 8th day of December 1980.

Ernest G. Green,

Assistant Secretary for Employment and Training.

[FR Doc. 80-40338 Filed 12-29-80; 8:45 am]

BILLING CODE 4510-30-M

Labor Surplus Area Classifications Under Executive Orders 12073 and 10582; Additions to Annual List of Labor Surplus Areas

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The purpose of this notice is to announce a determination by the Department to add 19 areas to the list of labor surplus areas effective October 1, 1980.

FOR FURTHER INFORMATION CONTACT: James W. Higgins, Assistant Chief, Division of Labor Market Information, 601 D Street, NW., Washington, D.C. 20213 (202–376–6263).

SUPPLEMENTARY INFORMATION: The areas described below have been classified by the Assistant Secretary for Employment and Training as labor surplus areas for purposes of Executive Orders 12073 and 10582 pursuant to 20 CFR 654.5(c) and added to the "Listing of Eligible Labor Surplus Areas" for June 1, 1980, through May 31, 1981, effective October 1, 1980.

Executive Order 12073 requires executive agencies to emphasize procurement set-asides in labor surplus areas. The Secretary of Labor is responsible under this Order for classifying and designating areas which are labor surplus areas. Under Executive Order 10582, executive agencies may reject bids or offers of foreign materials

in favor of the lowest offer by a domestic supplier, provided that the domestic supplier undertakes to produce substantially all of the materials in areas of substantial unemployment, as defined by the Secretary of Labor. Areas of substantial unemployment are defined by Department of Labor regulations as labor surplus areas at 20 CFR 654.13.

The Department's labor surplus area classification procedures are set forth at 20 CFR Part 654, Subpart A. The regulations require that the Assistant Secretary for Employment and Training classify labor surplus areas and publish the labor surplus areas together with corresponding geographic descriptions. Accordingly, the following additions to the list of labor surplus areas are published for the use of all Federal departments and agencies in directing procurement activity.

Additions to List of Eligible Labor Surplus Areas Under Executive Orders 12073 and 10582

June 1, 1980 through May 31, 1981.

Labor Surplus Area, and Geographic Description

Illinois
Whiteside County, Whiteside County.
Michigan
Balance of Eaton County, Eaton County less Lansing City (part).
Balance of Ingham County, Ingham County less East Lansing City and Lansing City (part).
Balance of Kent County, Kent County less Grand Rapids City and Wyoming City.
Lincoln Park City, Lincoln Park City in Wayne County.
Balance of Saginaw County, Saginaw County less Saginaw City.
Balance of Washtenaw County, Washtenaw County less Ann Arbor City.
Wyoming City, Wyoming City in Kent County.
New York
Chemung County, Chemung County.
Orange County, Orange County.
Orleans County, Orleans County.
Ohio
Elyria City, Elyria City in Lorain County.
Erie County, Erie County.
Huron County, Huron County.
Lorain City, Lorain City in Lorain County.
Balance of Lorain County, Lorain County less Elyria and Lorain Cities.
Marion County, Marion County.
Medina County, Medina County.
Balance of Summit County, Summit County less Akron City.

Signed at Washington, D.C. the 24th day of November, 1980.

Ernest G. Green,

Assistant Secretary for Employment and Training.

[FR Doc. 80-40339 Filed 12-29-80; 8:45 am]
BILLING CODE 4510-30-M

Pension and Welfare Benefit Programs

[Application No. D-2219]

United Cotton Goods Company, Inc., Employee Stock Ownership Plan; Griffin, Georgia; Proposed Exemption for Certain Transactions

AGENCY: Department of Labor

ACTION: Notice of Proposed Exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor (the Department) of a proposed exemption from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (the Act) and the Internal Revenue Code of 1954 (the Code). The proposed exemption would exempt, effective December 30, 1980: (1) the sale by the United Cotton Goods Company, Inc. Employee Stock Ownership Plan (the Plan) of 56,109 shares (the Plan Shares) of the common stock of United Cotton Goods Company, Inc. (United) to Doag Georgia, Inc. (Georgia), for cash and a note of Georgia (the Purchase Money Note); (2) the extension of credit by the Plan to Georgia; and (3) the guarantee of payment on the Purchase Money Note by Doag USA, Inc. (USA), the parent of Gerogia. The proposed exemption, if granted would affect United, Georgia, USA, the participants and benefificaries of the Plan and other persons participating in the transaction.

DATES: Written comments and requests for a public hearing must be received by the Department on or before February 6, 1981.

ADDRESS: All written comments and requests for a hearing (at least three copies) should be sent to the Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20216, Attention: Application No. D-2219. The application for exemption and the comments received will be available for public inspection in the Public Documents Room of Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue, N.W., Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT: Mr. Paul R. Antsen of the Department, Telephone (202) 523-6915. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of an application for exemption from the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and from the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code. The proposed exemption was requested in an application filed by counsel for United pursuant to section 408(a) of the Act and section 4975(c) (2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, this notice of pendency is issued solely by the Department.

Summary of Facts and Representations

The application contains representations with regard to the proposed exemption which are summarized below. Interested persons are referred to the application on file with the Department for the complete representations of the applicant.

1. The Plan is an employee stock ownership plan established effective September 1, 1975. The assets of a prior frozen profit sharing plan were transferred to the Plan on its effective date so the Plan contains both employer securities and a segregated fund containing the assets of the prior profit sharing plan. As of August 31, 1980, the Plan had assets of approximately $1,944,000 and 240 participants. The corporate trustee of the Plan is the Commercial Bank and Trust Company, (Commercial). Commercial is a directed trustee with all instructions regarding purchase or sale of United stock coming from the Plan's Administrative Committee. The Administrative Committee is composed of A. L. Blanton (Blanton), J. Frank Stovall (Stovall) and Joyce M. Jones (Jones), all of whom are officers, directors and/or employees of United. However, pursuant to a resolution of the Board of Directors of United, Commercial will be designated as having complete fiduciary responsibility with respect to this transaction. This responsibility will include: (1) evaluating the terms and conditions of the Purchase Money Note and (2) determining whether the sale of the Plan Shares is in the best interests of the participants and beneficiaries of the Plan.

2. United is a closely held corporation engaged in the business of importing, manufacturing and selling textile products to hospital, physicians, hotels, motels and linen supply companies. United's principal place of business is Griffin, Georgia. There is no public trading market for the common stock of

United. As of August 31, 1979, the net worth of United was $6,245,965 or $22.57 per share. Earnings for the fiscal year after taxes were $905,073 or $3.27 per share.

3. On November 2, 1980, United had issued and outstanding 229,022 shares of common stock, of which 149,381 shares or sixty five (65) percent were held by Blanton and Stovall, the principals of United, and their immediate families. The remaining shares and their percentage of the total issued and outstanding shares of United were held as follows: (1) the Plan Shares—twenty five (25) percent; (2) three United employees (including Jones)—15,925 shares or seven percent; and (3) twenty six (26) minority shareholders each owning less than 3,000 shares—7,498 shares or three percent.

4. The proposed transaction was described in an agreement (the Agreement and Plan of Merger) which was executed by the parties on October 24, 1980. The Agreement and Plan of Merger states that the transaction involves the acquisition by merger of United by Doag Griffin, Inc. (Griffin). It is anticipated that the effective date of the merger (Effective Date) will be December 30, 1980. The surviving corporate entity will retain the name United.

5. Griffin is a wholly owned subsidiary of Georgia which in turn is a wholly owned subsidiary of USA. All three Doag corporations are incorporated in Georgia. All outstanding and issued stock of USA is owned by Doag Warenhandels, a Republic of West Germany corporation having its principal office in Hamburg, Germany, and whose stock is traded on both the Hamburg and Berlin stock exchanges.

6. Prior to November 2, 1980, Angelica Corp. (Angelica), an entity unrelated to any of the parties to this transaction, had been a minority shareholder of United and held 54,208 shares of United common stock. In seeking to implement the Agreement and Plan of Merger, the management of United was advised by Angelica that Angelica would not consent to the Agreement and Plan of Merger unless it could be guaranteed by September 30, 1980, that the transaction would close in one of two specified fiscal periods. Angelica was motivated by, among other reasons, its desire to book the entire transaction in the same fiscal year that it contemplated losses from a change in its accounting procedures. Since absolute assurances could not be given to Angelica of such a closing and since their dissent could preclude a closing, management of United negotiatied with Angelica on September 30, 1980, to redeem for cash all of Angelica's shares of United stock on November 1, 1980, at a discount price of $27.00 per share. The total cost to United for such redemption was $1,463,616.

7. In order to defray the impact on United of such redemption, Georgia has agreed to contribute $1,000,000 to the capital of United on February 10, 1981 by the purchase of additional common stock of United and the pledge of such stock as additional collateral for the Purchase Money Note. This redemption, in addition to allowing the transaction to be consummated, results in an increase in the purchase price being paid all other United shareholders of approximately $1.55 per share. The Plan will receive approximately $85,000 more from the proposed transaction as a result of the redemption of Angelica's stock.

8. Pursuant to the agreement and Plan of Merger, Griffin will be merged into United with each issued and outstanding share of common stock of United being converted into and exchanged for either cash, or cash and a participation in the Purchase Money Note equal to that percentage of stock ownership covered by the Purchase Money Note. Each share of common stock of Griffin will be converted into and exchanged for one share of United common stock. As a result of the merger, United will become a wholly owned subsidiary of Georgia.

9. Based on the results of a certified audit of United, prepared by Touche ross & Co., for its fiscal year ended August 31, 1980, the purchase price for all shares of United has been established as $8,093,725. When this amount is rounded to a per share value each share of United common stock will have a value of $35.34. The purchase price for each share of United reflects an increase in the per share value of $12.77 from the 1979 audit valuation. This amount will be reduced by the expenses of the transaction which shall be borne proportionately by the shareholders of United. It has been represented that the maximum projections for such expenses will not exceed sixty-five (65) cents per share. Therefore, the net sale price to all shareholders of United, including the Plan, will be not less than $34.69 per share.

10. The terms of the Agreement and Plan of Merger provide that all shareholders of United, except as noted below, will be treated equally. The method of payment for the respective stock interests will be twenty-nine (29) percent in cash on the Effective Date of the Agreement and Plan of Merger and the balance represented by a participation in the Purchase Money Note payable over a five year period with interest at ten (10) percent per annum. It is anticipated that the expenses of the transaction will be paid from the funds received on the Effective Date of the Agreement and Plan of Merger and charged to the separate accounts of the United Shareholders in proportion to their respective stock interests.

11. As set forth in paragraph 3 above, twenty-six (26) shareholders, some of whom are employees of United, own a total of 7,498 shares of United's common stock. In order to accommodate this proposed transaction without the necessity of registering the Purchase Money Note under the Securities Act of 1933 and complying with the Trust Indenture Act as a part of such registration, thereby incurring additional costs and delays, the Agreement and Plan of Merger provides that these minority shareholders will receive full cash payment for their stock on the Effective Date.

12. The Purchase Money Note will be secured by the guaranty of USA and the pledge of all of the issued and outstanding stock of United with Commercial, an independent commercial bank, as escrow agent. The escrow agreement (Escrow Agreement) states that holders of the Purchase Money Note shall exercise their rights and remedies through a person or persons designated as the Holders Representatives. Blanton and Stovall have been designated as the Holders Representatives. In addition, Commercial has been designated a Holders Representative insofar as the Plan is concerned. Accordingly, Commercial, in the event of a breach of any of the terms or conditions of the Purchase Money Note, shall have the unilateral authority to initiate action to protect the Plan's interests. In the event of a default, any of the Representatives would notify Commercial, who, in turn, shall make a written demand upon Georgia. Such written demand would notify Georgia of the acceleration of the Purchase Money Note and would demand payment of all accrued interest and unpaid principal remaining on the Purchase Money Note within ten (10) days of such notice. In addition to the normal safeguards present in a security arrangement of this type, additional safeguards will be provided as follows:

a. Existing management (Messrs. Blanton and Stovall) will be retained under five year incentive employment agreements, including representation on the Board of Directors of United.

b. The employment agreements provide that existing management will retain operational control of United.

c. USA will be precluded from upstreaming any funds from United other than those that may result from tax savings for a period of two years and thereafter only if such funding transfers do not result in the net worth of United dropping below an amount equal to twice the amount of the then outstanding principal balance and remaining interest due on the Purchase Money Note.

d. At the end of each fiscal year, United will be required to have a minimum of $5,000,000 working capital and a ratio of current assets to current liabilities equal to the lower of (i) 2 to 1 or (ii) United's ratio at August 31, 1980 (3 to 1).

13. In summary, the applicant represents that the statutory cirteria contained in section 408(a) of the Act have been satisfied as follows: (a) the Administrative Committee represents that the Plan is receiving equal treatment with all other shareholders of United (except for those small shareholders who will be receiving a cash only distribution on the Effective Date); (b) the price per share represents a price exceeding that price paid in prior transactions involving United common stock and substantially exceeds the valuation arrived at by and independent appraiser in 1979; (c) no public trading market existed in which the Plan Shares could alternatively have been sold; (d) the rights of the Plan under the Purchase Money Note are protected through the Escrow Agreement; (e) the Purchase Money Note is collateralized by the common stock of United which exceeds the balance owed to the Plan and other United shareholders; and (f) prior to the effective date of the exemption Commercial, as and independent fiduciary on behalf of the Plan, will review the terms and conditions of the Purchase Money Note and make a determination that the transaction is in the best interests of the Plan and its participants.

Notice to Interested Persons

Within five days following the publication in the Federal Register notice of the proposed exemption will be provided to all active Plan participants and to all former participants or benificiaries who have outstanding account balances, and to Commercial, as corporate trustee of the Plan. The notice will be posted prominently in locations customarily used by United for notices to employees with regard to labor-management relations; notice by mail will be given as required for persons who cannot reasonably be expected to receive notice by the posting. Such notice shall contain a copy of the notice of pendency of the exemption as published in the Federal Register and inform the interested persons of their right to comment and the right to request a hearing within the period set forth in the notice of pendency.

General Information

The attention of interested persons is directed to the following: (1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) The proposed exemption, if granted, will not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code;

(3) Before an exemption may be granted under section 408(a) of the Act and section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(4) The proposed exemption, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an Administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemption to the address above, within the time period set forth above. All comments will be made a part of the record. Comments and requests for a hearing should state the reasons for the writer's interest in the pending exemption. Comments received will be available for public inspection with the application for exemption at the address set forth above.

Proposed Exemption

Based on the facts and representations set forth in the application, the Department is considering granting the requested exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code shall not apply, effective December 30, 1980 to: (1) the sale of the Plan Shares of United to Georgia provided that the Plan recieve not less than fair market value at the time of sale; (2) the extension of credit by the Plan to Georgia; and (3) the guarantee of payment on the Purchase Money Note by USA.

The proposed exemption, if granted, will be subject to the express conditions that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to the exemption.

Signed at Washington, D.C., this 23rd day of December, 1980.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 80-40551 Filed 12-24-80; 8:45 am]

BILLING CODE 4510-29-M

[Application No. D-1522 and Application No. D-1611]

Proposed Class Exemption for Life Insurance Company Discretionary Asset Management

AGENCY: Department of Labor.

ACTION: Notice of Proposed Exemption.

SUMMARY: This document is a notice of pendency before the Department of Labor (the Department) of a proposed exemption from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and from certain taxes imposed with respect to such transactions under the Internal Revenue code of 1954 (the Code).The proposed

exemption would allow a life insurance company to direct the allocation of assets of employee pension plans among certain investment funds, including separate accounts maintained by such insurance company, and to receive reasonable compensation for the performance of such allocation services. If it is granted, the proposed exemption would affect participants and beneficiaries of certain employee pension plans, fiduciaries of such plans, and life insurance companies.

DATE: Written comments and requests for a public hearing must be received by March 2, 1981.

ADDRESS: Written comments and requests for a public hearing (preferably at least three copies) should be sent to: Office of Fiduciary Standards, Pension and Welfare Benefit Programs, Room C-4526, U.S. Department of Labor, Washington, D.C. 20216. Attention: Discretionary Asset Management Exemption. The applications for exemption, as well as all comments and requests for a public hearing, will be available for public inspection in the Public Documents Room, Pension and Welfare Benefit Programs, U.S. Department of Labor, Room N-4677, 200 Constitution Avenue, N.W., Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT: William A. Schmidt, Plan Benefits Security Division, Office of the Solicitor, U.S. Department of Labor, Washington, D.C. 20216, telephone (202) 523-8610. This not a toll free number.

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of a proposed class exemption from certain of the prohibited transaction restrictions of section 406 or ERISA, and from the taxes imposed by section 4975(a) and (b) of the Code by reason of certain transactions described in section 4975(c)(1) thereof.[1] The relief provided by the proposed exemption was requested in an application filed by six life insurance companies [2] and in an application filed by the American Council of Life Insurance [3] (the six insurance companies and the American Council of Life Insurance are collectively referred to in this notice as the "applicants"). The applications were filed pursuant to section 408(a) of ERISA and section 4975(c)(2) of the Code, and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975).

Summary of the Applications

The representations made by the applicants with respect to the proposed class exemption are summarized below. However, interested persons are referred to the applications on file with the Department for the complete representations of the applicants.

The applicants request an exemption that would permit life insurance companies, and certain affiliates of such companies, to perform "discretionary asset management" services for employee benefit plans, and to receive compensation for such services. Generally, the expression "discretionary asset management," as used in reference to these applications, means the allocation of plan assets among separate accouts maintained by a life insurance company, or among separate accounts and one or more "advisory accounts" with respect to which the life insurance company provides investment advice or serves as investment manager. Discretionary asset management services may also consist of the allocation of assets within a separate account to different categories of investments with respect to which different fees are charged.

Life insurance companies issue contracts to employee benefit plans under which all or part of the insurance company's obligation is based on the investment results of a separate account of the company.[4] Typically, a group annuity contract is issued to the trustees of the plan or to an employer, and such contract provides for the deposit and accumulation of funds under both the "general account" provisions of the contract and the "separate account" provisions of the contract.

Pooled separated accounts are accounts established for a number of plans each of which has an interest in the account. When a plan's funds are allocated to a pooled separate account, the plan is usually credited with units of participation in the account which reflect a unit value based on the fair market value of the account's assets on valuation dates specified in the contract, and when such funds are withdrawn, these units are liquidated and the amounts paid are also determined on the basis of unit values. Instead of using the unit method, some companies state a plan's interest in a pooled separate account as a dollar amount which reflects the fair market value of account assets on the applicable valuation dates. Transfers of funds between separate accounts are generally based on the fair market value of the interests being acquired or disposed of.

Some separate accounts are established to hold all or part of the funds of a plan or plans of a single employer or sponsor. Traditionally, such accounts have been maintained in order to invest the plan's assets in one category of investments. However, some insurers may invest funds which are allocated to a single customer account in more than one category of investments.

In addition to its authority to direct the investments of its separate accounts, an insurer also may have discretion over funds of an employee benefit plan which are held by an entity unrelated to the insurance company, such as a bank. These funds are referred to as "advisory accounts." In some cases, the insurer may be authorized to allocate funds among one or more advisory accounts and one or more separate accounts. In other cases, the insurer may be authorized to allocate plan assets only among two or more adivsory accounts, and, in these circumstances, plan assets may not be invested in any of the insurer's separate accounts.

Discretionary asset management services are performed pursuant to a written agreement between the life insurance company performing such services and an independent plan fiduciary, and such an independent fiduciary is informed of the terms on which the life insurance company will perform discretionary asset management. Ordinarily the insurer's exercise of discretion with respect to the investment of plan assets is preceded by analysis intended to established a desired ratio of fixed income to equity risk for the plan, taking into account plan liquidity and diversification needs, current and projected benefit payments, the general funding status of the plan,

[1] Section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978), effective December 31, 1078 (44 FR 1065, January 3, 1979), transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor.

[2] Application Number D-1522, filed August 31, 1979. The six insurance company applicants are: Aetna Life Insurance Company, Connecticut General Life Insurance Company, The Equitable Life Assurance Society of the United States, John Hancock Mutual Life Insurance Company, The Mutual Life Insurance Company of New York, and The Prudential Insurance Company of America.

[3] Application Number D-1711, filed October 31, 1979.

[4] Separate accounts are established by resolution of boards of directors of life insurance companies and are maintained pursuant to provisions of state laws relating to separate accounts. The applicants also state that the principal feature of separate accounts is that the insurer's contractual obligation normally varies in direct relation to the investment results, including changes in market value, of the assets that are held in the separate account. This description is consistent with section 3(17) of ERISA which provides that the term "separate account" means "an account established or maintained by an insurance company under which income, gains, and losses, whether or not realized, from assets allocated to such account, are, in accordance with the applicable contract, credited to or charged against such account without regard to other income, gains, or losses of the insurance company."

and the financial stability of the plan's sponsor. Once the insurer has directed investment of plan assets in order to achieve the basic asset mix objective, the insurer's investment personnel monitor, and from time to time make changes in, the plan's participation in the accounts available to the plan under its agreement with the insurer. Plan fiduciaries are regularly informed of allocations and transfers made by the insurer pursuant to its discretionary authority.

A plan fiduciary may generally terminate an insurer's discretionary authority and, once the fiduciary indicates its intention to terminate the insurance company's authority, such termination is typically effective within a period not exceeding 30 days after notice to the insurer. The plan fiduciary may also discontinue the plan's participation in one or more separate accounts; however, the applicable group annuity contract may impose limitations on large withdrawals which the insurer may invoke when necessary to maintain stability and liquidity in the account. In addition, some pooled separate accounts are designed to invest in a selected group of long-term debt obligations on a closed-end basis, and these accounts, by their terms, substantially limit withdrawals.

Life insurance companies that perform discretionary asset management services receive fees for managing the assets in a single customer or pooled separate account or in an advisory account. This investment management fee is usually expressed as a percentage of the value of a plan's investment in the account and varies depending on the kind of investments that are made by the account.[5] In addition, some of the applicants use the same fee structure for their various separate accounts, but scale the investment management fee downward at specified breakpoints as the plan's total interest in the various accounts of that insurer increases.

In those cases where an insurer invests in different categories of investments within a single customer separate account, the investment management fee for that account may be determined by applying the fee for each category of investment to the amount of account assets invested in that category.

Life insurance companies also make certain other charges in connection with their management of plan assets invested in a separate account. For example, a charge is commonly made by a life insurance company to cover its accounting and recordkeeping expenses incurred in connection with a plan's disposition of an interest in one account and its acquisition of an interest in another. Also, the applicants state that when a plan invests funds in a separate account, or withdraws funds from the account, a charge is made in order to compensate the separate account for the expenses related to the investment or withdrawal of such funds.

Some of the life insurance companies that provide discretionary asset management services make a separate charge for such services. In one case, the fee charged to the plan is based on the actual time spent by insurance company personnel in providing such services. In another case, the life insurance company charges a fee expressed as a percentage of plan assets under discretionary asset management.

The applicants request an exemption which would provide that the restrictions of section 406 of ERISA and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c)(1) thereof shall not apply to any transaction, including the provision of services, involving the allocation or transfer of plan assets by, or at the direction of, a life insurance company or certain affiliates of such life insurance company [6]—(1) between two or more life insurance company separate accounts, (2) between one or more advisory accounts and one or more separate accounts, or, (3) within a single customer separate account if such separate account is invested in different types of assets. The exemption suggested by the applicants would be subject to several conditions including a condition requiring that discretionary asset management services be provided pursuant to a written agreement between the life insurance company and an unrelated plan fiduciary. In addition, other conditions to the suggested exemption would provide for written disclosure of certain information to the authorizing plan fiduciary concerning fees with respect to each separate account or advisory account in which the plan may participate; information concerning the contractual provisions for discontinuance of discretionary asset management services (which would be required to be permitted on no more than 30 days' notice); and information concerning the contractual provisions relating to the discontinuance of a plan's participation in a separate account. The applicants also suggest a condition which would require that a life insurance company disclosure to the authorizing fiduciary any changes in the information previously disclosed if the effect of such changes is adverse to the plan; and a condition requiring quarterly reporting to the authorizing plan fiduciary of all allocations and transfers among separate accounts and advisory accounts. Finally, the applicants suggest a condition which would require that no commission or similar fee be payable to the life insurance company solely on account of an allocation of plan assets to a separate account or advisory account at the direction of the life insurance company.

The exemption requested by the applicants also would permit an insurance company to make a separate charge for the performance of discretionary asset management services. In this regard, the applicants state that provision for a separate charge for life insurance company discretionary asset management and a separate charge for portfolio management of an account in which a plan may have an interest is not inconsistent with Prohibited Transaction Exemption 77–4,[7] which permits a fiduciary who is an investment advisor with respect to a plan to cause the plan to purchase shares in a mutual fund for which the fiduciary also serves as investment manager. Among the conditions to the availability of that exemption is a requirement that the plan whose assets are managed by an investment advisor who also manages the assets of a mutual fund does not pay an investment management, investment advisory, or similar fee with respect to plan assets that are invested in shares of such mutual fund for the entire period of such investment.

According to the applicants, an insurance company that provides asset management services, unlike an investment advisor subject to Prohibited Transaction Exemption 77–4, undertakes two separate responsibilities: the responsibility to manage the assets of its separate accounts, and the responsibility to determine the proper asset mix of the plan and the timing of allocations or transfers among the

[5] Investment management fees are charged regardless of whether a plan's interest in an account is acquired at the direction of an insurance company pursuant to discretionary asset management authority. The applicants indicate that investment management fees charged with respect to funds invested in common stock and bond separate accounts may range from .25 to .40 percent of asset value, and that investment management fees for real estate separate accounts may range from 1 to 1.25 percent of asset value; fees for private placement accounts are between those for common stock and bond accounts and those for real estate accounts.

[6] The applicants suggest that the exemption be made available to any affiliate of the life insurance company that is a member of any "controlled group of corporations," as defined in section 1563(a) of the Code, of which the life insurance company is also a member.

[7] 42 FR 18732, April 8, 1977.

available accounts. In addition, the applicants state that proper performance of the insurer's responsibility as investment manager to its separate accounts requires that time and attention be given to the composition of the account in light of the objectives and policies established for that account, while proper performance of its discretionary asset management responsibility requires that time and attention be given to the mix of assets of a particular plan in light of its needs and objectives and the range of available alternatives. Accordingly, the applicants assert, a separate fee for discretionary asset management is for a separate service, and is not duplicative of the separate account investment management fee.

The applicants state that the exemption is in the interests of plans and their participants and beneficiaries because it will assure the availability of investment services that are desired by plans and will better enable plan fiduciaries to carry out their responsibilities with respect to the management of plan assets. In this regard, the applicants represent that plan fiduciaries have expressed a strong interest in discretionary asset management services, and insurance companies have begun providing such services in order to satisfy the needs of plan sponsors and fiduciaries. Further the applicants state that they are not aware of any investment advisors or consultants who currently provide advice to plans with respect to the allocation and transfer of plan assets among life insurance company separate accounts, and that the provision of such services by unrelated parties would result in fees that would almost surely be significantly higher than those charged by an insurance company.

The applicants state that the exemption would be protective of plan participants and beneficiaries because an independent fiduciary would approve the provision of such services after being provided with sufficient disclosure materials to evaluate the transaction, and because such authorizing fiduciary would receive periodic reports that would enable him to evaluate the performance of such services. In addition, the applicants note that the suggested exemption would require that the authorizing fiduciary retain the right to terminate the insurer's discretionary asset management authority.

Finally, the applicants state that the exemption they request is administratively feasible because it establishes objective criteria for its application, and an insurance company's compliance with such criteria may be readily determined and audited.

Treatment of Discretionary Asset Management Under ERISA

Assets held in a separate account of an insurance company to support obligations under contracts purchased by, or on behalf of, employee benefit plans are plan assets, and thus, an insurance company maintaining such a separate account is, under section 3(21) of ERISA, a fiduciary with respect to those plan assets and also is, under section 3(14)(A) of ERISA, a party in interest with respect to the plans that participate in such separate account.[8] Similarly, an insurance company that exercises any authority or control respecting management or disposition of plan assets held in an advisory account or renders investment advice for a fee or other compensation, direct or indirect, with respect to such assets, or has any authority or responsibility to do so, would be a fiduciary with respect to such assets and, therefore, a party in interest with respect to the plans that participate in the advisory account. *See* section 3(21)(a)(ii) of ERISA.

In performing discretionary asset management services an insurance company would also be exercising control over plan assets other than the investments of the separate account—*i.e.*, a plan's interest in the separate account—and, therefore, would be a fiduciary with respect to the plans for which it performs such services. In this regard, section 408(b)(8) of ERISA provides an exemption from the prohibitions of section 406(a) for, among other things, the sale or purchase of an interest in a pooled investment fund of an insurance company qualified to do business in a State provided certain conditions are met. The transactions described in section 406(b) of ERISA, however, impose additional restrictions regarding the conduct of fiduciaries, and are separately prohibited. The Department is not prepared to state that the exemption in section 408(b)(8) applies to such transactions.[9]

The Proposed Exemption

The exemption being proposed by the Department in this notice would permit life insurance companies to perform discretionary asset management services of the kind described in the application. However, the exemption is subject to a number of conditions that differ from, or are in addition to, those suggested by the applicants. These conditions are primarily to provide sufficient protection to plans whose assets are held in a separate account (and to protect participants and beneficiaries of such plans) by means of assuring that the transactions are subject to approval and periodic review by an informed and disinterested fiduciary. This approach is similar to that taken by the Department in other "multiple services" exemptions—specifically Prohibited Transaction Exemption 77–9, referred to above, and Prohibited Transaction Exemption 79–1 (44 FR 5963, January 30, 1979), (relating to the effecting or execution of securities transactions on behalf of a plan by a person who is a fiduciary with respect to the plan)—and elements of the conditions to each of these exemptions are incorporated in the conditions to the exemption being proposed in this notice.

The major features of the proposed exemption are discussed below.

I. Scope.

The proposed exemption would provide relief from the prohibitions of sections 406(a)(1) (A), (C), and (D) and 406(b) (1) and (2) of ERISA and from the taxes imposed by section 4975(a) and (b) of the Code by reason of section 4975(c)(1) (A), (C), (D) and (E) thereof for certain described transactions. First, the exemption would permit the acquisition or sale of an interest in a pooled separate account at the direction of the life insurance company that maintains such separate account, and the transfer of assets to or from an advisory account at the direction of a life insurance company that provides investment advice to, or serves as investment manager of, such advisory account. Second, the exemption would allow a

[8] *See* the Notice of Proposal of an Exemption (42 FR 54866, October 11, 1977) to what was subsequently adopted as Prohibited Transaction Exemption 78–19 (43 FR 59915, October 22, 1978). *See also*, the Department's proposed rule under section 401 of ERISA which states in part that in the case of a plan which is funded in whole or in part by a contract or policy of insurance issued by an insurer, the assets of the plan shall include the contract or policy under which the benefits are insured but shall not, solely by reason of the issuance of such contract or policy under which the benefits are insured but shall not, solely by reason of the issuance of such contract or policy, include the assets of the insurer issuing the contract or policy except to the extent that such assets are maintained by the insurer in one or more separate accounts and do not constitute surplus in any such account. Proposed 29 CFR 2550.401b–1(d), 44 FR 50363, 50366, August 28, 1979.

[9] In addition Prohibited Transaction Exemption 77–9, as amended, (42 FR 32395, June 24, 1977; as amended 44 FR 1479, January 5, 1979, and 44 FR 52365, September 7, 1979) provides an exemption from the prohibitions of section 406(a) and 406(b) of ERISA for the purchase with plan assets, or sale of an insurance or annuity contract from an insurance company. However, this exemption is not available for a transaction involving a fiduciary who is expressly authorized in writing to manage, acquire or dispose of assets of a plan on a discretionary basis.

life insurance company to recommend the allocation of plan assets among its separate accounts or between one or more of its separate accounts and one or more advisory accounts with respect to which it provides investment advice or serves as investment manager. Third, a life insurance company would be permitted to receive periodic investment management or advisory fees with respect to a separate account or advisory account in which plan assets have been invested at the direction of such life insurance company.[10] Finally, the proposed exemption would allow a life insurance company to allocate assets held in a separate account that is maintained for the plan or plans of a single employer among different classes of investments, notwithstanding that the fees received by the insurance company with respect to the assets held in such account are determined at different rates for each of the different classes of investments to which the assets of the account may be allocated.

II. Conditions to the Exemption

A. *General Conditions.* The proposed exemption, if granted, would be effective from January 1, 1975. However, the exemption would be subject to two conditions that would be applicable both before and after the date a final exemption is published. First, the discretionary asset management services must be authorized pursuant to a written agreement between the insurance company and the plan (or a fiduciary on behalf of the plan), signed by an independent fiduciary.[11] Second, the combined total of all fees, commissions, and other consideration received by the life insurance company and its affiliates for the provision of services to the plan, in connection with the purchase of any insurance or annuity contracts, and in connection with the investment of plan assets in a separate account or an advisory account may not exceed "reasonable compensation" within the contemplation of section 408(b)(2) and 408(c)(2) of ERISA and section 4975(d)(2) and 4975(d)(10) of the Code.[12] *See* 29 CFR 2550.408b-2(d), 2550.408c-2(b).

B. *Prospective Conditions.* The proposed exemption includes a number of conditions that would be applicable, in addition to the two conditions described above, for transactions occurring on and after a date 90 days from the date and exemption is granted.

1. *Conditions Relating to a Life Insurance Company's Authorization to Engage in Certain Transactions.* The first prospective condition to the proposed exemption would require that neither the insurance company providing discretionary asset management services to a plan pursuant to the exemption nor any affiliate of the insurance company may be a trustee or administrator of the plan or an employer of any participant in the plan. This condition is included because the proposed exemption provides for the supervision and monitoring of discretionary asset management services by an informed and disinterested fiduciary in order to protect affected plans and their participants,[13] and an exemption that would be available in circumstances where the insurer can effectively control the activities of the plan (such as where it is a sponsoring employer with respect to the plan) presents additional issues not specifically addressed by the applicants.[14] Although the proposed exemption therefore would not be available for discretionary asset management services performed by an insurance company for a plan covering its own employees, the Department would consider expanding the scope of the exemption to cover such transactions if the comments received provide a sufficient basis for such relief.

The second prospective condition to the proposed exemption would require an independent plan fiduciary to specifically approve the allocation of plan assets to a pooled separate account or advisory account any of the assets of which are invested in assets other than "publicly traded" securities (or, in the case of a single-customer separate account, any investment of plan assets in such property).[15] This condition is included because the Department believes that is would not necessarily be in the interests of plan participants, or protective of their rights, for an insurance company to allocate plan assets to an account the assets of which are composed of relatively illiquid securities or real property (and with respect to which the insurance company will receive periodic investment management fees) without specific scrutiny by an independent plan fiduciary. However, in view of the additional burden this condition may impose on the insurance company and the authorizing fiduciary, the Department specifically invites comments concerning other ways in which meaningful supervison of the insurance company's allocation of plan assets to illiquid investment funds can be assured.

Another condition to the proposed exemption would require that an independent plan fiduciary renew its authorization of discretionary asset management services at least annually. In addition, the insurance company is required to provide the authorizing fiduciary with such reasonably available information as the life insurance company believes is

[10] The proposed exemption would not expressly permit an insurance company to receive fees for the performance of asset allocation services on behalf of a plan. However, section 408(b)(2) of ERISA provides an exemption from the restrictions of section 406(a) of ERISA for, among other things, contracting for services necessary to the operation of the plan if no more than reasonable compensation is paid, and section 408(c)(2) of ERISA generally permits a fiduciary to receive reasonable compensation for services rendered. Accordingly, the receipt by a life insurance company of reasonable compensation for the performance of asset allocation services would not, in itself, be a prohibited transaction. *See* 29 CFR 2550.408b-2; 29 CFR 2550.408c-2. Nonetheless, as discussed below, the proposed exemption would not be available if the aggregate of all fees received by the insurance company exceeds "reasonable compensation."

[11] In the Department's view, a transaction entered into by an insurance company would be "authorized" only if the authority existed at the time of the transaction; therefore, an independent fiduciary's ratification of past activities of an insurance company would not satisfy this condition.

[12] As discussed below, the exemption would be available for transactions occuring on and after a date 90 days from the date an exemption is granted only if the insurer receives no fees in connection with an investment of plan assets in a separate account or advisory account at the direction or recommendation of the insurer other than those that are specified in a condition to the exemption.

[13] In other exemptions that permit a fiduciary to perform multiple services for a plan, the Department has included conditions that preclude application of the exemption to transactions involving fiduciaries whose influence over the general operation of the plan is so great that another plan fiduciary would not be able to examine critically and objectively the multiple service arrangements. *See e.g.*, section V(a) of Prohibited Transaction Exemption 77–9, as amended, (44 FR 1479, 1483, January 30, 1979).

[14] *Cf.* note 13, above (describing the provisions of other "multiple service" exemptions issued by the Department). In this regard, the Department has granted an exemption for transactions involving the "in-house" plans of certain investment advisors [Prohibited Transaction Exemption 77–3; 42 FR 18734, April 18, 1977). In addition, section 408(b)(5) of ERISA and section 4975(d)(5) of the Code provide an exemption from the prohibited transaction restrictions of ERISA for the purchase of life insurance, health insurance or annuities from a life insurance company that employs participants in a plan if certain conditions are met. Further, the Department recognizes that the policy underlying these exemptions might also apply to an exemption permitting the provision of discretionary asset management services by an insurance company to a plan in which its employees participate. *Cf.* H.R. Rep. No. 1280, 93d Cong., 2d Sess., 314 (1974) (indicating that it would be contrary to normal business practice to require the plan of an insurance company to purchase its insurance from another insurance company). However, the Department is not prepared to conclude at this time that section 408(b)(5) provides an exemption for the performance of discretionary asset management services by an insurance company for a plan covering its own employees.

[15] "Publicly traded" securities are defined in the proposed exemption as securities that are not "restricted securities" within the meaning of Rule 144 under the Securities Act of 1933.

reasonably necessary in order for the independent fiduciary to determine whether the authorization should be granted or renewed, and also requires that the insurance company provide certain additional information concerning the matter in response to a reasonable request from the independent fiduciary.

The general disclosure standard with respect to an independent plan fiduciary's grant or renewal of an authorization is supplemented by conditions that require certain specific information to be disclosed to an authorizing fiduciary in connection with an initial authorization or the renewal of an authorization, as the case may be. These specific requirements are intended to assure that information that is essential to informed approval of discretionary asset management services, and to the effective oversight of the performance of such services, is brought to the attention of the authorizing fiduciary. Further, no change in the matters specifically required to be described in connection with an initial authorization may be effective as to a plan until the change has been disclosed to an authorizing fiduciary, and such fiduciary has either specifically consented to the change or has renewed the insurance company's authorization after such disclosure has been made.

2. *Conditions Relating to Periodic Reporting Regarding Performance of Discretionary Asset Management Services.* A prospective condition to the proposed exemption would require an insurance company that performs discretionary asset management services for a plan to provide quarterly reports to the plan fiduciary who authorized such services. This report would include a statement of the total charges incurred by the plan in connection with any plan assets with respect to which the life insurance company provides asset allocation services, and a further description of such charges by category. In addition, the report would include a description of each acquisition with plan assets or disposition of an interest in a separate account, as well as each transfer of plan assets to or from an advisory account. This quarterly report is intended to allow the authorizing fiduciary to monitor, on a continuing basis, the services performed on behalf of the plan by the insurance company.

3. *Conditions Relating to Fees Imposed in Connection With the Investment of Plan Assets in a Separate Account or Advisory Account.* In addition to the general standard of reasonableness applicable to transactions that would be subject to the exemption, the prospective conditions describe the specific fees that a life insurance company may charge in connection with the investment of plan assets in a separate account or advisory account. Generally, these charges are limited to fees for asset allocation and investment management services that are specifically disclosed to an authorizing plan fiduciary; a reasonable charge for accounting and recordkeeping services actually rendered in connection with an investment of plan assets in a separate account or advisory account; and charges that do not exceed the amount reasonably necessary to reimburse a separate account or advisory account for direct expenses properly and actually incurred in connection with the investment of plan assets that have been allocated to such an account.[16]

In regard to the fees that are permitted to be charged by an insurance company providing discretionary asset management services, as discussed above, Prohibited Transaction Exemption 77–4 would not permit an investment advisor who invests plan assets in a mutual fund pursuant to that exemption to receive a separate investment advisory fee with respect to the assets so invested. In addition, as the department indicated in the notice accompanying the proposed exemption that was granted as Prohibited Transaction Exemption 77–4[17] the applicants for that exemption represented that it has generally been the practice of investment advisory firms utilizing publicly marketed mutual funds in the management of plan assets to deduct the value of assets invested in mutual fund shares from the asset base on which the plan account fees are periodically computed, and that this procedure essentially eliminates the possibility of the investment advisor receiving a "double fee" on assets invested in mutual fund shares.

Notwithstanding the provisions of Prohibited Transaction Exemption 77–4, the Department has not included in the exemption being proposed here a condition that would prohibit an insurance company which performs discretionary asset management services from making a separate charge for such services because the applicants state that the performance of discretionary asset management services imposes responsibilities on the insurer that are distinct from the insurer's responsibilities as investment manager of its separate accounts.[18] However, the Department specifically invites comments addressing whether, in light of the restrictions imposed by Prohibited Transaction Exemption 77–4 on the fees that may be charged by an investment advisor, an additional condition should be included in the final class exemption relating to discretionary asset management that would prohibit or restrict an insurance company's imposition of separate charges for the performance of asset allocation services.

4. *Conditions Relating to Termination of an Agreement to Perform Discretionary Asset Management Services and Liquidation of a Plan's Investment in a Separate Account or Advisory Account.* Prospective conditions to the proposed exemption provide that the portion of any agreement under which an insurance company performs discretionary asset management services must be terminable by the plan, without penalty or other charge, on no more than 30 days' notice. In addition, the proposed exemption contains a condition that would enable a plan to withdraw from any separate account or advisory account in which its assets have been invested at the direction of a life insurance company that acts as investment manager of, or provides investment advice to, such account on not more than 90 days' notice (unless an independent plan fiduciary has consented in writing to an extension of such 90-day period).[19]

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[16] The Department's regulations under section 408(c)(2) of ERISA indicate that an expense is not a direct expense to the extent it would have been sustained had the service not been provided or if it represents an allocable portion of overhead costs. 29 CFR 2550.408c–2(b)(3).

[17] 41 FR 50516, November 16, 1976.

[18] Although an insurance company would, under the proposed exemption, be permitted to impose a separate charge for the performance of discretionary asset management services, other conditions to the proposed exemption would require the insurer to specifically disclose all charges to an authorizing fiduciary, and also could require that the fees charged by the insurance company be, in the aggregate, reasonable. In the Department's view, if an insurer is paid a separate charge that is characterized as a charge for "discretionary asset management" where the services involved merely duplicate services that the insurer is required to perform in managing plan assets that are invested in its separate accounts, the aggregate fees received by the insurer would not, in such circumstances, be reasonable. Therefore, an independent fiduciary authorizing the payment of such fees would violate his obligations in approving the payment. In addition, in determining whether to pay a separate fee to an insurance company for the performance of discretionary asset management services, an authorizing fiduciary would be obligated to consider the terms on which the plan could obtain comparable services from other sources. *See e.g.*, sections 404(a)(1)(A)–(B), 405(a) and section 406(a)(1)(D) of ERISA.

[19] As discussed above, the applicants indicate that some pooled separate accounts limit withdrawals. Accordingly, the requirement that a plan be permitted to liquidate its interest in a

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Another condition specifies the charges that an insurance company may impose with respect to a plan's withdrawal from an account. Generally, these are limited to charges for accounting and recordkeeping expenses, and charges that reimburse the separate account or advisory account for direct expenses properly and actually incurred in connection with the plan's withdrawal (*e.g.*, the direct costs of disposing of securities in order to liquidate the plan's interest in the account).[20] However, where assets of a separate account consist of investments that may be illiquid, an additional charge is permitted to be made. This charge is equal to the difference between the fair market value of plan assets that are disposed of in order to liquidate the plan's interest in the account and the amount actually received on such disposition (adjusted to exclude that portion of the difference that is attributable to the withdrawing plan's interest in the account), and is intended to allow an insurance company to prevent any diminution in the value of other plans's interests in the separate account that might otherwise occur as a result of the plan's withdrawal from the account.[21]

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separate account within a fixed period may require alteration of insurance companies' existing practices in some cases. Nonetheless, the Department believes that the ability of an independent fiduciary to terminate a plan's relationship with an insurance company is a very important factor in the fiduciary's effective supervision of discretionary asset management services. However, as discussed below, because prompt liquidation of a plan's investment in a pooled separate account may, in some cases, have adverse consequences to other plans that participate in the account, another condition to the proposed exemption would permit certain additional charges to be made to a plan that withdraws from separate accounts whose assets are illiquid. These charges are intended to protect the interests of other plans that participate in such accounts (see note 21, below). The Department is also prepared to consider modifications to the condition that requires that a plan be permitted to withdraw from a separate account if the changes would protect the interests of the withdrawing plan as well as other plans for which the insurance company is acting as a fiduciary.

[20] See note 16, above.

[21] The additional charge described in the proposed exemption is intended to allow an insurance company to protect the interests of other plans in a separate account from any diminution in the value of their interests in the account that would result from the sale of assets held in the separate account for an amount less than "fair market value" in order to promptly liquidate the interest of the withdrawing plan. In this regard, if the value of the assets of a separate account are determined on a basis other than fair market value, the disposition of assets at a discount attributable to interest rate fluctuations in order to liquidate the interest of a withdrawing plan may arguably also result in a diminution in the interests of the plans that continue to participate in the account. The proposed exemption does not permit a separate charge to prevent such diminution because the applicants indicate that assets of separate accounts are generally determined on the basis of fair market value and no other basis for valuation is described in the applications. Nonetheless, the Department recognizes that an insurance company has fiduciary obligations with respect to plans that retain interests in a separate account as well as plans that elect to liquidate their interests, and, accordingly, it will consider, on the basis of public comments received regarding the proposed exemption, permitting other charges to be made on a plan's withdrawal from certain separate accounts if such charges are equitable to the withdrawing plan and reasonably designed to protect the interests of plans that continue to participate in the account.

[22] See *e.g.*, Prohibited Transaction Exemption 78-19 (43 FR 59915, December 22, 1978).

III. Definitions

The proposed exemption contains definitions of various terms used in the exemption which generally are the same as the definitions of those terms in other class exemptions available to life insurance companies.[22] However, the term "life insurance company" is defined to include a corporate affiliate of a life insurance company that is a member of a "controlled group of corporations," within the meaning of section 1563(a) of the Code, of which the life insurance company also is a member. This definition has the effect of allowing certain affiliates of life insurance companies to perform discretionary asset management services under the exemption.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act which require, among other things, that a fiduciary discharge his duties respecting the plan solely in the interests of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) The proposed exemption, if granted, will not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code;

(3) Before an exemption may be granted under section 408(a) of the Act and section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible; in the interest of the plan(s) and of participants and beneficiaries of the plan(s); and protective of the rights of such participants and beneficiaries.

(4) The proposed exemption, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the proposed exemption to the address and within the time period set forth above. All comments will be made a part of the record. Comments and requests for a hearing should state the reasons for the writer's interest in the proposed exemption. Comments received will be available for public inspection with the application for exemption at the address set forth above.

Proposed Exemption

The Department has under consideration the granting of the following class exemption pursuant to the authority of section 408(a) of the Act and section 497(c)(2) of the Code and in accordance with the procedure set forth in ERISA Procedure 75-1.

Section I. Covered Transactions. Effective January 1, 1975, the restrictions of sections 406(a)(1)(A), (C) and (D), 406(b)(1), and 406(b)(2) of the Act and the taxes imposed by section 4975 (a) and (b) of the Code by reason of section 4975(c)(1)(A), (C)(D), and (E) therof shall not apply to the transactions described below if the applicable conditions set forth in Section II are met.

A. The acquisition with pension plan assets, or disposition, of an interest in a pooled separate account at the direction of the life insurance company that maintains such account.

B. The transfer of pension plan assets to or from an advisory account at the direction of a life insurance company that provides investment advice to, or serves as investment manager of, such advisory account.

C. A life insurance company's recommendation that pension plan assets be allocated to—

1. a separate account maintained by such life insurance company, or,

2. an advisory account for which such life insurance company serves as investment manager, or to which it provides investment advice, and any investment of pension plan assets in a separate account or advisory account that results from such recommendation.

D. The receipt by a life insurance company of periodic investment management or advisory fees with respect to a separate account or advisory account in which plan assets have been invested at the direction or recommendation of such life insurance company.

E. The allocation by a life insurance company of pension plan assets among different classes of investments within a separate account that is maintained by such life insurance company and which is funded solely by assets of pension plans that are sponsored by a single employer or by affiliated employers, the receipt by such life insurance company of compensation for such services, and the receipt by such life insurance company of periodic investment management fees with respect to the assets held in such separate account, notwithstanding that the fees received by such life insurance company are determined at different rates for each of the different classes of investments to which plan assets may be allocated.

For the purposes of this exemption, asset allocation services that constitute, or may result in, a transaction described in this Section I are referred to as "discretionary asset management services."

Section II. Conditions. A. Effective January 1, 1975, the exemption provided for transactions described in Section I is available only if each of the following conditions is met:

1. The descretionary asset management services are authorized pursuant to a written agreement between a plan (or a fiduciary on behalf of a plan) and an insurance company, which agreement has been signed by an independent fiduciary of the plan for which the discretionary asset management services are performed.

2. The combined total of all fees, commissions, and other consideration received by such life insurance company and its affiliates:

(a) For the provision of services to the plan and,

(b) In connection with the purchase of insurance or annuity contracts by such plan, or by a fiduciary on behalf of the plan, or in connection with the investment of plan assets in a separate account or an advisory account.

Is not in excess of "reasonable compensation" within the contemplation of section 408(b)(2) and 408(c)(2) of the Act and section 4975(d)(2) and 4975(d)(10) of the Code.

B. Effective [a date 90 days from the date an exemption is granted], the exemption provided for transactions described in Section I is available only if each of the following conditions is satisfied in addition to each of the conditions described in paragraph A of this Section II:

1. Neither the life insurance company engaging in the transaction nor any affiliate of such life insurance company is a trustee or administrator of the plan or an employer of any employee covered by the plan.

2. In the case of any transaction described in paragraphs A through C of Section I that constitutes, or results in, the investment of plan assets in any separate account or advisory account any of the assets or which are, or may be, assets other than "publicly traded securities," and any transaction described in paragraph E of Section I that constitutes or results in, an investment in assets other than "publicly traded securities," such transaction is specifically authorized by an independent fiduciary of the plan whose assets are involved in such transaction. For the purposes of this paragraph B(2) and paragraph B(12)(c) of this section, "publicly traded securities" are securities that are not "restricted securities" within the meaning of Rule 144 of the Securities Act of 1933.

3. The authorization referred to in paragraph A(1) of this section (relating to the authorization of a life insuraance company to perform discretionary asset management services) continues in effect for more than one year only if such continuance is authorized in writing at least annually by an independent fiduciary of the plan for which the discretionary asset management services are performed.

4. No such authorization is made or renewed unless the life insurance company receiveing such authorization shall have furnished the authorizing plan fiduciary with any reasonably available information which the life insurance company which seeks the authorization reasonably believes to be necessary to determine whether such authorization should be made or renewed, and any other reasonably available information regarding the matter that the authorizing fiduciary may reasonably request.

5. In the case of an intial authorization, the information required by paragraph B(4) of this Section II shall include, but is not limited to:

(a) a description of the discretionary asset management services to be rendered by such life insurance company;

(b) the schedule of the specific fees charged by the life insurance company for the performance of discretionary asset management services, and the schedule of any asset management or advisory fees charged by such life insurance company with respect to—

(i) any separate account or advisory account in which plan assets may be invested at the direction or recommendation of such life insurance company; or,

(ii) any separate account for which a life insurance company performs allocation services described in paragraph E of Section I;

(c) a description of all other charges that may be imposed with respect to the performance of discretionary asset management services and in connection with each separate account or advisory account in which plan assets may be invested at the direction or recommendation of such life insurance company, including fees charged in connection with the acquisition or disposition of an interest in a separate account or the transfer of plan assets to or from an advisory account;

(d) a description of the steps a plan must take in order to terminate the agreement made for it by its independent fiduciary with the life insurance company which authorizes the performance of discretionay asset management services;

(e) a description of the steps a plan must take to liquidate its investment in any separate account or advisory account that has been made at the direction or recommendation of such life insurance company; and,

(f) a full description of the consequences to the plan of terminating any agreement under which the insurance company performs discretionary asset management services and a full description of the consequences to the plan of the liquidation of any investment of plan assets in a separate account or advisory account that may be made at the direction or recommendation of such life insurance company.

6. In the case of any renewal of an authorization, the information required to be disclosed by paragraph B(4) of this Section II shall include, but is not limited to:

(a) a description of any changes in matters specifically required to be disclosed by paragraph B(5) of this Section II (relating to an initial authoriaztion);

(b) a statement of the value, as of a date within 90 days of the date such information is furnished, of the plan's

investment, if any, in each separate account or advisory account to which its assets have been allocated at the direction or recommendation of such life insurance company (regardless of when such allocation was made);

(c) a general statement of the manner in which such life insurance company determines the value of the plan's investment in each separate account or advisory account to which its assets have been allocated.

7. No change in the substance of any matter specifically required to be disclosed by paragraph B(5) of this Section II (relating to an initial authorization) is effective as to a plan until the earlier of:

(a) the date on which an independent plan fiduciary specifically consents to such change; or,

(b) the first date after disclosure of such change pursuant to paragraph B(6) of this Section II on which an independent plan fiduciary renews the insurance company's authorization to perform discretionary asset management services.

8. The life insurance company furnishes the authorizing fiduciary with a report containing at least the following information not less frequently than every three months and not later than 45 days following the end of the period to which the report relates:

(a) the total of all charges incurred by the plan during the preceding three months in connection with any plan assets with respect to which the life insurance company provides discretionary asset management services;

(b) the amount of such charges, by category, including

(i) fees for the provision of discretionary asset management services,

(ii) the investment management, or advisory fee charged to the plan (or that portion of any such fee charged to a separate account or advisory account that is attributable to the plan's interest is such account) with respect to each separate account or advisory account in which the plan's assets are invested during the period to which the report relates,

(iii) any charge relating to the acquisition or disposition of an interest in a separate account or the transfer of plan assets to or from an advisory account; and,

(c) a description of each acquisition with plan assets or disposition of the plan's interest in a separate account and each transfer of plan assets to or from an advisory account, including the date of such transaction and the amount involved.

9. No commission or other charge is payable to a life insurance company performing discretionary asset management services or to any affiliate of such life insurance company, in connection with any investment of plan assets in a separate account or advisory account at the direction or recommendation of such life insurance company or affiliate, except the following:

(a) fees that are described in paragraph (B)(5)(b) of this Section II;

(b) a reasonable charge for accounting and recordkeeping services actually rendered in connection with such investment; and,

(c) a charge not in excess of the amount reasonably necessary to reimburse the separate account or advisory account for direct expenses properly and actually incurred in connection with the initial investment of plan assets that have been allocated to such account.

10. That portion of any agreement pursuant to which a life insurance company performs discretionary asset management services is terminable by the plan, without penalty or charge, on not more than 30 days' notice.

11. The plan is able to liquidate its investment in any separate account or advisory account to which its assets have been allocated at the direction or recommendation of a life insurance company on not more than 90 days' notice (unless an independent plan fiduciary has agreed in writing to an extension of such 90 day period).

12. No penalty or other charge is made with respect to the withdrawal of plan assets from a separate account or advisory account, except the following:

(a) a reasonable charge for accounting and recordkeeping services actually rendered in connection with such liquidation;

(b) a charge not in excess of the amount reasonably necessary to reimburse the separate account or advisory account for direct expenses properly and actually incurred in connection with the liquidation of the plan's investment in the account; and,

(c) in a case where a plan has requested withdrawal of its assets from a separate account any of the assets of which are invested in property other than "publicly traded securities" (as defined in paragraph B(2) of this Section II), a charge not in excess of the amount reasonably necessary to reimburse to such separate account an amount equal to—

(i) the difference, if any, between the "fair market value," determined as of the date of withdrawal, of any assets of the account that are disposed of in order to liquidate the plan's investment and the amount actually received on disposition; less,

(ii) that portion of such difference that bears the same relationship to the total amount of the difference as the value of the withdrawing plan's interest in the separate account, determined immediately prior to its withdrawal, bears to the aggregate value of all interests in such separate account, determined immediately prior to the plan's withdrawal.

For the purposes of this paragraph B(12), the "fair market value" of an asset means the fair market value of such asset as reasonably determined in writing by a person who is reasonably qualified to form an opinion regarding the fair market value of the asset and who is agreed to in writing by an independent fiduciary of the withdrawing plan. Such person may be designated in the instrument authorizing the life insurance company to perform discretionary asset management services.

Section III. Definitions. For the purpose of this exemption—

A. An "advisory account" means an asset or pool of assets, other than a life insurance company's general assets or a separate account, with respect to which a life insurance company provides investment management services or investment advice.

B. An "affiliate" of a person includes—

(1) any person, directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) any officer, director, employee (including in the case of an insurance company, an insurance agent thereof, whether or not the agent is a common law employee of the insurance company), or relative of, or partner in, any such person; and,

(3) any corporation or partnership of which such person is an officer, director, partner or employee.

C. The term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

D. The term "discretionary asset management services" has the meaning given it in Section I.

E. The term "life insurance company" means an insurance company authorized to do business as a life insurance company under the laws of a State. For purposes of this exemption, the term "life insurance company" shall include a corporate affiliate of a life

insurance company that is a member of a "controlled group of corporations," within the meaning of section 1563(a) of the Code, of which such life insurance company is a member.

F. The term "party in interest" includes a "disqualified person" described in section 4975(e)(2) of the Code.

G. The term "relative" means a "relative" as that term is defined in section 3(15) of the Act (or a "member of the family" as that term is defined in section 4975(e)(5) of the Code), or a brother, a sister, or a spouse of a brother or sister.

Signed at Washington, D.C. this 22nd day of December 1980.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 80-40436 Filed 12-29-80; 8:45 am]

BILLING CODE 4510-29-M

Office of the Secretary

[TA-W-8602]

Active Products Corp.; Correction and Clarification

On June 9, 1980, the Department instituted an investigation under TA-W-8602 incorrectly designating the petitioning workers as Active Tool and Manufacturing Company, Incorporated, Detroit, Michigan, published in the **Federal Register** on June 13, 1980 (45 FR 40257). In fact, the petition was filed on behalf of workers at the company's division, Active Products Corporation, Marion, Indiana.

On June 27, 1980, the Department published in the **Federal Register** (45 FR 43484) a Notice of Termination of Investigation concering employees of Active Tool and Manufacturing, Detroit, Michigan (TA-W-8602). Subsequently, the Department on its own motion reinstituted the investigation of the petition having recognized that the intent of petition TA-W-8602 was to petition for assistance of the Marion workers. The Department inadvertently failed to publish notice of the reinstitution of the investigation of the Marion workers. In due course, following investigation, the Department issued a Notice of Negative Determination denying trade adjustment assistance to the Marion workers on December 10, 1980, published in the **Federal Register** on December , 1980 (45 FR ———).

Signed at Washington, D.C., this 15th day of December 1980.

Harold A. Bratt,

Deputy Director, Office of Trade Adjustment Assistance.

[FR Doc. 80-40545 Filed 12-29-80; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-11,277]

APCO Knitwear, Inc. (Formerly Known as APCO Manufacturing Company, Incorporated); Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on October 14, 1980 in response to a worker petition received on October 6, 1980 which was filed by the Amalgamated Clothing and Textile Workers' Union on behalf of workers and former workers producing men's and boys' knit shirts at APCO Knitwear, Incorporated, Brodhead, Wisconsin.

The Notice of Investigation was published in the **Federal Register**. No public hearing was requested and none was held.

The petitioning group of workers in this case was included in a determination (TA-W-4752) issued on March 30, 1979 which certified as eligible to apply for adjustment assistance all workers engaged in employment related to the production of men's knit sport shirts at APCO Manufacturing Company, Incorporated, Brodhead, Wisconsin. APCO Manufacturing Company was sold in September 1979 and the name was changed to APCO Knitwear, Incorporated. No changes were made in the day-to-day operation of the firm. Only the name and ownership changed. Since all workers separated, totally or partially from APCO Knitwear, Incorporated, formerly known as APCO Manufacturing Company, Incorporated, on or after January 18, 1978 (impact date) and before March 30, 1981 (expiration date of the determination) are covered by an existing determination, a new investigation would serve no purpose. Therefore, this investigation has been terminated.

Signed at Washington, D.C. this 19th day of December 1980.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 80-40547 Filed 12-29-80; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-8193]

Borg-Warner Corp., Warner Gear Division; Affirmative Determination Regarding Application for Reconsideration

On November 25, 1980, after being granted a filing extension, counsel for the petitioners requested administrative reconsideration of the Department of Labor's Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance for workers and former workers of the Warner Gear Division plant in Muncie, Indiana of the Borg-Warner Corporation. The determination was published in the **Federal Register** on October 3, 1980 (45 FR 65703).

Among other things, the application for reconsideration claimed that the Department's customer survey was not adequate.

Conclusion

After review of the application, I conclude that the counsel's claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, D.C., this 17th day of December 1980.

James F. Taylor,

Director, Office of Management Administration and Planning.

[FR Doc. 80-40548 Filed 12-29-80; 8:45 am]

BILLING CODE 4510-28-M

Determinations Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for worker adjustment assistance issued during the period December 15-19, 1980.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number of proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have

contributed importantly to the separations, or threat, thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases it has been concluded that at least one of the above criteria has not been met.

TA-W-8095; Firestone Tire and Rubber Co., Corporate Headquarters, Akron, OH. Investigation revealed that criterion (3) has not been met. A survey of customers of the subject firm indicated that increased imports did not contribute importantly to sales declines and worker separations at the subject firm.

TA-W-9331; Weldmation, Inc., Madison Heights, MI. Investigation revealed that criterion (3) has not been met. Aggregate U.S. imports of welding and assembly machinery are negligible.

TA-W-9970; Gathen Industries, Inc., Roseville, MI. Investigation revealed that criterion (3) has not been met. Aggregate U.S. imports of automobile tools and dies are negligible.

TA-W-7948; C.A. Baltz and Sons, Inc., Kingston, NY. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-8159; Lattimore and Tessmer, Inc., Southfield, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-8808 & 8808A; Means Stamping Industries, Inc., Means Stamping Div., Saginaw, MI and Delta Metal Products Div., Bay City, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-9481; Adell Industries, Inc., Novi, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-7997; Motor City Stamping, Inc., Sterling Heights, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-8343; Excel Pattern Works, Inc., Dearborn, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-8646; Shuron Division of Textron, Inc., Rochester, NY. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-8887; Eagle Clothes, Inc., New York, NY. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-9300 & 9300A-B; American Sunroof Corp., Paramount, CA, Los Angeles, CA, and San Francisco, CA. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-8811; General Tire and Rubber Co., Aldora Mills, Barnesville, GA. Investigation revealed that criterion (3) has not been met. Aggregate U.S. imports of tire cord are negligible.

TA-W-8286; McIntosh—Division of Norris Industries, Detroit, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-8334; Eifel Pattern and Model, Fraser, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-9328; Tiger Babe Sportswear, Inc., Newark, NJ. Investigation revealed that criterion (3) has not been met. Aggregate U.S. imports of blouses did not increase as required for certification.

TA-W-9615 & 9973; Republic Steel Corp., Buffalo District, New York Plant, Buffalo, NY and New York Sales Office, Amherst, NY. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-7351, 9241, & 10,993; General Electric Co., Engineering Section, Cleveland, OH, Memphis, TN, and Lexington, KY. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-8588, 8589, 8673-76, 8678, 8679, and 8681-83; Walker Mfg. Co., Grass Lake, MI, Jackson, MI, Seward, NE, Racine, WI, Newark, OH, Jonesboro, AR, Harrisonburg, VA, Greenville, TX, Batavia, IL, Arden, NC, and Aberdeen, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-9164; Rockford Headed Products, Inc., Rockford, IL. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-8346; Visioneering, Inc., Fraser, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-8039 & 8039A-M; American Sunroof Corp., Southgate, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-11,147; American Sunroof Corp., Glass and Trim Plant, Lansing, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-10,459; American Sunroof Corp., Warren, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-10,963; Square D Environmental Contracting Corp., Detroit, MI. Investigation revealed that criterion (3) has not been met. Aggregate U.S. imports of duct work are negligible.

TA-W-9993 & 9993A; Quinault Cedar Products, Neilton, WA. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA-W-9060; Hall Heating and Air Conditioning, Inc., Burton, MI. Investigation revealed that criterion (3) has not been met. Aggregate U.S. imports of duct work are negligible.

TA-W-7947; Balfour Industries, Inc, Detroit, MI. Investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

Affirmative Determinations

TA-W-9055; Rockwell International, Inc., Logansport, IN. With respect to workers producing suspension springs, a certification was issued applicable to all

such workers separated from employment on or after June 16, 1979.

With respect to workers producing mechnical springs the investigation revealed that criterion (3) has not been met Surveyed customers did not increase purchases of imports while decreasing purchases from the subject firm.

TA–W–10,689; Keuffel and Esser Co., Cape May Court House, NJ. A certification was issued covering all workers of the firm separated on or after April 1, 1980 and before October 1, 1980.

TA–W–10,510; Trim Trends, Inc., Clawson, MI. A certification was issued covering all workers of the firm separated on or after March 15, 1980.

TA–W–8203; Motor Wheel Corp., Mendota, IL. A certification was issued applicable to all workers engaged in employment related to the production of automobile wheels who were separated from employment on or after August 6, 1979.

With respect to workers engaged in employment related to the production of agricultural and industrial wheels, criterion (3) has not been met. Surveyed customers did not buy imports of agricultural of industrial wheels.

I hereby certify that the aforementioned determinations were issued during the period December 15–19, 1980. Copies of these determinations are available for inspection in Room S–5314, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, D.C. 20210 during normal working hours or will be mailed to persons who write to the above address.

Dated: December 22, 1980

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 60–40550 Filed 12–29–80; 8:45 am]

BILLING CODE 4510–28–M

[TA–W–10,699]

First Ford; Negative Determination Regarding Application for Reconsideration

By letter of November 17, 1980, (copy attached) one of the petitioners for the former workers requested administrative reconsideration of the Department of Labor's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance in the case of former workers of that company. The determination was published in the **Federal Register** on October 24, 1980, (45 FR 70604).

Pursuant to 29 CFR 90.18(c), reconsideration may be granted under the following circumstances:

(1) if it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) if it appears that the determination complained of was based on a mistake in the determination of facts previously considered; or

(3) if, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justifies reconsideration of the decision.

The petitioner claims that Ford Motor Company (Ford) has a substantial degree of proprietary control over First Ford since the loss of auto sales caused Ford to close First Ford.

The Department's review showed that First Ford was an independent, franchised dealership which sold and serviced Ford automobiles and trucks and, as such, did not produce an article within the meaning of Section 222(3) of the Trade Act.

Since workers at First Ford do not produce an article, they may be certified only if Ford is the "workers' firm" within the meaning of Section 222 of the Act. Ford may be determined to be the "workers' firm" if Ford and First Ford, an independent dealership, are related by ownership or by a substantial degree of proprietary control, or if the workers are *de facto* employees of Ford. Ford is not the "workers' firm" under either test. There is no element of ownership or control between the firms. The workers also are not *de facto* employees of Ford since all payroll transactions, personnel actions and employee benefits are under the control of First Ford. The mere fact that the Ford Motor Credit Company, a subsidiary of Ford, lent First Ford money to purchase new cars and equipment and the further fact that Ford Leasing Development Company petitioned the Des Plaines Zoning Board of Appeals for a change in zoning are not sufficient in themselves to support a determination that the Ford Motor Company is the "workers' firm".

Conclusion

After review of the application and the investigative file, I conclude that there has been no error or misinterpretation of the law which would justify reconsideration of the Department of Labor's prior decision. The application is, therefore, denied.

Signed at Washington, D.C., this 15th day of December 1980.

C. Michael Aho,

Director, Office of Foreign Economic Research.

[FR Doc. 80–40546 Filed 12–29–80; 8:45 am]

BILLING CODE 4510–28–M

[TA–W–9957]

Solix Sportswear Corp., Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on August 11, 1980 in response to a worker petition received on July 29, 1980 which was filed on behalf of former workers at Solix Sportswear Corporation, New York, New York. The workers produced men's outerwear.

The investigation revealed that the petitioning group of workers in this case was included in a determination (TA–W–8051) issued on June 25, 980 which certified as eligible to apply for adjustment assistance all workers of Solix Sportswear Corporation who became totally or partially separated from employment on or after May 8, 1979 and before December 1, 1979. The three workers who filed the present petition were separated from employment at Solix in November 1979 and were never recalled. All production of men's outerwear by Solix ceased in November 1979. A totaliy new product line was introduced during February 1980.

Since all workers separated totally or partially from Solix Sportswear Corporation, New York, New York on or after May 8, 1979 and before December 1, 1979 are eligible to apply for adjustment assistance under an existing determination a new investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C. this 17th day of December 1980.

Marvin M. Fooks,

Director, Office of Trade Administration Assistance.

[FR Doc. 80–40549 Filed 12–29–80; 8:45 am]

BILLING CODE 4510–28–M

NATIONAL ADVISORY COMMITTEE ON OCEANS AND ATMOSPHERE

Meeting

Pursuant to Sec. 10(a)(2), of the Federal Advisory Committee Act, 5 U.S.C. App. (1976), notice is hereby given that the Marine Transportation Subgroup of the Independent Areas Task Force (IATF) of the National Advisory Committee on Oceans and

Atmosphere (NACOA) will meet Thursday and Friday, January 15–16, 1981. The Subgroup will meet in the B–100 conference room of Page Building No. 1, 2001 Wisconsin Avenue, NW., Washington, D.C.

The session, which will be open to the public, will convene at 9:00 a.m. and adjourn at 4:00 p.m. each day. The agenda for the meeting of the Marine Transportation Subgroup is as follows:

Ocean Problems and Transoceanic Shipping

A. U.S. merchant marine capabilities to meet national trade and defense needs.
B. Flags of convenience.
C. Other issues.

NACOA has initiated a study to formulate national goals and objectives for the oceans in the decade of the 1980's and beyond. To support the conduct of this study, the Secretary of Commerce has established the IATF for NACOA. The IATF will be responsible for the preparation of preliminary recommendations in the areas of energy, fisheries, marine transportation, ocean minerals, ocean operations and services, pollution, and waste management.

Persons desiring to attend will be admitted to the extent seating is available. Persons wishing to make formal statements should notify the Chairperson of the Subgroup on Marine Transportation, Dr. Don Walsh, in advance of the meeting. The Chairperson retains the prerogative to impose limits on the duration of oral statements and discussion. Written statements may be submitted before or after each session.

Additional information concerning this meeting may be obtained through the NACOA Executive Director, Mr. Steven N. Anastasion, or CDR Tom Nunes, the Staff Member for the Marine Transportation Subgroup. The mailing address is: NACOA, 3300 Whitehaven Street NW. (Suite 438, Page Building No. 1), Washington, D.C. 20235.

Steven N. Anastasion,

Executive Director.

[FR Doc. 80–40455 Filed 12–29–80; 8:45 am]

BILLING CODE 3510–12–M

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Behavioral and Neural Sciences; Subcommittee for Psychobiology; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Science Foundation announces the following meeting:

Name: Subcommittee on Psychobiology of the Advisory Committee for Behavioral and Neural Sciences.
Date & Time: January 23–24, 1981, 8:30 a.m.–5:00 p.m. each day.
Place: Hilton Inn, Room 339, Salt Lake City, Utah.
Type of Meeting: Closed.
Contact Person: Dr. Fred Stollnitz Program Director, Psychobiology Program, Room 320, National Science Foundation, Washington, D.C. (202) 357–7949.
Purpose of Subcommittee: To provide advice and recommendations concerning support for research in psychobiology.
Agenda: To review and evaluate research proposals as part of the selection process for awards.
Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information, financical data, such as salaries, and personal information concerning individuals associated with the proposals. These matters are within exemptions (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.
Authority To Close Meeting: This determination was made by the Committee Management Officer pursuant to provisions of Section 10(d) of Pub. L. 92–463. The committee Management Officer was delegated the authority to make such determinations by the Director, NSF, on July 6, 1979.

M. Rebecca Winkler,

Committee Management Coordinator.

December 22, 1980.

[FR Doc. 80–40458 Filed 12–29–80; 8:45 am]

BILLING CODE 7555–01–M

Advisory Committee for Physics; Subcommittee on Computational Facilities for Theoretical Research; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, the National Science Foundation announces the following meeting:

Name: Advisory Committee for Physics—Subcommittee on Computational Facilities for Theoretical Research.
Date and Time: January 15–17, 1981; 9 a.m. to 5 p.m. each day.
Place: National Science Foundation, 1800 G Street, NW., Washington, D.C. 20550. Room 628 each day.
Type of Meeting: Open.
Contact Person: Dr. Richard A. Isaacson, Division of Physics, National Science Foundation, Washington, D.C. 20550. Telephone (202) 357–7979.
Summary of Minutes: Will be available as an attachment to the minutes of the full Committee meeting to be held in February, 1981.
Purpose of Subcommittee: To examine present and future trends for the usage of computers for university-based Theoretical Physics research and recommend an appropriate strategy for meeting the computational needs of this area of research.
Agenda:

January 15, 1981, 9 a.m. to 5 p.m.: Review of available studies on the usage of computers for theoretical research by university scientists. Preliminary discussion of Subcommittee recommendations.

January 16, 1981, 9 a.m. to 5 p.m.: Continuation of previous day's discussion.

January 17, 1981, 9 a.m. to 5 p.m.: Continuation of previous day's discussion.

M. Rebecca Winkler,

Committee Management Coordinator.

December 22, 1980.

[FR Doc. 80–40459 Filed 12–29–80; 8:45 am]

BILLING CODE 7555–01–M

Advisory Council; Task Group No. 15; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, the National Science Foundation announces the following meeting:

Name: Task Group No. 15 of the NSF Advisory Council.
Place: Room 523, National Science Foundation, 1800 G Street, N.W., Washington, D.C. 20550.
Date: Friday, January 30, 1981.
Time: 9:00 a.m. till 5:00 p.m.
Type of Meeting: Open.
Contact Person: Ms. Jeanne Hudson, Executive Secretary of the NSF Advisory Council, National Science Foundation, Room 518, 1800 G Street, N.W., Washington, D.C. 20550. Telephone: 202/357–9433.
Purpose of Task Group: The purpose of the Task Group, composed of members of the NSF Advisory Council, is to provide the full Advisory Council with a mechanism to consider numerous issues of interest to the Council that have been assigned by the National Science Foundation.
Summary Minutes: May be obtained from the contact person at above stated address.
Agenda: The Task Group is asked to determine the role of NSF in the science education for the general public. The task Group will focus on mechanisms to encourage greater interagency cooperation and will suggest mechanisms to foster increased and/or expanded in-school as well as out-of-school programs for education in the sciences and technology.

M. Rebecca Winkler,

Committee Management Coordinator.

December 22, 1980.

[FR Doc. 80–40460 Filed 12–29–80; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-389]

Florida Power & Light Co. (St. Lucie Nuclear Power Plant, Unit 2); Reconstitution of Atomic Safety and Licensing Appeal Board

Notice is hereby given that, in accordance with the authority conferred by 10 CFR 2.787(a), the Chairman of the Atomic Safety and Licensing Appeal Panel has assigned the following panel members to serve as the Atomic Safety and Licensing Appeal Board for this construction permit proceeding:

Richard S. Salzman, Chairman.
Dr. W. Reed Johnson.

Dated: December 19, 1980.

C. Jean Bishop,
Secretary to the Appeal Board.

[FR Doc. 80-40376 Filed 12-29-80; 8:45 am]
BILLING CODE 7590-01-M

[Docket Nos. 50-354 and 50-355]

Public Service Electric & Gas Co. and Atlantic City Electric Co. (Hope Creek Generating Station, Units 1 and 2); Reconstitution of Atomic Safety and Licensing Appeal Board

Notice is hereby given that, in accordance with the authority conferred by 10 CFR 2.787(a), the Chairman of the Atomic Safety and Licensing Appeal Panel has assigned the following Panel members to serve as the Atomic Safety and Licensing Appeal Board for this construction permit proceeding:

Richard S. Salzman, Chairman.
Dr. W. Reed Johnson.
Thomas S. Moore.

Dated: December 18, 1980.

C. Jean Bishop,
Secretary to the Appeal Board.

[FR Doc. 80-40377 Filed 12-29-80; 8:45 am]
BILLING CODE 7590-01-M

NUCLEAR REGULATORY COMMISSION

FEDERAL EMERGENCY MANAGEMENT AGENCY

Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants (NUREG-0654/FEMA-REP-1, Rev. 1)

In January 1980, NUREG-0654/FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," was issued for interim use and comment. Comments have been received and evaluated. The Nuclear Regulatory Commission and the Federal Emergency Management Agency have used the comments in revising the document. The revision process included close coordination with State and local planning groups.

As a result, Revision 1 of NUREG-0654/FEMA-REP-1 was published in November 1980. Wide distribution is being made to industry and to State and local officials who are responsible for radiological emergency planning and preparedness. This document is consistent with NRC and FEMA regulations and supersedes other previous guidance and criteria published by FEMA and NRC on this subject. It will be used by reviewers in determining the adequacy of State, local, and nuclear power plant licensee emergency plans and preparedness.

Single copies of this document are available free, to the extent of supply, by writing to the Director, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; or to Headquarters, Federal Emergency Management Agency, 1725 I Street NW., Washington, D.C. 20472, Attention: Administrative Services Division. Copies will also be available for review in the NRC Public Document Room, Washington, D.C.; the local NRC Public Document Rooms; at FEMA Headquarters, Administrative Services Division; and the FEMA Regional Offices.

Dated at Washington, D.C., this 17th day of December 1980.

For the Nuclear Regulatory Commission.

E. Kevin Cornell,
Deputy Executive Director for Operations.

For the Federal Emergency Management Agency.

Frank A. Camm,
Associate Director for Plans and Preparedness.

[FR Doc. 80-40378 Filed 12-29-80; 8:45 am]
BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

Cincinnati Stock Exchange; Application for Unlisted Trading Privileges and of Opportunity for Hearing

December 18, 1980.

The above named national securities exchange has filed an application with the Securities and Exchange Commission pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the common stock of:

Dart & Kraft Incorporated, Common Stock, $2.50 Par Value (File No. 7-5795).

This security is listed and registered on one or more other national securities exchanges and is reported on the consolidated transaction reporting system.

Interested persons are invited to submit on or before January 12, 1981 written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extension of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons,
Secretary.

[FR Doc. 80-40383 Filed 12-29-80; 8:45 am]
BILLING CODE 8010-01-M

Philadelphia Stock Exchange, Inc.; Application for Unlisted Trading Privileges and of Opportunity for Hearing

December 18, 1980.

The above named national securities exchange has filed an application with the Securities and Exchange Commission pursuant to Section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the common stock of:

Paine Webber, Inc., Common Stock, $1 Par Value (File No. 7-5796).

This security is listed and registered on one or more other national securities exchanges and is reported on the consolidated transaction reporting system.

Interested persons are invited to submit on or before January 12, 1981 written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission,

Washington, D.C. 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based on all the information available to it, that the extension of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 80-40382 Filed 12-29-80; 8:45 am]

BILLING CODE 8010-01-M

SYNTHETIC FUELS CORPORATION

Proposal Workshops

Action: Notice/Invitation.

Summary

The U.S. Synthetic Fuels Corporation will conduct two pre-proposal workshops on January 19 at the Hilton Hotel in New York City and on January 28 at the Fairmont Hotel in Denver. The purpose of these workshops is to provide prospective proposers and interested parties an opportunity to meet SFC officers and staff to discuss our solicitation, evaluation and selection process and the various forms of financial assistance available through the SFC.

Note.—The SFC is authorized to financially assist the commercial production of synthetic fuels from coal (including peat and lignite), shale, tar sands (including heavy oils), and water (as a source of hydrogen through electrolysis).

Inquiries: Lillian Clarke/Jim Ajello, Telephone 202/653-4400.

Address: 1200 New Hampshire Avenue, N.W., Suite 460, Washington, D.C. 20586.

United States Synthetic Fuels Corporation.

For the Board of Directors.

John C. Sawhill,

Chairman.

December 22, 1980.

[FR Doc. 80-40386 Filed 12-29-80; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF THE TREASURY

[Supplement to Department Circular Public Debt Series No. 38-80]

Series H-1984 Notes; Interest Rate

December 22, 1980.

The Secretary announced on December 18, 1980 that the interest rate on the notes designated Series H-1984 described in Department Circular—Public Debt Series—No. 38-80 dated December 11, 1980, will be 14 percent. Interest on the notes will be payable at the rate of 14 percent per annum.

Paul H. Taylor,

Fiscal Assistant Secretary.

Supplementary Statement

The announcement set forth above does not meet the Department's criteria for significant regulations and, accordingly, may be published without compliance with the Departmental procedures applicable to such regulations.

[FR Doc. 80-40475 Filed 12-29-80; 8:45 am]

BILLING CODE 4810-40-M

Sunshine Act Meetings

Federal Register
Vol. 45, No. 251
Tuesday, December 30, 1980

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

1

NATIONAL CREDIT UNION ADMINISTRATION.

TIME AND DATE: 10 a.m., Tuesday, December 30, 1980.

PLACE: 1776 G. Street, NW., Washington, D.C., 7th Floor Board Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Merger. Closed pursuant to examptions (8) and (9)(A)(ii).
2. Establishment of Special Reserves under Section 201 of the Federal Credit Union Act or Alternatively Administrative Actions under Section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii) and (10).
3. Requests from federally insured credit unions for special assistance under Section 208 of the Federal Credit Union Act. Closed pursuant to exemptions (8) and (9)(A)(ii).

FOR MORE INFORMATION CONTACT: Joan O'Neill, Program Assistant, telephone (202) 357-1100.

[S-2356-80 Filed 12-29-80; 8:45 am]

BILLING CODE 7535-01-M

2

NATIONAL CREDIT UNION ADMINISTRATION.

Notice of Change in Subject of Meeting

The National Credit Union Administration Board determined that its business required that the previously announced open meeting on December 18, 1980, include an additional item, which was open to public observation.

Consideration of DIDC Actions of December 12, 1980.

The previously announced items were:

1. Review of Central Liquidity Facility Lending Rate.
2. Consideration of a waiver of the regular reserve transfer for the fourth quarter of 1980.
3. Consideration of a revision of the regulations applying to retirement accounts.
4. Consideration of Advance Notice of Proposed Rulemaking for revising Regulation 721, Federal Credit Union insurance and group purchasing activities.
5. Consideration of Interpretive Ruling and Policy Statement regarding the use of statistical sampling for the verification of members' accounts that is required by Section 115 of the Federal Credit Union Act and Section 741.2 of the NCUA Rules and Regulations.
6. Final Rule on Premiums.
7. Adoption of an NCUA System of Grievance Records.
8. Publication of Fifth Semi-Annual Agenda in Federal Register.
9. Report on actions taken under delegations of authority.
10. Applications for charters, amendments to charters, bylaw amendments, mergers as may be pending at that time.

The meeting was held at 9:30 a.m., in the 7th Floor Board Room, 1776 G St., NW., Washington, D.C.

FOR MORE INFORMATION CONTACT: Rosemary Brady, Secretary of the Board, telephone (202) 357-1100.

[S-2357-80 Filed 12-29-80; 8:45 am]

BILLING CODE 7535-01-M

3

NATIONAL CREDIT UNION ADMINISTRATION.

Notice of Change in Subject of Meeting

The National Credit Union Administration Board determined that its business required that the previously announced closed meeting on December 18, 1980, include an additional item, which was closed to public observation.

Personnel Action. Closed pursuant to examption (2).

The previously announced items were:

1. Proposed mergers. Closed pursuant to exemptions (8) and (9)(A)(ii).
2. Report of action taken under Section 201(c)(2) of the Federal Credit Union Act. Closed pursuant to exemption (9)(A)(ii).
3. Administrative Actions under Section 120 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii) and (10).
4. Administrative Action under Section 206 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii) and (10).
5. Administrative Actions under Section 207 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii) and (9)(B).
6. Requests from federally insured credit unions for special assistance under Section 208 of the Federal Credit Union Act. Closed pursuant to exemptions (8) and (9)(A)(ii).
7. Division of Assets, Liabilities and Capital. Closed pursuant to exemptions (8) and (9)(A)(ii).
8. Request for special assistance under Section 208 and purchase and assumption under Sections 107 and 205 of the Federal Credit Union Act. Closed pursuant to exemptions (8) and (9)(A)(ii).
9. Allocations of Executive Positions and Noncareer Appointment Authority. Closed pursuant to exemptions (2) and (6).
10. Consideration of change to NCUA policy regarding share-to-Loan Transfers in involuntary liquidations. Closed pursuant to exemption (9)(B).
11. Delegation of 208 Assistance to assist in the voluntary liquidation of solvent insured credit unions. Closed pursuant to exemption (2).
12. Consideration of Policy change to permit the use of collection agencies. Closed pursuant to exemption (9)(B).
13. Consideration of Policy change to allow Finance companies to bid on loan portfolios. Closed pursuant to exemption (9)(B).

The meeting was held at 10:30 a.m., in the 7th Floor Board Room, 1776 G Street, NW., Washington, D.C.

FOR MORE INFORMATION CONTACT: Rosemary Brady, Secretary of the Board, telephone (202) 357-1100.

[S-2358-80 Filed 12-29-80; 8:45 am]

BILLING CODE 7535-01-M

4

NATIONAL MEDIATION BOARD.

TIME AND DATE: 2 p.m., Wednesday, January 7, 1981.

PLACE: Board Hearing Room, 8th Floor, 1425 K Street, NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

(1) Ratification of Board actions taken by notation voting during the month of December, 1980.

(2) Other priority matters which may come before the Board for which notice will be given at the earliest practicable time.

SUPPLEMENTARY INFORMATION: Copies of the monthly report of the Board's notation voting actions will be available from the Executive Secretary's office following the meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Rowland K. Quinn, Jr., Executive Secretary, Tel: (202) 523-5920.

DATE OF NOTICE: December 22, 1980.

[S-2359-80 Filed 12-29-80; 8:45 am]

BILLING CODE 7550-01-M

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday). This is a voluntary program. (See OFR NOTICE 41 FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/SECRETARY	USDA/ASCS		DOT/SECRETARY	USDA/ASCS
DOT/COAST GUARD	USDA/FNS		DOT/COAST GUARD	USDA/FNS
DOT/FAA	USDA/FSQS		DOT/FAA	USDA/FSQS
DOT/FHWA	USDA/REA		DOT/FHWA	USDA/REA
DOT/FRA	MSPB/OPM		DOT/FRA	MSPB/OPM
DOT/NHTSA	LABOR		DOT/NHTSA	LABOR
DOT/RSPA	HHS/FDA		DOT/RSPA	HHS/FDA
DOT/SLSDC			DOT/SLSDC	
DOT/UMTA			DOT/UMTA	
CSA			CSA	

Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday.
Comments on this program are still invited.
Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408

NOTE: As of September 2, 1980, documents from the Animal and Plant Health Inspection Service, Department of Agriculture, will no longer be assigned to the Tuesday/Friday publication schedule.

REMINDERS

The "reminders" below identify documents that appeared in issues of the **Federal Register** 15 days or more ago. Inclusion or exclusion from this list has no legal significance.

Rules Going Into Effect Today

Note: There were no items eligible for inclusion in the list of **Rules Going Into Effect Today.**

List of Public Laws

Last Listing December 30, 1980

This is a continuing listing of public bills from the current session of Congress which have become Federal laws. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (telephone 202–275–3030).

H.J. Res. 615 / Pub. L. 96–563 Providing for appointment of David C. Acheson as a citizen regent of the Board of Regents of the Smithsonian Institution (December 22, 1980; 94 Stat. 3304) Price $1.

S. 2227 / Pub. L. 96–564 To grant the consent of the United States to the Red River Compact among the States of Arkansas, Louisiana, Oklahoma, and Texas (December 22, 1980; 94 Stat. 3305) Price $1.25.

H.R. 7217 / Pub. L. 96–565 To establish the Kalaupapa National Historical Park in the State of Hawaii, and for other purposes (December 22, 1980; 94 Stat. 3321) Price $1.

H.J. Res. 642 / Pub. L. 96–566 Providing for convening of the first regular session of the Ninety-seventh Congress on January 5, 1981, and for other purposes (December 22, 1980; 94 Stat. 3328) Price $1.

H.R. 7865 / Pub. L. 96–567 Nuclear Safety Research, Development, and Demonstration Act of 1980 (December 22, 1980; 94 Stat. 3329) Price $1.

S. 3027 / Pub. L. 96–568 Disaster Relief Act Amendments of 1980 (December 22, 1980; 94 Stat. 3334) Price $1.

S. 2726 / Pub. L. 96–569 Environmental Research, Development, and Demonstration Authorization Act of 1981 (December 22, 1980; 94 Stat. 3335) Price $1.

H.R. 2111 / Pub. L. 96–570 To extend the service area for the Sacramento Valley Canals, Central Valley project, California, and for other purposes (December 22, 1980; 94 Stat. 3339) Price $1.

S. 1784 / Pub. L. 96–571 Alaska Federal-Civilian Energy Efficiency Swap Act of 1980 (December 22, 1980; 94 Stat. 3341) Price $1.

S. 1148 / Pub. L. 96–572 To reauthorize title I of the Marine Protection, Research, and Sanctuaries Act, and for other purposes (December 22, 1980; 94 Stat. 3344) Price $1.

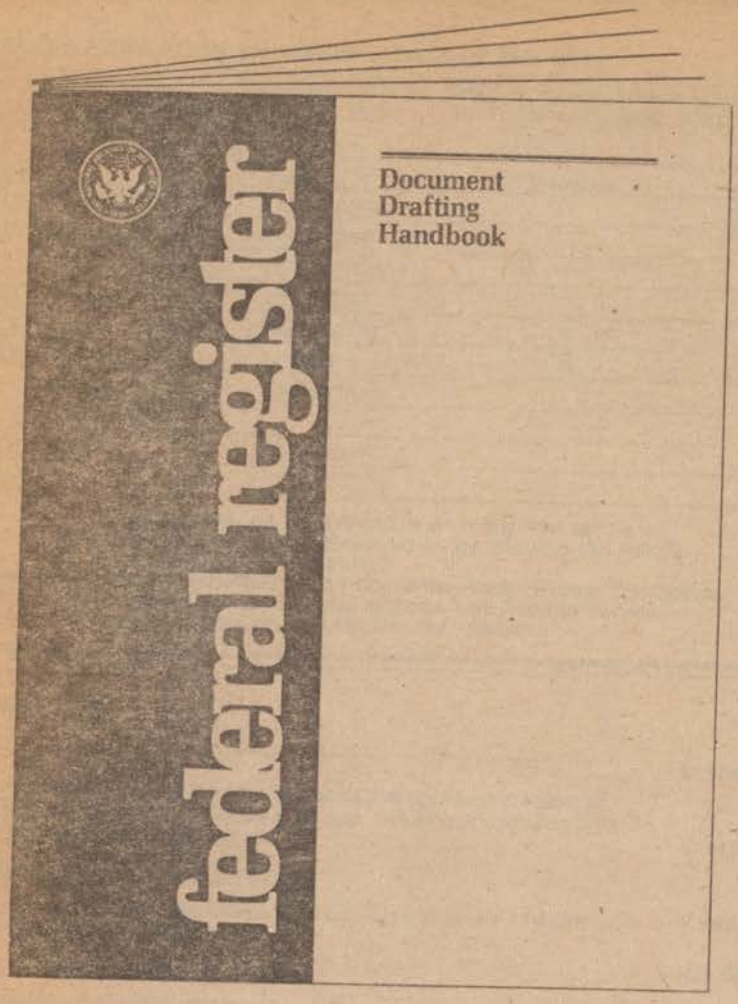
S. 2189 / Pub. L. 96–573 Low-Level Radioactive Waste Policy Act (December 22, 1980; 94 Stat. 3347) Price $1.

H.R. 999 / Pub. L. 96–574 To amend the Plant Variety Protection Act (7 U.S.C. 2321 et seq.) to clarify its provisions, and for other purposes (December 22, 1980; 94 Stat. 3350) Price $1.

H.R. 4941 / Pub. L. 96–575 To name a dam and reservoir on the San Gabriel River, Texas, as the "North San Gabriel Dam" and "Lake Georgetown", respectively (December 22, 1980; 94 Stat. 3353) Price $1.

H.R. 8345 / Pub. L. 96–576 To name the United States Customs House in Ogdensburg, New York, the "Robert C. McEwen United States Customs House" (December 22, 1980; 94 Stat. 3355) Price $1.

H. J. Res. 337 / Pub. L. 96–577 Designating February 11, 1981, "National Inventors' Day" (December 22, 1980; 94 Stat. 3357) Price $1.



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Tuesday, December 30, 1980

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Tuesday
December 30, 1980

Part II

Department of Commerce

International Trade Administration

Publication of Advisory Notes, the Commodity Control List and Commodity Interpretations in the Code of Federal Regulations

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Parts 385 and 399

Publication of Advisory Notes, the Commodity Control List and Commodity Interpretations in the Code of Federal Regulations

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: This revision makes technical changes in the regulations which are necessary to include the full text of the following sections in the Code of Federal Regulation (CFR): Advisory Notes for Selected CCL Entries (Supplement No. 1 to Part 385), Commodity Control List (§ 399.1), and Commodity Interpretations (§ 399.2). In prior years these documents were incorporated by reference. This document also revises the authority citation for Part 399 by updating it to reflect the latest statutory and departmental authorizations.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: Richard J. Isadore, Acting Director, Operations Division, Office of Export Administration, Room 1617M, Washington, D.C. 20230, 202–377–4738.

SUPPLEMENTARY INFORMATION:

Advisory Notes for Selected CCL Entries

The Advisory Notes appear in Supplement 1 to Part 385. They were printed in the **Federal Register** on June 25, 1980 (45 FR 43012–43054). They are revised and set out in full text in today's document. The Advisory Notes will be included in the next edition of Title 15 of the CFR, revised as of January 1, 1981.

Commodity Control List (CCL)

The Commodity Control List was printed in the **Federal Register** on June 25, 1980 (45 FR 43060–43138). Today, the Department announces its intention to include the CCL in full text in the next revision of Title 15 of the CFR. The CCL is designated Supplement 1 to § 399.1. In addition, replacement pages issued since the June 25, 1980, publication are printed in today's document and the authority section is revised and updated.

Commodity Interpretations

The Department has decided to include the Commodity Interpretations in the next revision of Title 15 of the CFR. Therefore, the full text of the interpretations is included in today's document as Supplement 1 to § 399.2.

Rulemaking Requirements

Section 13(a) of the Export Administration Act of 1979 ("the Act") exempts regulations promulgated thereunder from the public participation in rulemaking procedures of the Administrative Procedure Act. Section 13(b) of the Act, which expresses the intent of Congress that where practicable "regulations imposing controls on exports" be published in proposed form, is not applicable because these regulations do not impose controls on exports. It has been determined that these regulations are not "significant" within the meaning of Department of Commerce Administrative Order 218–7 (44 FR 2082, January 9, 1979) and International Trade Administration Administrative Instruction 1–6 (44 FR 2093, January 9, 1979) which implement Executive Order 12044 (43 FR 12661, March 23, 1978), "Improving Government Regulations." Therefore these regulations are issued in final form. Although there is no formal comment period, public comments on the regulations are welcome on a continuing basis.

In consideration of the reasons set out in the preamble, 15 CFR Chapter III is amended as set forth below.

(Secs. 4, 5, 6, 7, 13, 15, 17(d) and 21, Pub. L. 96–72 (50 U.S.C. app. 2401 *et seq.*); Executive Order 12214 (45 FR 29783, May 6, 1980); Departmental Organization Order 10–3 (45 FR 6141, January 25, 1980); International Trade Administration Organization and Function Order 41–1 (45 FR 11862, January 30, 1980))

Kent N. Knowles,

Director, Office of Export Administration.

1. Supplement 1 to Part 385 is revised to read as follows:

Supplement No. 1 to Part 385—Advisory Notes for Selected CCL Entries

2018A Specialized machinery, equipment, gear, and specially designed parts and accessories therefor, specially designed for the examination, manufacture, testing, and checking of the arms, ammunition, appliances, machines, and implements of war.

Note.—Licenses are likely to be approved for export to satisfactory end-users of equipment used to determine the safety data of explosives, as required by the International Convention on the Transport of Dangerous Goods (C.I.M.), articles 3 and 4 in Annex 1 RID, provided that such equipment will be used only by the railway authorities of current C.I.M. members, or by Government accredited testing facilities in those countries, for the testing of explosives to transport safety standards, as follows:

(a) Equipment for determining the ignition and deflagration temperatures;

(b) Equipment for steel-shell tests;

(c) Drop hammers not exceeding 20 kg in weight for determining the sensitivity of explosives to shock;

(d) Equipment for determining the friction sensitivity of explosives when exposed to charges not exceeding 36 kg in weight.

1081A Machinery for use in the manufacture of aircraft, as follows:

(a) Machinery specially designed for the working or forming of aircraft sheet, plate or extrusion; or

(b) Machinery specially designed for the milling of aircraft skin.

Note.—Licenses are likely to be approved for export to satisfactory end-users provided that the machinery does not present an improvement on machinery in production before the 1st January of the year ten years preceding the year of the proposed export.

1091A (a) Units for numerically controlling simultaneously coordinated (contouring and continuous path) movements of machine tools and dimensional inspection machines in two or more axes, *except units having all of the following characteristics:*

(1) Hardwired (not softwired, i.e., not Computerized Numerical Control (CNC));

(2) No more than two contouring interpolating axes can be simultaneously coordinated (interpolating is understood to be any mathematical function including linear and circular; the units may have one or more positioning axes in addition to two contouring axes. The units may have more than one set of two contouring axes (e.g. units controlling two independent railheads on a vertical turret lathe), provided a separate feedrate number is required for each set of two contouring axes, and a single feedrate number (standard or optional) does not control more than two contouring axes);

(3) Minimum programmable increment equal to or greater (coarser) than 0.001 mm (0.0004 in.); and

(4) Without interface to allow direct computer input;

(b) Machine tools and dimensional inspection machines, which according to the manufacturer's technical specifications can be equipped with controls described in sub-entry (a) above, *except:*

(1) Boring mills, milling machines, and machining centers, having all of the following characteristics:

(i) Maximum slide travel in any axis equal to or less than 3,000 mm (10 ft.);

(ii) Positioning accuracy of any axis equal to or greater than ±0.01 mm per 300 mm (0.0004 in./ft.) and 0.005 mm for each additional 300 mm (.0002 in./additional ft.);

(iii) Spindle horsepower equal to or less than 20 kW (25 hp);

(iv) Single-working spindle;

(v) Axial and radial axis motion measured at the spindle axis in one revolution of the spindle equal to or greater than $D \times 2 \times 10^{-5}$ TIR (peak-to-peak) where D is the spindle diameter; and

(vi) Not more than 3 axes capable of simultaneously coordinated contouring motion regardless of the NC unit connected to the machine;

(2) Machine tools (other than the machines described in sub-entry (1) above) and dimensional inspection machines having all of the following characteristics:

(i) Positioning accuracy of any axis equal to or greater than ±0.01 mm per 300 mm

(0.0004 in./ft.) and 0.005 mm for each additional 300 mm (0.0002 in./additional ft.);

(ii) Radial axis motion measured at the spindle axis equal to or greater than 0.0008 mm (0.00003 in.) TIR (peak-to-peak) in one revolution of the spindle (for lathes and other turning machines); and

(iii) Not more than 3 axes capable of simultaneously coordinated contouring motion regardless of the NC unit connected to the machine; (the machines in sub-entry (b)(*1*)(*iv*) above may have multiple tool heads or turrets, but only one working spindle (standard or optional) may be operative at a time; the machines defined in sub-entries (b)(*1*)(*vi*) and (b)(*2*)(*iii*) above may have more than one work station, but each station shall be limited to 2-axes contouring (e.g. vertical turret lathes with two independent railheads). The machines may have one or more discrete positioning mode axes (e.g. discrete positioning index table) in addition to the three contouring axes. Secondary contouring axes parallel to primary contouring axes (e.g. W-axis of a boring mill that has a primary Z-axis) are not to be considered when determining the number of contouring axes; the value of the positioning accuracy described in sub-entries (b)(*1*)(*ii*) and (b)(*2*)(*i*) above does not include the width of blacklash. This value is determined by the usual statistical methods (random tests), i.e. by approaching from only one direction a minimum of five measurement points up to a maximum of twenty-five measurement positions as random tests along one axis. National standards, e.g. the German VDI standards No. 2354, sheet 1 and/or the United States NMTBA standard ("Definition and Evaluation of Accuracy and Repeatability for Numerically-controlled Machine-Tools," August 1972), can be taken as binding standards for this measuring method);

(c) Direct Numerical Control (DNC) systems consisting of a dedicated stored program computer acting as a host computer and controlling, on-line or off-line, one or more numerically-controlled machine tools or inspection machines, as defined in sub-entry (b) above, related software, and interface and communication equipment for data transfer between the host computer memory, the interpolation functions, and the numerically-controlled machine tools; and

(d) Specially designed sub-assemblies which, according to the manufacturer's technical specifications, can upgrade the capabilities of numerical control units and machine tools to meet the specifications described in sub-entries (a), (b), or (c) above.

Note.—Licenses are likely to be approved for export to satisfactory end-users of Computer Numerical Control (CNC) units for uses other than aerospace, provided that:

(a) At the time of export, the units are mounted on non-controlled machine tools or equipment;

(b) The CNC units are designed to have all of the following characteristics:

(1) No more than two contouring interpolating axes can be simultaneously coordinated ("Interpolating" is understood to be any mathematical function including linear and circular. Units may not have additional positioning axes);

(2) The cabinet shall be designed for only 2-axes operation (i.e. there shall be no additional card rack locations, wiring provisions for more than two servo-loops, nor physical space for later additions of these types of items);

(3) Memory is limited to and not capable of being extended beyond that enabling a maximum of two-axes simultaneous velocity and path generation, plus 400 characters (8-bit) of part program storage;

(4) Power supply is limited to two-axes operation;

(5) Minimum programmable increment equal to or greater (coarser) than 0.001 mm; and

(6) Without interface to enable data exchange with another computer;

(c) The information exported with and pertaining to the control unit shall:

(1) Be limited to machine language, binary format, control software enabling a maximum of two-axes simultaneous velocity and path generation;

(2) Not include flow charts, logic diagrams, nor source program documentation for the control software;

(3) Reflect only two-axes parameters in all electrical/mechanical installation, operation, or maintenance of documentation.

2120A Cryogenic equipment, the following:

(a) * * *

(b) Electrical, magnetic, and electronic equipment or components, and electrical conductors, specially designed for operation continously or discontinuously at ambient temperatures below −274° F (−170° C), as follows:

(1) Superconductive metals, alloys, compounds, composites, and intercalate materials, *except:*

(i) Superconductive wire having a filament cross-sectional area of 4.42 x 10^{-3} sq.mm. (or 75 microns diameter) or greater; or

(ii) Superconductive niobium-titanium wire having a filament cross-sectional area of 1.26 x 10^{-3} sq.mm. (or 40 microns diameter) or greater in a copper matrix;

(2) * * *

(3) * * *

(4) * * *

(c) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of individual shipments of niobium-titanium wire covered by sub-entry (b)(1) above having a filament cross-sectional area of 9.5 x 10^{-5} sq.mm. (or 11 microns diameter) or greater in a copper matrix, in quantities not exceeding 10 kg.

1131A Pumps (except vacuum pumps listed under entry No. 1129) having *any* of the following characteristics:

(a) * * *

(b) Having all flow contact surfaces made of 90 percent or more tantalum, titanium, or zirconium, either separately or combined, *except when such surfaces are made of materials containing more than 97 percent and less than 99.7 percent titanium; and*

(c) * * *

Note.—Licenses are likely to be approved for export of pumps covered by sub-entry (b) above to bona fide civil end-users for non-aerospace end-uses.

1133A Valves, cocks and pressure regulators having all flow contact surfaces made of 90% or more tantalum, titanium or zirconium, either separately or combined, *except when such surfaces are made of materials containing more than 97% and less than 99.7% titanium.*

Note.—Licenses are likely to be approved for export of valves, cocks and pressure regulators to bona fide civil end-users for non-aerospace end-uses.

1205A Electro-chemical, semi-conductor, and radioactive devices for the direct conversion of chemical, solar, or nuclear energy to electrical energy, as follows:

(a) Electro-chemical devices, as follows:

(1) Fuel cells operating at temperatures of 392° F (200° C) or less, including regenerative cells, i.e., cells for generating electric power, to which all the consumable components are supplied from outside the cell (the temperature of 392° F (200° C) or less is intended to refer to the fuel cell and not the fuel conditioning equipment, which may be either an ancillary or an integral part of the fuel cell battery and which may operate at over 392° F (200° C));

(2) * * *

(3) * * *

(4) * * *

(b) * * *

(c) Power sources other than nuclear reactors based on radioactive materials systems, *except:*

(1) *Those having an output power of less than 0.5 Watt and a total weight of more than 200 lbs. (90.7 kg); or*

(2) *Those specially designed and developed for medical use within the human body; and*

(d) * * *

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of fuel cells covered by sub-entry (a)(1) above, having a maximum output power level greater than 10 kW using gaseous pure hydrogen and oxygen/air reactants, alkaline electrolytic, and a catalyst support by carbon either pressed on a metal mesh electrode, or attached to a conducting porous plastic.

2. Licenses are likely to be approved for export to satisfactory end-users of devices covered by sub-entry (c) above, having an output power of 0.5 Watt or more and an overall efficiency of 6 percent or less. (The overall efficiency is obtained by dividing the electrical output, expressed in watts, by the thermal input, expressed in watts. It is understood that this efficiency is to be measured at the beginning of life.)

3261A Neutron generator systems, including tubes, designed for operation without an external vacuum system and utilizing electrostatic acceleration to induce a tritium-deuterium nuclear reaction; and specially designed parts therefor.

Note.—Licenses are likely to be approved for the export to satisfactory end-users of tubes and systems whose technical specifications are essentially the same as those for previously approved exports, provided that they are for civil use.

1312A Presses and specialized controls, accessories, and parts therefor, as follows:

(a) * * *

(b) Hydraulic presses, as follows:

(1) Vertical presses having a total rated force of over 10,000 tons; or

(2) Horizontal presses having a total rated force of over 5,000 tons;

(c) Isostatic presses, as follows (isostatic presses are those capable of pressurizing a closed cavity through various media (gas, liquid, solid particles, etc.) to create equal force in all directions within the cavity upon a workpiece or material):

(1) Capable of achieving a maximum working pressure of 20,000 psi (1,406 kg/cm²) or greater and possessing a chamber cavity with an inside diameter in excess of 16 inches (40.6 cm); or

(2) Capable of achieving a maximum working pressure of 5,000 psi (351 kg/cm²) or greater and having a controlled thermal environment within the closed cavity, *except those possessing a chamber cavity with an inside diameter of less than 5 inches (127 mm) and which are also capable of achieving and maintaining a controlled thermal environment only between +176° F (+80° C) and −31° F (−35° C);* and

(d) Control equipment, accessories, and parts which are specially designed for the above presses.

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of hydraulic presses covered by sub-entry (b) above, provided that:

(i) The total rated force is less than 30,000 tons for vertical presses, and 10,000 tons or less for horizontal presses;

(ii) The presses are not specially designed for use in forming aircraft, missile or space vehicle parts, in powder metallurgy or in ceramics production; and

(iii) The presses could not reasonably be used for strategic purposes.

2. Licenses are likely to be approved for export to satisfactory end-users of isostatic presses covered by sub-entry (c) above, provided that:

(i) Isostatic presses having a controlled thermal environment within the closed cavity are limited as follows:

(a) Maximum working pressure not exceeding 20,000 psi (1,406kg/cm²);

(b) Chamber cavity with an inside diameter not exceeding 10 inches (25.4 cm);

(c) Capable of achieving and maintaining a controlled thermal environment within the closed cavity of no greater than 1,200° C;

(ii) Isostatic presses, other than those dealt with under sub-paragraph (i) above, are limited as follows:

(a) Maximum working pressure not exceeding 30,000 psi (2,109 kg/cm²);

(b) Chamber cavity with an inside diameter not exceeding 20 inches (50.8); and provided the equipment will be used for specific non-strategic applications and will not be used for any nuclear or aerospace applications.

3. Licenses are likely to be approved for export to satisfactory end-users of normal amounts of equipment covered by sub-entry (d) above to service presses licensed for export under Note 1 above.

1353A Equipment specially designed for the manufacture of communication cable described in entry No. 1526.

Note.—Licenses are likely to be approved for export to satisfactory end-users of equipment specially designed for the manufacture of cable covered by entry No. 1526 sub-entry II (b).

1355A Machinery and equipment for the manufacture of electronic equipment, components and materials; related test gear; parts and specialized controls and accessories thereof, as follows:

(a) * * *

(b) Equipment for the manufacture of semi-conductor, acoustic wave and film memory devices, of electronic equipment and components covered by sub-entry 1564II (b) and (c), and of parts, materials and subassemblies thereof, as follows:

(1) Equipment for the processing of semi-conductor materials for the manufacture of devices, equipment and components specified in the heading of this sub-entry as follows:

(i) * * *

(ii) Crystal pullers, furnaces, and gas systems, as follows:

(a) * * *

(b) * * *

(c) * * *

(d) * * *

(e) Crystal pullers having any of the following characteristics:

(1) * * *

(2) Capable of operation at pressures above 10^5 pascals (1 atmosphere absolute);

(3) * * *

(f) * * *

(iii) * * *

(iv) * * *

(v) * * *

(vi) * * *

(vii) * * *

(viii) * * *

(ix) * * *

(2) * * *

(3) * * *

(4) * * *

(5) * * *

(6) * * *

Note.—Licenses are likely to be approved for satisfactory civil end-users of crystal pullers covered by subparagraph (b)(1)(ii)(e)(2) above which can be operated at pressures up to 2.5×10^5 pascals (2.5 atmospheres absolute).

1361A Wind tunnels, as follows:

(a) Supersonic (Mach 1.4 to Mach 5), hypersonic (Mach 5 to Mach 15) and hypervelocity (above Mach 15) wind tunnels, *except wind tunnels specially designed for educational purposes and having a test section size (measured internally) of less than 10 in.* (25 cm). (By "test section size" is understood the diameter of the circle, or the side of the square, or the longest side of the rectangle constituting possible shapes of the test section.);

(b) * * *

(c) * * *

(d) Specially designed parts and accessories.

Notes.— 1. Licenses are likely to be approved for export to satisfactory end-users of supersonic wind tunnels which are capable of Mach velocities of 1.4 or more but less than 5, and are not specially designed for or fitted with means of preheating the air.

2. Licenses are likely to be approved for export to satisfactory end-users of specialized parts and assemblies covered by sub-entry (d) for wind tunnels previously exported under Note 1, provided that such parts and assemblies will not upgrade the performance of the wind tunnel and, for normally-consumable replacement parts, will not exceed a 6-month supply.

1371A Anti-friction bearings, as follows:

(a) Ball and roller bearings having an inner bore diameter of 10 mm or less and tolerances of ABEC 5, RBEC 5 (or national equivalents) or better and either of the following characteristics:

(1) Made of special materials, *i.e.* with rings, balls or rollers made from any steel alloy or other material including, but not limited to high-speed tool steels, Monel metal, beryllium, metaloids, ceramic, and sintered metal composites, *except the following: low-carbon steel; SAE–52100 high carbon chromium steel; SAE–4615 nickel molybdenum steel; AISI–440C (SAE 51440C) stainless steel; or national equivalents; and/or*

(2) Manufactured for use at normal operating temperatures over 302° F (150° C) either by use of special materials or by special heat treatment;

(b) Ball and roller bearings *except separable ball bearings and thrust ball bearings,* having an inner bore diameter exceeding 10 mm and having tolerances of ABEC 7, RBEC 7 (or national equivalents) or better (ABEC 5 in the case of hollow bearings) and either of the following characteristics:

(1) Made of special materials, *i.e.* with rings, balls or rollers made from any steel alloy or other material including, but not limited to high-speed tool steels, Monel metal, beryllium, metaloids, ceramic, and sintered metal composites, *except the following: low-carbon steel; SAE–52100 high carbon chromium steel; SAE–4615 nickel molybdenum steel; AISI.440C (SAE 51440C) stainless steel; or national equivalents;* and or

(2) Manufactured for use at normal operating temperatures over 302° F (150° C) either by use of special materials or by special heat treatment;

(c) Ball and roller bearings having tolerances better than ABEC 7 (or national equivalents); and

(d) Bearing parts usable only for bearings covered by this entry, as follows: outer rings, inner rings, retainers, balls, rollers, and sub-assemblies. (See § 376.7.)

Note.—Licenses are likely to be approved for export of reasonable quantities of bearings covered by this item to satisfactory civil end-users which have furnished assurances that the bearings will be incorporated in equipment previously imported from Canada or countries in Country Group T or V.

1485A Compasses, gyroscopes, accelerometers, and inertial equipment, as follows:

(a) * * *

(b) Integrated flight instrument systems for aircraft which include gyrostabilizers and/or automatic pilots (An integrated flight instrument system is a primary instrument display system of attitude and azimuth with facilities for giving maneuver guidance information to the pilot and often integrated with an autopilot to the extent of embodying a common unit for setting up the required demands);

(c) * * *

(d) Gyrostabilizers used for other purposes than aircraft control, *except those for stabilizing an entire surface vessel;*

(e) * * *

(f) Accelerometers with a threshold of 0.005 g or less, or a linearity error within 0.25 percent of full scale output or both, which are designed for use in intertial navigation systems or in guidance systems of all types;

(g) Gyros with a rated free directional drift rate (rated free precession) of less than 0.5 degree (1 Sigma or r.m.s.) per hour in a 1 g environment;

(h) * * *

(i) Specially designed parts and components, and test, calibration, and alignment equipment for the above.

Note.—Licenses are likely to be approved for export to satisfactory end-users of equipment, as follows:

(a) Types and series covered by sub-entry (b) above, provided the equipment has been in normal civil use for more than two years, is standard equipment of aircraft excluded from control under entry No. 1460, and is, or is to be, installed in civilian aircraft.

(b) Types and series covered by sub-entry (d) above, provided the equipment has been in normal civil use for more than two years and is intended for a clearly civil application in the importing country.

(c) Parts, components and equipment covered by sub-entry (i) above, provided they are not also covered by sub-entries (f) and (g) above, and are intended for use with exports meeting the conditions of sub-paragraphs (a) and (b) of this Note.

1501A Navigation, direction finding, radar and airborne communication equipment, as follows: (See also entry No. 1485 sub-entries (b) and (h), and entry No. 2120 sub-entries (b) and (c).)

(a) Airborne communication equipment and specialized parts and components therefor, having *any* of the following characteristics:

(1) Designed to operate at frequencies greater than 156 MHz;

(2) Incorporating facilities for:

(i) The rapid selection of more than 200 channels per equipment, or

(ii) Equipment using frequency synthesis techniques (see also entry No. 1531), *except equipment operating in the frequency range of 108 to 136 MHz with 720 channels or fewer at not less than 25 kHz spacing, and which has been in normal civil use for at least one year;*

(3) Pressurized throughout;

(4) Rated for continuous operation over a range of ambient temperatures extending from below −55° C to +55° C; or

(5) Designed for modulating methods employing any form of digital modulation using time and frequency redundancy such as "Quantized Frequency Modulation" (QFM);

(b) Navigation and direction finding equipment (and specialized parts and accessories, specialized testing or calibrating equipment and training or simulating equipment therefor), as follows:

(1) Airborne navigation equipment and direction finding equipment, as follows:

(i) Designed to make use of "Doppler" frequency phenomena;

(ii) Utilizing the constant velocity and/or rectilinear propagation characteristics of electromagnetic waves having frequency less than 4×10^{14} Hz (0.75 micron);

(iii) Radio altimeters, the following:

(*a*) Pulse modulated;

(*b*) Frequency modulated having a displayed electrical output accuracy better than ±3 feet (±0.914 m) over the range between 0 and 100 feet (30.4 m) or better than ±3 percent above 100 feet (30.4 m); or

(*c*) Frequency modulated which have been in normal civil use for less than one year;

(iv) Direction finding equipment operating at frequencies greater than 5 MHz, *except equipment specially designed for search and rescue purposes, provided that the receiver operates on a crystal controlled fixed frequency of 121.5 MHZ or an alternating frequencies of 121.5 MHz and 243 MHz;*

(v) Pressurized throughout; or

(vi) Rated for continuous operation over a range of ambient temperatures extending from below −55° C to above +55° C;

(2) Ground and marine equipment for use with airborne navigation equipment utilizing the constant velocity and/or the rectilinear propagation characteristics of electromagnetic waves having frequency less than 4×10^{14} Hz (0.75 micron); or

(3) Ground and marine direction finding equipment operating at frequencies greater than 30 MHz; and

(c) Radar equipment and specialized parts and accessories, specialized testing or calibrating equipment and training or simulating equipment therefor, as follows: (For Lidar Equipment see entry No. 1522.)

(1) Airborne radar equipment; or

(2) Ground and marine radar equipment having one or more of the following features:

(i) Operating at a frequency not in normal civil use or at a frequency of more than 10.5 GHz;

(ii) Operating at a frequency of less than 1.5 GHz and having a peak output power from the transmitter greater than 2.5 MW; or operating at a frequency within the range of 1.5 to 3.5 GHz and having a peak output power from the transmitter greater than 1.5 MW; or operating at a frequency within the range of 3.5 to 6 GHz and having a peak output power from the transmitter greater than 1 MW; or operating at a frequency within the range of 6 to 10.5 GHz and having a peak output power from the transmitter greater than 500 kW;

(iii) Operating at a frequency of less than 3.5 GHz and having an 80 percent or better probability of detection for a 10 sq. m. target at a free space range of 250 nautical miles; or operating at a frequency within the range of 3.5 to 10.5 GHz and having an 80 percent or better probability of detection for a 10 sq. m. target at a free space range of 100 nautical miles;

(iv) Utilizing other than pulse modulation with a constant and/or staggered pulse repetition frequency, in which the carrier frequency of the transmitted signal is not changed deliberately between groups of pulses, from pulse to pulse or within a single pulse, *except civil commercial airport radars using a carrier frequency that may change from pulse to pulse between two fixed frequencies separated in time and in frequency by constant magnitudes;*

(v) Utilizing a Doppler technique for any purpose, other than M.T.I. systems using a conventional double or triple pulse delay line cancellation technique *except those utilized for surveillance and control radar for aerial navigation in civil airports;*

(vi) Including any digital signal processing techniques used for automatic target tracking, or having a facility for electronic tracking;

(vii) Including signal processing techniques other than those covered by sub-entry (c)(2)(vi) above, which have been in normal civil use for a period of less than two years; or

(viii) In the case of ground radar, having been in commercial use for a period of less than one year.

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of commercial airborne equipment needed to equip civil aircraft, or as normal standard equipment incorporated in civil aircraft being exported for civil commercial use, and not containing characteristics in sub-entry (a)(5) above.

2. Licenses are likely to be approved for export to satisfactory end-users of navigation equipment covered by sub-entry (b)(1)(i) above, provided that it is to be installed in civil aircraft or helicopters, and is normal standard equipment of a type installed in civil aircraft or helicopters in TV country groups.

3. Licenses are likely to be approved for export to satisfactory end-users of standard commercial airborne equipment listed in sub-entries (b)(1) (ii) and (iii) above, needed to equip civil aircraft, or as normal standard equipment incorporated in civil aircraft being exported for civil commercial use, provided that such equipment is equivalent in all characteristics and performance to standard equipment of aircraft not subject to control, and which:

(a) For equipment covered by sub-entry (b)(1)(ii) above, is in conformity with ICAO standards and assures no function exceeding those resulting from such standards, and is not designed to make use of hyperbolic grids at frequencies greater than 3 MHz. (Standard commercial airborne equipment designed to make use of hyperbolic grids at frequencies of less than 3 MHz may be exported if coordinate conversion equipment, which has been in normal civil use for less than one year, or which could not be shipped under the provisions of entry No. 1565, is not included and is not separately supplied), and

(b) For equipment covered by sub-entry (b)(1)(iii) above, are frequency modulated radio altimeters which have been in normal civil use for a period of more than one year.

4. Licenses are likely to be approved for export to satisfactory end-users of ground equipment for use at civil airports or for civil use in association with airborne equipment which meets the criterion of Note 3 to sub-entry (b)(1)(ii) above, and approved for export, provided that such equipment:

(a) is in conformity with ICAO standards and assures no function exceeding those resulting from such standards;

(b) is not designed to make use of hyperbolic grids at frequencies greater than 3 MHz.

5. Licenses are likely to be approved for export to satisfactory end-users of equipment covered by sub-entry (b)(3) above, provided:

(a) The equipment is to be installed at civil airports or for use on civil air routes;

(b) The equipment is designed to operate at frequencies between 30 MHz and 157 MHz, excluding single side band equipment;

(c) The equipment employs a loop system or a system employing a number of spaced vertical aerials uniformly disposed around the circumference of a circle, excluding electronically commutated types.

6. Licenses are likely to be approved for export to satisfactory end-users of equipment covered by sub-entry (c) above, when it is to be installed in civil aircraft, provided that this equipment:

(a) Has been in normal commercial service for at least one year;

(b) Is specially designed for use as a commercial weather radar;

(c) Is a normal and reasonable equipment for such civil aircraft; and

(d) Does not contain significant advanced technology of strategic value for other applications.

7. Licenses are likely to be approved for export to, satisfactory end-users of secondary radar equipment covered by sub-entry (c) above, designed specifically for civil air traffic identification and control purposes.

8. Licenses are likely to be approved for export to satisfactory end-users of the following:

(a) Radar equipment covered only sub-entries (c)(2) (i), (ii) and/or (iii) above, provided that both of the following conditions are met:

(i) It is specially designed for the surveillance and coordination of airfield surface traffic; and

(ii) It is to be installed at airports operating scheduled commercial flights.

(b) Radar equipment covered only by sub-entries (c)(2) (ii) or (iii) above, or by both, provided that all the following conditions are met:

(i) Operating at a frequency of not more than 1.5 GHz and having a peak output power from the transmitter not greater than 5 MW; or operating at a frequency within the range of 1.5 to 3.5 GHz and having a peak output power not greater than 2.5 MW;

(ii) Having an 80 percent or better probability of detection for a 10 sq. m. target at a free space range of 270 nautical miles;

(iii) Having a pulse repetition frequency exceeding 300 pulses per second; and

(iv) It is to be installed for air traffic control of scheduled international commercial flights;

(c) Radar equipment covered only by sub-entries (c)(2) (iv) and/or (v) above, provided it is to be installed for air traffic control purposes in international airports and has been in normal civil use for a period of not less than three years;

(d) Radar equipment covered by sub-entry (c)(2)(vi) above, provided it is specially designed for marine, harbor or meteorological use, or has been in normal civil use for not less than three years;

(e) Radar equipment covered only by sub-entry (c)(2)(vii) above, provided it is specially designed for marine (or harbor) use, or radar equipment covered only by sub-entries (c)(2) (vii) or (viii) above, or both, provided it is specially designed for meteorological observation.

1502A Communication, detection or tracking equipment of a kind using ultra-violet radiation, infrared radiation or ultrasonic waves; *except ultrasonic devices which operate in contact with a controlled material to be inspected, or which are used for industrial cleaning, sorting or materials handling, industrial and civilian intrusion alarm, traffic and industrial movement control and counting systems, medical applications, emulsification, homogenisation, or simple educational or entertainment devices; underwater ultrasonic communications equipment designed for operation with amplitude modulation and having a communications range of 500 m or less (sea state 1), a carrier frequency of 40 to 60 kHz and a carrier power supplied to the transducer of 1 W or less; industrial equipment employing cells not described in entry Nos. 1548 or 1550; industrial and civilian intrusion alarm, traffic and industrial movement control and counting systems; medical equipment; industrial equipment used for inspection, sorting or analysis of the properties of materials; simple educational or entertainment devices which employ photo cells; flame detectors for industrial furnaces; equipment for non-contact temperature measurement for laboratory or industrial purposes utilizing a single detector cell with no scanning of the detector; or instruments capable of measuring radiated power or energy having a response time constant exceeding 10 milliseconds;* and specialized parts therefor.

Note.—Licenses are likely to be approved for export to satisfactory end-users of infra-red geodetic equipment covered by this entry, provided that the equipment uses a lighting source other than a laser and is manually operated, or that it uses a lighting source (other than a laser or a light-emitting diode) remote from the measuring equipment.

1510A Acoustic and/or ultrasonic systems or equipment specially designed for detecting or locating underwater or subterranean objects or features, and specially-designed components of such systems or equipment (including but not limited to hydrophones and transducers, towed hydrophone arrays, software therefor, and beamformers), *except:*

(i) *Marine systems or equipment, as follows:*

(A) * * *

(B) Passive (receiving, whether or not related in normal application to separate active equipment) acoustic hydrophones and/or transducers having *all* of the following characteristics:

(1) Incorporating sensitive elements made of piezoelectric ceramics or crystal, and with a sensitivity no greater than −192 dB (reference 1 volt per micropascal);

(2) Not designed for operation at depths greater than 100 meters;

(3) Independently mounted or configured and not reasonably capable of assembly by the users into a towed hydrophone array;

(ii) * * *

Notes.—1. Licenses are likely to be approved for export for civil end-use by civil end-users of acoustic hydrophones and transducers which have all of the other characteristics of sub-entry (i)(B), but which either:

(a) Have a sensitivity no greater than −204 dB (reference 1 volt micropascal), and are designed for operation at greater than 100 meters depth but not greater than 1,000 meters depth; or

(b) Are not acceleration compensated, have a sensitivity no greater than −180 dB (reference 1 volt per micropascal) and are not designed for operation at depths greater than 100 meters.

2. Licenses are likely to be approved for export for civil end-use by civil end-users of towed acoustic hydrophone arrays having all of the following characteristics:

(a) Not specially designed for operation at greater than 100 meters depth or at tow speeds in excess of 8 knots;

(b) Not incorporating temperature or heading sensors;

(c) Having hydrophone groups uniformly spaced at not less than 25 meters and not more than 60 meters;

(d) Having an assembled diameter of 40 mm or greater and using metallic strength members only;

(e) Not having multiplexed hydrophone group signals;

(f) Not having a configuration for multiple or overlapping acoustic aperture operation;

(g) Not having characteristics better than those specified in sub-entries (i)(B) (1) and (2) above;

(h) Not having associated processing equipment which provides any of the following features:

(1) Electronically-steerable beamforming capabilities;

(2) Side-lobe suppression techniques such as shading coefficients;

(3) On-line real-time processing or off-line batch pre-processing capabilities exceeding the limits specified in entries 1529 and 1565.

1519A Single and multi-channel communications transmission equipment, including terminal, intermediate amplifer or repeater equipment and multiplex equipment used for communications (line, cable, optical fiber cable, or radio) systems, and data modems making use of the aforementioned communication systems and associated multiplex equipment, *except telemetering, telecommand and telesignalling equipment designed for industrial purposes, together with data transmission equipment not intended for the transmission of written or printed text and specialized parts, accessories and test equipment therefor (by telemetering, telecommand and telesignalling equipment is meant: sensing heads for the conversion of information into electrical information, the systems used for its long-distance transmission, the processes used to translate electrical information into coded data (telemetering), into control signals (telecommand), and into display signals (telesignalling)); facsimile equipment other than that employing cipher, cryptographic and/or coding devices and equipment that are designed to ensure the secrecy of communications and thus prevent clear reception by anyone other than the intended receiver (see Supplement No. 2 to Part 370);*

equipment employing exclusively the direct current transmission technique; electronic measuring equipment, suitable for use with PCM transmission equipment defined in CCITT recommendation series G 700 (ITU Geneva), as follows:

(a) Employing analog transmission techniques with analog input and output, designed to deliver, carry or receive baseband frequencies higher than 19 MHz into, or in, a communications system, but only higher than 300 kHz for equipment suitable for use with submarine cable (analog transmission techniques include, inter alia, frequency division multiplex (FDM));

(b) Employing digital transmission techniques designed for operation at a data signalling rate exceeding 2.1 Megabits per second, with analog input and output, designed for use on communications circuits (digital transmission techniques include, inter alia, pulse code modulation (PCM));

(c) Data communications equipment employing digital transmission with digital input and output, including telegraphic and data transmission, having any of the following characteristics:

(1) Designed for operation at a data signalling rate in bits per second, excluding servicing and administrative channels, numerically exceeding either:

(i) 4,800; or

(ii) 160 percent of the channel (or sub-channel) bandwidth in Hertz;

(2) Employing an automatic error detection and correction system having both of the following characteristics:

(i) Retransmission is not required for correction; and

(ii) A data signalling rate exceeding 300 bits per second; and

(d) Components, accessories, and sub-assemblies specially designed for the above equipment, and test equipment specially designed for the equipment covered by sub-entry (b) above, except connectors for use with optical fibers or cable with a repeatable coupling loss of 0.5 dB or more.

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of equipment covered by sub-item (a) above, and components, accessories and sub-assemblies thereof, as follows:

(a) Equipment specially designed for the transmission of television signals by cable between camera and studio or between studio and television transmitter not exceeding 50 miles (80 km) for a link with respect to any one installation. (For radio relay links see entry No. 1520.)

(b) Equipment to be used for closed circuit television or television distribution (community aerial systems and cable television systems) with an upper frequency limit of 960 MHz.

(c) Equipment designed to deliver, carry or receive baseband frequencies up to and including 62 MHz.

2. Licenses are likely to be approved for the export to satisfactory end-users of equipment covered by sub-item (b) above, and components, accessories and sub-assemblies and cable therefor, provided that it is for other than submarine use, is to be permanently installed in a circuit operated by the civilian authorities of the importing country, and is to be used for general commercial traffic, as follows:

(a) A total digital bit rate at the highest level multiplex point of 8.5 million bits per second or less; and either

(b) A total number of voice channels per each physical bearer (wire or radio) of 120 or less; or

(c) A monochrome or color television channel with a maximum nominal bandwidth of 6 MHz, and associated sound channels.

3. Licenses are likely to be approved for the export to satisfactory end-users of the data modems described in sub-entry (c)(1) above, conforming to CCITT recommendations and/or specially designed for civil end-use, and operating at speeds up to 9,600 bits per second or 320% of the channel (or sub-channel) bandwidth in hertz, provided they are to be permanently installed in a circuit operated by the civilian authorities of the importing countries for general commerical traffic.

1520A Radio relay communications equipment designed for use at frequencies exceeding 960 MHz, and components, accessories and sub-assemblies therefor.

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of equipment covered by this item, and components, accessories and sub-assemblies therefor, specially designed for the transmission of television signals between camera and studio or between studio and television transmitter, and not exceeding a line of sight distance with respect to any one installation.

2. Licenses are likely to be approved for export to satisfactory end-users of equipment covered by this item, and components, accessories and sub-assemblies therefor, as follows:

(a) Ground communication radio equipment for use with temporary fixed services operated by the civilian authorities of the importing country and designed to be used at fixed frequencies not exceeding 13.5 GHz with a power output of not more than 5 watts;

(b) Equipment to be permanently installed in a circuit operated by the civilian authorities of the importing country for civil television transmission nor for general commerical traffic, provided that:

(1) Associated multiplex equipment is considered separately under the provisions of entry No. 1519; and

(2) No equipment with a base bandwidth exceeding the limits set forth in Note 3 to entry No. 1519 is included.

3. Licenses are likely to be approved for export to satisfactory end-users of equipment covered by this item, for communications satellite earth stations provided that it is to be installed for operation in the framework of an INTELSAT satellite communications system.

4. Licenses are likely to be approved for export to satisfactory end-users of equipment with a maximum capacity of 300 voice channels of 4 kHz each, components, accessories, sub-assemblies and specialized test equipment for industrial use, e.g. remote supervision, control and metering of oil and gas pipelines, public utility services (e.g. electricity networks) including telephone channels for the operation of such networks and the engineering service circuits required for the maintenance of telecommunications links.

5. Licenses are likely to be approved for the export to satisfactory end-users of tropospheric scatter communication equipment, and components, accessories and sub-assemblies therefor, covered by this entry, provide that it will be permanently installed at specified sites for civil communication purposes and has all of the following characteristics:

(a) Fixed frequency of 2.7 GHz or less;

(b) Frequency modulation;

(c) Power amplifier output of 10 kW or less.

1522A Lasers and laser systems (including active and passive components in semi-fabricated forms as well as in fabricated forms) and equipment containing them, as follows:

(a) Lasers and specially designed components and parts therefor, including amplification stages, *except the following when not contained in equipment:*

(i) * * *

(ii) * * *

(iii) * * *

(iv) * * *

(v) * * *

(vi) Nd: YAG lasers having an output wavelength of 1.06 micrometers with either of the following characteristics:

(1) A pulsed output not exceeding 0.5 joule per pulse and a maximum rated average single- or multi-mode output power not exceeding 10 watts or a continuous wave maximum rated single- or multi-mode output power not exceeding 50 watts;

(2) * * *

(vii) Nd: Glass lasers with both of the following characteristics:

(1) An output wavelength of 1.06 micrometers;

(2) A pulsed output not exceeding 0.5 joule per pulse;

(viii) * * *

(ix) * * *

(x) * * *

(b) Equipment containing lasers and laser systems, *except equipment listed below containing lasers listed in (a) above as exceptions:*

(i) Specially designed for industrial and civilian intrusion detection and alarm systems;

(ii) Specially designed for medical applications;

(iii) Equipment for educational and laboratory purposes;

(iv) Specially designed for traffic and industrial movement control and counting systems;

(v) Specially designed for detection of environmental pollution;

(vi) Optical spectrometers and densitometers;

(vii) Equipment containing continuous wave helium-neon gas lasers but see sub-entries (c) and (d) below;

(viii) Textile-cutting and textile-bonding equipment;

(ix) Paper cutting equipment;

(x) Equipment containing lasers for drilling diamond dies for the wire drawing industry;

(xi) Electronic daylight scanning equipment with auxiliary electronic

screening units especially designed for printing processes;

(xii) Laser-radar (lidar) equipment specially designed for surveying or meteorological observation;

(xiii) Consumer, disc-type video and audio recorders and reproducers;

(xiv) Price scanners (point of sale); and

(xv) Systems designed for surveying purposes; provided there is no capability of measuring range;

(c) * * *

(d) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of equipment listed in sub-entry (b) containing lasers described in (a) (vi)(1) and (vii) provided the lasers have a maximum pulsed output not exceeding 2 joules per pulse. The shipment of spare laser rods for equipment exported under this Note will be restricted to rods having no greater output power and/or energy capability than those originally exported with the equipment.

1526A Cable, as follows:

I. * * *

II. Communications cable, as follows:

(a) Submarine cable, as follows:

(1) Reversed-twist, double-armored cable used for towing or suspending and communicating with submerged devices;

(2) Unarmored or single-armored ocean cable having an attenuation of 1.8 dB per nautical mile (0.97 dB/km) or less, measured at a frequency of 600 kHz;

(b) Coaxial cable using a dielectric aired by discs, beads, spiral, screw, or any other means, with an inner diameter of the outer conductor of the cores greater than 14 mm (0.551 in.);

(c) Graded index or single-mode step index optical fiber communications cable and optical fibers therefor, having either of the following characteristics:

(1) An attenuation at any operating wavelength of 5 dB/km or less;

(2) A tensile strength greater than 7×10^9 N/m^2; or

(d) * * *

Notes.—1. Licenses are likely to be approved for the export to satisfactory end-users of cable covered by sub-entry II(a)(1) above when used for civil applications in oceanographic research or in natural resources exploration.

2. Licenses are likely to be approved for the export to satisfactory end-users of cable covered by sub-entries II (a)(2), (b) and (c) above, provided that:

(a) The cable is for a specific civil end-use;

(b) The quantities of cable required are normal for the purpose; and

(c) (applicable to sub-entry II(c) above only) The cable is not specially designed for underwater use.

1529A Electronic measuring, calibrating, counting, testing, and/or time interval measuring equipment, whether or not incorporating frequency standards, having any of the following characteristics:

(a) Equipment, as follows:

(1) * * *

(2) Designed for fixed ground use and containing frequency standard(s), with a stability over 24 hours of 1 part in 10^9 or better; or

(3) * * *

(b) Instruments, as follows:

(1) * * *

(2) * * *

(3) * * *

(4) Spectrum analyzers employing time compression of the input signal or FFT (Fast Fourier Transform) techniques;

(5) Incorporating computing facilities with user accessible reprogramming capability and an alterable memory of more than 8,192 bits;

(6) * * *

(c) * * *

(d) * * *

(e) * * *

(f) * * *

(g) * * *

(h) * * *

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of items covered only by sub-entry (a)(2) above, provided that:

(a) The stability over 24 hours is not better than 5 parts in 10^{10}; and

(b) The equipment is a reasonable requirement for the stated legitimate civil end-use.

2. Licenses are likely to be approved for export to satisfactory end-users of items covered by sub-entry (b)(4) above, having either of the following characteristics:

(a) Capable of computing 512 complex spectral lines in 200 milliseconds or more;

(b) Capable of computing 512 real spectral lines in 100 milliseconds or more;

3. Licenses are likely to be approved for export to satisfactory end-users of instruments covered by sub-entry (b)(5) above, provided that:

(a) The instruments have been designed for non-strategic use and by nature of design, software, microprogram control (firmware), specialized logic control (hardware) or performance are substantially restricted to the particular application for which they have been designed.

(b) The instruments are not covered by any other part of this entry and do not exceed the limits of Note 4 to entry No. 1565.

1531A Frequency synthesizers (and equipment containing such frequency synthesizers), as follows (frequency synthesizer means any kind of frequency source or signal generator, regardless of the actual technique used, providing a multiplicity of simultaneous or alternative output frequencies, from one or more outputs, controlled by, derived from or disciplined by a lesser number of standard (or master) frequencies):

(a) * * *

(b) Instrument frequency synthesizers and synthesized signal generators designed for ground laboratory use, producing output frequencies whose accuracy and short and long term stability are controlled by, derived from or disciplined by the input frequency or internal master standard frequency, and having any of the following characteristics:

(1) * * *

(2) * * *

(3) Electrically programmable (in that the output frequency can be controlled or selected by the injection of digitally coded electrical signals from an external control source) with a switching speed from one selected output frequency to another selected output frequency less than 10 milliseconds;

(4) * * *

(5) * * *

(6) * * *

(7) * * *

(c) * * *

(d) * * *

(e) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of equipment covered by sub-entry (b)(3) above, with a switching speed not less than 5 milliseconds.

1532A Precision linear and angular measuring systems and components, as follows:

(a) Contact-type systems and linear voltage differential transformers (LVDT) therefor, as follows:

(1) Systems having all of the following characteristics:

(i) Range equal to or less than 5 mm;

(ii) Linearity equal to or less than 0.1 percent;

(iii) Drift equal to or less than 0.1 percent per day at standard ambient test room temperatures ±1° C;

(2) Linear voltage differential transformers with no compensation networks and having either of the following characteristics:

(i) Range equal to or less than 5 mm;

(ii) Linearity equal to or less than 0.2 percent; (linearity measurements are made in the static mode);

(b) Linear measuring machines, *except optical comparators,* with two or more axes having both of the following characteristics:

(1) Range in any axis greater than 200 mm;

(2) Accuracy (including any compensation) less (finer) than 0.0008 mm per any 300 mm segment of travel;

(c) Angular measuring systems having an accuracy equal to or less than 1 second of arc, *except optical instruments, such as autocollimators, using collimated light to detect angular displacements of a mirror;*

(d) Non-contact type systems having either of the following characteristics:

(1) Effective probe measurement diameter less than 0.5 mm and drift less than 0.5 percent per day at standard ambient test room temperatures ±1° C;

(2) Linearity less than 0.3 percent and drift less than 0.5 percent per day at standard ambient test room temperature ±1° C.

Note.—Licenses are likely to be approved for export of equipment covered by this item to civil end-users not engaged in aerospace activities.

1533A Radio spectrum analyzers (i.e. apparatus capable of indicating the single-frequency components of multi-frequency signals), specialized components, accessories and parts therefor, as follows (for spectrum analyzers employing time compression of the input signal or FFT techniques, see entry No. 1529(b)(4)):

(a) * * *

(b) * * *

(c) * * *

(d) Incorporating computing facilities with user accessible reprogramming capability and an alterable memory of more than 8,192 bits;

(e) * * *
(f) * * *
(g) * * *

Note.—Licenses are likely to be approved for export to bona fide civil end-users for civil end-use of equipment covered by sub-entry (d) above.

1534A Flatbed microdensitometers, *except cathode-ray types*, specially designed parts, components and assemblies therefor, having any of the following characteristics:

(a) A recording or scanning rate exceeding 5,000 data points per second;

(b) A figure of merit better (less) than 0.1, defined as the product of the density resolution (expressed in density units) and the spatial resolution (expressed in micrometers);

(c) An optical density range greater than 0 to 4.

Notes.—1. Licenses are likely to be approved for export of equipment specially designed for medical applications, provided the equipment is a reasonable requirement for the stated application.

2. Licenses are likely to be approved for export to civil end-users for civil end-uses of equipment covered only by sub-entry (b) above, provided the spatial resolution is not better (less) than 2 micrometers and the density resolution is not better (less) than 0.01 in density units.

1537A Microwave equipment, including parametric amplifiers, capable at frequencies over 1 GHz (other than microwave equipment covered by entries 1501, 1517, 1520, 1526(I), 1529 and Supplement No. 2 to part 370), as follows:

(a) * * *
(b) * * *
(c) Waveguide components, as follows:
(1) * * *
(2) * * *

(3) Magnetic including gyro-magnetic waveguide components;

(d) TEM mode device using magnetic including gyro-magnetic properties;

(e) TR and anti-TR tubes and components therefor *except those designed for use in waveguides and having any of the following characteristics, which are in normal civil use for ground or marine radar:*

(i) Operating at a peak power not exceeding 3 MW and at a frequency of 1.5 GHz or less;

(ii) Operating at a peak power not exceeding 1.2 MW and at a frequency over the range of 1.5 GHz to 6 GHz; or

(iii) Operating at a peak power not exceeding 300 kW and at a frequency over the range of 6 GHz to 10.5 GHz;

(f) Assemblies and sub-assemblies in which the isolating base material functions as a dielectric (as used in stripline, microstrip or slotline) except for those items specifically designed for use in civil television systems to meet ITU standards and using as an isolating material paper base phenolics, glass cloth melamine, glass epoxy resin, polyethylene terephthalate or other isolating material with an operating temperature not exceeding 302° F (150° C);

(g) * * *

(h) Microwave assemblies and sub-assemblies having circuits fabricated by the same processes used in integrated circuit technology, which include active circuit elements (for acoustic wave devices, see entry No. 1586) (see also entry No. 1564);

(i) * * *

(j) Amplifiers (see also entry No. 1521);

(k) * * *

(l) * * *

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of items covered by sub-entries (c)(3) and (d) above, required as replacement parts in specific civil equipment not exceeding the capability of that which could be exported under entry No. 1501 or entry No. 1520, provided such parts do not upgrade the initial performance of that equipment.

2. Licenses are likely to be approved for export to satisfactory end-users of items covered by sub-entry (e) above required as replacement parts in specific civilian equipment not exceeding the capability of that which could be exported under entry No. 1501, provided such parts do not upgrade the initial performance of that equipment.

3. Licenses are likely to be approved for export to satisfactory end-users of items covered by sub-entry (f) above, designed and intended for use in civil telecommunications systems at frequencies allocated by the ITU for that purpose.

4. Licenses are likely to be approved for export to satisfactory end-users of items covered by sub-entry (h) above, for use at frequencies between 1 GHz and 3 GHz.

5. Licenses are likely to be approved for export to satisfactory end-users of equipment containing parametric amplifying or paramagnetic amplifiers covered by sub-entry (j) above;

(a) Specially designed for medical applications or for use in simple educational devices and operating at ISM frequencies; or

(b) Having an output power of not more than 10 watts, which is specially designed for industrial and civilian intrusion detection and alarm systems, traffic and industrial movement control and counting systems, environmental pollution of air or water detection systems, or for simple educational devices.

1541A Cathode-ray tubes having any of the following characteristics:

(a) * * *

(b) With traveling wave or distributed deflection structure using delay lines, or incorporating other techniques to miminize mismatch of fast phenomena signals to the deflection structure; or

(c) * * *
(d) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of cathode-ray tubes covered by sub-entry (b) above, which utilize segmented plate (sectioned Y-plate) structures.

1544A Semi-conductor diodes and dice and wafers therefor (*except those made from germanium, selenium or copper oxide*), designed or rated for use at input or output frequencies above 12.5 GHz or having any of the following characteristics:

(a) (i) * * *

(ii) Schottky diodes designed or rated for mixer use at input or output frequencies of:

(a) 3 GHz or less and having a noise figure of more than 6 dB; or

(b) Greater than 3 GHz and less than 12.5 GHz and having a noise figure of more than 6.5 dB;

(iii) Schottky diodes designed or rated for detector use at input or output frequencies of less than 12.5 GHz and having a minimum rated tangential sensitivity of either worse than −45 dBm under unbiased conditions to worse than −50 dBm under biased conditions;

(b) * * *
(c) * * *
(d) * * *
(e) * * *

(f) Non-coherent light-emitting diodes with a peak radiant intensity at a wavelength of greater than 1,000 nanometers (for coherent light-emitting diodes, see entry No. 1522).

(g) * * *

Notes.—1. Licenses are likely to be approved for the export to satisfactory end-users of shipments for civil use containing up to 200 of the Schottky diodes mentioned in sub-entries (a) (ii) and (iii) above, having a maximum frequency not exceeding 3 GHz irrespective of noise level or tangential sensitivity.

2. Licenses are likely to be approved for the export to satisfactory end-users of non-coherent light-emitting diodes covered by sub-entry (f) above, for use in identifiable civilian communications systems.

1545A Transistors and dice and wafers therefor (for phototransistors see entry No. 1548) as follows:

(a) * * *

(b) Using silicon as the bulk semi-conductor material and having any of the following characteristics:

(1) * * *

(2) An operating frequency of 1.5 MHz or below and a maximum collector dissipation exceeding 300 watts, or an operating frequency greater than 1.5 MHz and a maximum collector dissipation exceeding 250 watts;

(3) An operating frequency greater than 200 MHz and a product of the operating frequency (in GHz) and the maximum collector dissipation (in watts) exceeding 5;

(4) Majority carrier devices, including but not limited to junction field-effect transistors and metal-oxide semi-conductor transistors, *except field-effect transistors having a maximum power dissipation of 500 mW or less and a maximum operating frequency of 1 GHz or less.*

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of transistors covered by sub-entries (b) (2) and (3) above, specially designed for television transposers or for civil mobile communication equipment, and having a product of the operating frequency (in GHz) and the maximum collector dissipation (in watts) not exceeding 20.

2. Licenses are likely to be approved for export to satisfactory end-users of transistors covered by sub-entry (b)(4) above which are suitable for and will be used in civil TV, AM or FM receivers or audio frequency equipment.

1547A Thyristors and dice and wafers therefor, as follows:

(a) Designed for use in pulse modulators having a rated turn-on time of less than 1

microsecond where the rated peak current exceeds 150 Amperes;

(b) Having a rated turn-off time of less than 1 microsecond;

(c) Having a rated turn-off time of from 1 microsecond to less than 2.3 microseconds *except those having a rated peak current of 50 Amperes or less and encapsulated in non-hermetically sealed packages;*

(d) Having a rated turn-off time of from 2.3 to 10 microseconds and a figure of merit greater than 25 (the figure of merit is defined as the product of the repetitive peak off-state voltage (V DRM) in kilovolts and the repetitive peak on-state current (I TRM) in Amperes as shown on the thyristor data sheets; and

(e) Specially designed parts and accessories therefor.

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of thyristors required as replacement parts in specific civil equipment provided they do not upgrade the initial performance of that equipment.

2. Licenses are likely to be approved for export to satisfactory end-users of thyristors covered by this entry, provided that they have been designed and are intended for civil applications other than in radar or laser modulators.

1548A Photosensitive components and dice and wafers therefor, as follows:

(a) Photosensitive components (including photodiodes, phototransistors, photothyristors, photoconductive cells and similar photosensitive components) with a peak sensitivity at a wavelength longer than 1,200 nanometers or shorter than 190 nanometers;

(b) Semi-conductor photodiodes and phototransistors with a response time constant of 0.25 microsecond or less measured at the operating temperature for which the time constant reaches a minimum.

Notes.—1. Licenses are likely to be approved for the export to satisfactory end-users of infra-red single-element encapsulated photoconductive cells or pyroelectric detectors intended for civil applications and using any of the following:

(a) Evaporated lead sulphide;

(b) Triglycine sulphate with a surface area of 20 mm^2 or less;

(c) Lead-lanthanum-zirconium titanate ceramic.

2. Licenses are likely to be approved for the export to satisfactory end-users for civil applications of semi-conductor photodiodes covered by sub-entry (b) above, with a response time constant of 0.5 nanosecond or more and with a peak sensitivity at a wavelength neither longer than 920 nanometers nor shorter than 300 nanometers.

1549A Photomultiplier tubes, as follows:

(a) For which the maximum sensitivity occurs at wavelengths longer than 0.75 micrometer or shorter than 0.3 micrometer; or

(b) * * *

(c) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of non-ruggedized tubes covered by sub-entry (a) above, required as replacement parts for specific civil equipment not exceeding the capability of that which could be exported under the Commodity Control List, provided that these parts do not upgrade the initial performance of such equipment.

1555A Electron tubes and specialized components and parts therefor, *except commercial standard television camera tubes not having fiber optic faceplates and commercial standard X-ray amplifier tubes,* as follows:

(a) Image intensifiers and image converters incorporating fiber-optic faceplates and/or microchannel-plate electron multipliers, and camera tubes incorporating or coupled with such intensifiers or converters;

(b) Electronic storage tubes, including memory transformers of radar pictures, *except signal converter storage tubes specially designed for television purposes;*

(c) Camera tubes with fiber optic faceplates and/or microchannel-plate electron multipliers;

(d) Ruggedized camera tubes having a maximum length-to-bulb diameter ratio of 5:1 or less.

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of reasonable quantities of non-ruggedized tubes covered by this entry, provided that the tubes will be used for bona fide medical applications.

2. Licenses are likely to be approved for export to satisfactory end-users of non-ruggedized direct view storage tubes covered by sub-entry (b) above, having an effective diameter or diagonal not exceeding 280 mm, for civil radar or oscilloscope applications.

3. Licenses are likely to be approved for export to satisfactory end-users of camera tubes covered by sub-entries (c) and (d) incorporating fiber optic faceplates but not microchannel-plate electron multipliers, provided that the tubes will be used for bona fide civil television applications.

1558A Electronic vacuum tubes (valves), and specialized parts, as follows:

(a) Tubes in which space charge control is utilized as the primary functional parameter, including but not limited to triodes and tetrodes, as follows:

(1) Tubes rated for continuous wave operation having either of the following characteristics:

(i) Above 4 GHz at maximum rated anode dissipation; or

(ii) Within the frequency range 0.3 to 4 GHz and for which, under any condition of cooling, the product of the maximum rated anode dissipation (expressed in watts) and the square of the maximum frequency (expressed in GHz) at the maximum rated anode dissipation is greater than 10^4, *except for tubes specially designed for television transmitters operating in the frequency range of 0.47 to 0.96 GHz and rated for operation without a grid current, for which the product of the rated anode dissipation (expressed in watts) and the square of the maximum frequency (expressed in GHz) may reach* 2×10^4;

(2) Tubes rated only for pulse operation having either of the following characteristics:

(i) Above 1 GHz at the peak pulse output power; or

(ii) Between 0.3 and 1 GHz and for which, under any condition of cooling, the product of the peak pulse output power (expressed in watts) and the square of the maximum frequency (expressed in GHz) is greater than 4.5×10^4;

(3) Tubes specially designed for use as pulse modulators for radar or similar applications, having a peak anode voltage rating of 100 kV or more, or rated for a peak pulse power of 6 MW or more (see also entry No. 1514);

(b) Tubes which utilize interaction between a beam of electrons and microwave elements and in which the electrons travel in a direction perpendicular to the applied magnetic field, including but not limited to magnetrons, crossed-field amplifier tubes and crossed-field oscillator tubes, *except:*

(1) Fixed frequency and tunable pulsed magnetrons and crossed-field amplifier tubes which are in normal civil use in equipment which may be exported under the terms of this List as follows:

(i) Magnetrons designed to operate at frequencies below 3 GHz with a maximum rated peak output power of 1.5 MW or less, or between 3 and 12 GHz with the product of the maximum rated peak output power (expressed in kW) and the frequency (expressed in GHz) less than 4,200;

(ii) Crossed-field amplifier tubes designed to operate at frequencies below 4 GHz with a maximum rated peak output power of 1.2 MW or less and with less than 15 dB gain;

(2) Fixed frequency continuous wave magnetrons designed for medical use or for industrial heating or cooking purposes operating at a frequency of 2.375 GHz ±0.05 GHz or 2.45 GHz ±0.05 GHz with a maximum rated power not exceeding 6kW or at a frequency lower than 1 GHz with a maximum rated power not exceeding 25 kW;

(c) Tubes which utilize interaction between a beam of electrons and microwave elements or cavities and in which the electrons travel in a direction parallel to the applied magnetic field, including but not limited to klystrons and traveling wave tubes, *except:*

(1) Continuous wave tubes for use in civil communications designed for octave or lesser bandwidth (where the highest operating frequency is equal to or less than two times the lowest operating frequency) having the following characteristics:

(i) Designed to operate below 20 GHz;

(ii) The product of the rated output power (expressed in watts) and the frequency (expressed in GHz) is less than 800;

(2) Pulsed tubes for civil applications designed for octave or less bandwidth and having either of the following characteristics:

(i) Peak saturated output power not exceeding 1 kW and average power not exceeding 40 watts at or below 10 GHZ;

(ii) Peak saturated output power not exceeding 100 watts and average power not exceeding 20 watts between 10 and 20 GHz;

(3) Pulsed tubes for civil applications designed for fixed frequency operation at frequencies below 3.5 GHz, peak output power of 1.6 MW or less, and operating bandwidth less than 1 percent;

(4) Low power oscillator tubes designed to operate at frequencies below 20 GHz with maximum output power of less than 3 watts;

(d) * * *

(e) * * *

(f) * * *
(g) * * *
(h) * * *
(i) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of the following:

(a) Tubes covered by sub-entries (a) and (c) above, specially designed for television purposes and which are to be used in television transmitters, the precise location of which is known, for civil telecasting according to CCIR or OIR standards;

(b) Tubes covered by sub-entries (a), (b) and (c) above required as replacement parts for specific civilian equipment not exceeding the capability of that which could be exported under other Commodity Control List entries, provided that these parts do not upgrade the initial performance of that equipment;

(c) Pulsed amplifier klystrons and fixed frequency and mechanically tunable pulsed magnetrons covered by sub-entries (b) and (c) above intended for civil radar equipment previously exported, provided that they do not upgrade the initial performance of that equipment.

1559A Hydrogen thyratrons of ceramic-metal construction rated for a peak pulse power output of 12.5 MW or more; and specially designed parts and accessories therefor.

Note.—Licenses are likely to be approved for export to satisfactory end-users of ceramic-metal structured hydrogen thyratrons to replace such thyratrons in specific civil radar equipment previously exported, provided that they do not upgrade the initial performance of that equipment.

1564A Electronic component assemblies, sub-assemblies, printed circuit boards, and microcircuits:

I. * * *

II. Listed as follows:

(a) Printed circuit boards (single sided, double sided, or multilayer) designed to mount and provide interconnection between electronic components, *except those manufactured from any of the following insulating materials:*

(i) Paper base phenolics;

(ii) Glass cloth melamine;

(iii) Glass epoxy resin;

(iv) Polyethylene terephthalate; or

(v) Any insulating material with a maximum continuous rated operating temperature not exceeding 150° C;

(b) Assemblies, modules and printed circuit boards with mounted components, as follows:

(1) Those including printed circuit boards covered by sub-entry II(a) above;

(2) Those which contain microprocessor, microcomputer or memory microcircuits or embargoed components, *except:*

(i) Assemblies, not containing microprocessor, microcomputer, or memory circuits, whose only embargoed components are capacitors;

(ii) Power supply assemblies;

(c) Microcircuits (monolithic integrated circuits, microprocessor, microcomputer, multichip, hybrid, film or integrated optical types), *except:*

(i) Encapsulated passive networks; or

(ii) Encapsulated micro-circuits which are not designed or rated as radiation hardened, which are not rated for operation below −40° C or above +85° C, which are packaged in TO–5 outline cases (0.305 inch to 0.370 inch diameter) or in non-hermetically sealed cases and which are:

(1) Bipolar types designed for operation as digital logic circuit elements but limited to gates, inverters, buffers, bilateral switches, drivers, counters, latches, adders, comparators, parity generators, multiplexers, expanders, flip-flops, multivibrators, code converters, registers, encoders, decoders, demultiplexers, diode matrices, multipliers and Schmidt-triggers, and having all of the following characteristics:

(a) A product of the typical basic gate propagation delay time (in nanoseconds) and the power dissipation per basic gate (in milliwatts) not less than 30pJ (i.e. speed-power product/gate not less than 30pJ);

(b) A typical propagation delay time not less than 3 nanoseconds; and

(c) Encapsulated in a package having 24 terminals or less;

(2) CMOS types designed for operation as digital logic circuit elements but limited to gates, inverters, buffers, flip-flops, latches, multivibrators, bilateral switches, display drivers, fixed counters, fixed frequency dividers, storage registers, decoders, voltage translators, encoders, and Schmidt-triggers, and having both of the following characteristics:

(a) A minimum propagation delay time under any rated conditions of not less than 10 nanoseconds;

(b) Encapsulated in a package having 24 terminals or less;

(3) Silicon single-chip microcomputer microcircuits that are mask programmed for a civil application prior to export and having all of the following characteristics:

(a) A word size/speed ratio of less than or equal to a 0.4 bit per microsecond;

(b) A speed-power dissipation product of greater than or equal to 4 microjoules;

(c) An on-chip read-only memory (ROM), not including the microcode, of less than or equal to 2,048 bytes;

(d) An on-chip random-access memory (RAM) of less than or equal to 512 bits;

(e) An operand (data) word length of less than or equal to 8 bits;

(f) Not capable of addressing off-chip program memory;

(g) Not rated for operation below −20° C or above +75° C;

(Speed is defined as the time (in microseconds) to add C to D where C and D are both in memory, and put the result back in C.)

(4) Silicon microprocessor microcircuits having all of the following characeristics:

(a) A word size/speed ratio of less than or equal to 0.4 bit per microsecond;

(b) A speed-power dissipation product of greater than or equal to 4 microjoules;

(c) Containing no on-chip ROM or on-chip RAM;

(d) An operand (data) word length of less than or equal to 8 bits;

(e) Capable of addressing off-chip program memory of less than or equal to 32,768 bytes;

(f) Not rated for operation below −20° C or above +75° C;

(5) Memory microcircuits as follows:

(a) MOS dynamic RAM's having all of the following characteristics:

(i) A maximum number of bits per package of 1,024 bits and an access time of no less than 250 nanoseconds;

(ii) Not rated for operation below −20° C or above +75° C;

(b) Mask programmed ROMs not rated for operation below −20° C or above +75° C, as follows:

(i) With a maximum number of bits per package of 2,048 bits and an access time of no less than 450 nanoseconds;

(ii) PMOS or NMOS types with a maximum number of bits per package of 4,096 bits and an access time of no less than 700 nanoseconds;

(c) MOS static RAM's having both of the following characteristics:

(i) A maximum number of bits per package of 256 bits;

(ii) An access time of no less than 450 nanoseconds;

(d) Bipolar RAM's as follows:

(i) With a maximum number of bits per package of 64 bits and an access time of no less than 30 nanoseconds;

(ii) With a maximum number of bits per package of 256 bits and an access time of no less than 40 nanoseconds;

(iii) With a maximum number of bits per package of 1,024 bits and an access time of no less than 45 nanoseconds;

(6) (a) Non-reprogrammable microcircuits, not capable of addressing external memory, specially designed for, and which by virtue of circuit design are normally limited to use only for simple calculators which perform a single function in response to a keystroke, capable of performing a floating point addition of 13 decimal digits (mantissa only) or less in no less than 0.02 second;

(b) Programmable microcircuits specially designed for, and which by virtue of circuit design are normally limited to use only for simple key programmable calculators having both of the following characteristics:

(i) Capable of executing a sequence of no more than 256 program steps introduced into a program memory on the chip by a sequence of keystrokes;

(ii) Capable of performing a floating point addition of 13 decimal digits (mantissa only) or less in no less than 0.02 second;

(c) P-channel or N-channel MOS microcircuits specially designed as, and which by virtue of circuit design are normally limited to use only as, serial digital shift registers with a maximum clock rate of 2.5 MHz, and a maximum number of bits per package of 1,024;

(7) (a) Unturned AC amplifier microcircuits having a bandwidth of less than 3 MHz and a maximum rated power dissipation of 5 watts or less at a case temperature of 25° C;

(b) Audio amplifier microcircuits having a maximum rated continuous power output of 25 watts or less at a case temperature of 25° C;

(8) Operational amplifier microcircuits having all of the following characteristics:

(a) A typical unity-gain open-loop bandwidth of not more than 4MHz;

(b) A typical open-loop voltage gain of not ore than 500,000 or 115 dB;

(c) A maximum intrinsic rated input offset voltage of not less than 2.5 mV; and

(d) A typical slew rate at unity gain not exceeding 2.5 volts/microsecond;

(9) Analog multiplier and/or divider microcircuits having both of the following characteristics:

(a) A best case rated non-linearity of not better than 0.5 percent of full scale;

(b) A −3 dB small-signal bandwidth of not more than 500 kHz;

(10) Isolation amplifier microcircuits;

(11) Instrumentation amplifier microcircuits having all of the following characteristics:

(a) A best case rated non-linearity of not better than 0.02 percent at a gain of 100;

(b) A maximum gain-bandwidth product not greater than 5 MHz (e.g., a maximum band width of 50 kHz at −3 dB and at a gain of 100);

(c) A typical slew rate at unity gain not exceeding 1 volt/microsecond;

(12) Voltage regulator microcircuits, as follows:

(a) Linear types, having both of the following characteristics:

(i) A rated nominal output voltage of 40 volts or less;

(ii) A maximum output current of 1 A or less;

(b) Switching types, having both of the following characteristics:

(i) A rated nominal output voltage of 40 volts or less;

(ii) A maximum output current of 150 mA or less;

(For voltage regulators, the +85° C upper temperature limit specified in II(c)(ii) is not applicable. The lower limit of −40° C is applicable.)

(13) Voltage comparator microcircuits, having both of the following characteristics:

(a) A maximum input offset voltage of not less than 2 mV; and

(b) A typical switching speed or typical response time of not less than 30 nanoseconds;

(14) Bipolar microcircuits designed for operation in civil applications as externally controlled (by inductive, magnetic or optical means) electronic switches, or as threshold value switches with switching times of 0.5 microsecond or greater;

(15) Non-coherent light-emitting alphanumeric displays not incorporating an integrated circuit;

(16) Non-coherent light-emitting alphanumeric displays incorporating an integrated circuit used for decoding, controlling and/or driving that display, provided that the integrated circuit is not integral with the actual display device;

(17) Simple encapsulated photo-coupler (transoptor) assemblies with electrical input and output and which incorporate non-coherent light-emitting diodes;

(18) Interface microcircuits, as follows:

(a) Line drivers and line receivers having a typical propagation delay time from data input to output of not less than 15 nanoseconds;

(b) Sense amplifiers, having both of the following characteristics:

(i) A typical propagation delay time from data input to output of not less than 15 nanoseconds;

(ii) A typical input threshold voltage of not less than 10 millivolts;

(c) Memory and clock drivers, having all of the following characteristics:

(i) A maximum rated output current of 500 milliamperes or less;

(ii) A maximum rated output voltage of 30 volts or less;

(iii) A typical propagation delay time from data input to output of not less than 20 nanoseconds;

(d) Peripheral and display drivers, having all of the following characteristics:

(i) A maximum rated output current of 500 milliamperes or less;

(ii) A typical propagation delay time from data input to output of not less than 20 nanoseconds;

(iii) A maximum rated output voltage of 80 volts or less;

(When propagation delay time is not specified, typical turn-on or turn-off time, whichever is less, should be used.)

(19) Voltage-to-frequency converter microcircuits not employing delta or delta/sigma modulation techniques, having both of the following characteristics:

(a) A rated non-linearity of not better than 0.01 percent of full scale;

(b) A settling/response time of not less than 20 microseconds for a full scale input change;

(20) Rms-to-dc voltage converter microcircuits having both of the following characteristics:

(a) A rated conversion accuracy, with or without external adjustment, of not better than 0.2 percent of full scale;

(b) A ±1 percent amplitude error bandwidth of not greater than 100 kHz;

(21) Analog-to-digital and digital-to-analog converter microcircuits as follows:

(a) Analog-to-digital converter microcircuits having both of the following characteristics:

(i) A conversion time to maximum resolution of not less than 20 microseconds;

(ii) A rated non-linearity of not better than 0.05 percent of full scale over the specified operating temperature range;

(b) Digital-to-analog converter microcircuits having both of the following characteristics:

(i) A settling time to rated linearity of not less than 5 microseconds for "voltage output", and not less than 300 nanoseconds for units not incorporating an output amplifier;

(ii) A rated non-linearity of not better than 0.05 percent of full scale over the specified operating temperature range;

(22) Non-reprogrammable microcircuits which are specially designed for and by virtue of circuit design are normally limited to use for functional purposes in the following applications:

(a) Automotive, including safety, comfort, operations and pollution;

(b) Home electronics, including radio and television, appliances, clocks, watches, audio and video tape recorders, safety, comfort and amusement;

(c) Personal communications up to 150 MHz, including amateur radio communications and intercom;

(d) Unembargoed cameras (including cine cameras) but excluding imaging microcircuits;

(e) Cardiac pacemakers;

(A microcircuit whose function cannot be altered by accepting or executing instructions from any external source is non-reprogrammable.)

(Programmed microcircuits are only eligible for export if the program is unalterably stored at the time of manufacture and the performance of the function has been established for the intended end-use.)

(The temperature limits specified in the heading of II(c)(ii) above do not apply to sub-sections II(c)(ii)(22)(a) or (d).)

(23) Timing microcircuits having both of the following characteristics:

(a) A typical timing error of not less than 0.5 percent;

(b) A typical rise time of not less than 100 nanoseconds;

(iii) Unencapsulated monolithic integrated circuits which are not designed or rated as radiation hardened, and which are:

(1) Bipolar types designed for operation as digital logic circuit elements but limited to gates, inverters, buffers, bilateral switches, drivers, counters, latches, adders, comparators, parity generators, multiplexers, expanders, flip-flops, multivibrators, code converters, registers, encoders, decoders, demultiplexers, diode matrices, multipliers and Schmidt-triggers, and having both of the following characteristics:

(a) A product of the typical basic gate propagation delay time (in nanoseconds) and the power dissipation per basic gate (in milliwatts) not less than 70 pJ (i.e., speed-power product/gate not less than 70 pJ);

(b) A typical propagation delay time not less than 5 nanoseconds;

(2) Operational amplifiers, having all of the following characteristics:

(a) A typical unity-gain open-loop bandwidth of not more than 5 MHz;

(b) A typical open-loop voltage gain of not more than 100,000 or 100 dB;

(c) A maximum intrinsic rated input offset voltage of not less than 5 mV;

(d) A typical slew rate at unity gain not exceeding 1 volt/microsecond;

(3) Audio amplifiers having a maximum rated power output of 10 watts or less at a case temperature of 25° C;

(4) Non-reprogrammable types which are specifically designed for and by virture of circuit design are normally limited to civil uses in television and radio receivers, having all of the following characteristics:

(a) Rated for operation at 11 MHz or less;

(b) Not specially designed for station scanning applications;

(c) Not utilizing charge-coupled device (CCD) technology;

(d) Not intended for beam lead bonding;

(e) Not intended for video and/or luminance amplifiers with maximum rated supply voltages exceeding 30 volts or with typical bandwidths greater than 7.5 MHz.

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users for civil applications of assemblies, modules and printed circuit boards with mounted components (excluding those containing microprocessor, microcomputer and memory

microcircuits) covered by sub-entry II(b)(2) above, if the components are likely to be approved for export to satisfactory end-users.

2. Licenses are likely to be approved for export to satisfactory end-users of devices covered by sub-entry II(b), and not released by sub-entries II(c) (i) and (ii) above, when they consist of, or are incorporated in, plug-in printed circuit boards or plug-in modules for use in specifically identified equipment previously exported, and which do not upgrade the initial performance of that equipment, provided that the plug-in printed circuit boards or plug-in modules cannot operate independently from the equipment to which they are likely to be connected or inserted.

3. Licenses are likely to be approved for export to satisfactory end-users of integrated circuits covered by sub-entry II(c)(ii) above only by virture of being encased in hermetically sealed dual-in-line packages, provided that the stated legitimate civil end-use requires such a package.

4. Licenses are likely to be approved for export to satisfactory end-users of devices, encapsulated or unencapsulated, covered by sub-entries II (b) and (c) above, provided the devices have been designed specifically for identifiable civil applications and, by nature of design or performance, are substantially restricted to the particular application for which they have been designed.

1565A Electronic computers and related equipment, as follows:

(a) Analog computers designed or modified for use in airborne vehicles, missiles or space vehicles and rated for continuous operation at temperatures from below −45° C to above +55° C; and equipment or systems incorporating such computers;

(b) Other analog computers capable of accepting, processing and putting out data in the form of one or more continuous variables and capable of incorporating a total of at least 20 summers, integrators, multipliers or function generators with facilities for readily varying the interconnection of these components;

(c) Digital computers and digital differential analyzers (incremental computers), as follows:

(1) Designed or modified for use in airborne vehicles, missiles, or space vehicles and rated for continuous operation at temperatures from below −45° C to above +55° C;

(2) Designed or modified to limit electromagnetic radiation to levels much less than those required to meet appropriate government civil interference specifications;

(3) Designed as ruggedized equipment and capable of meeting military specifications for ruggedized equipment or modified for military use;

(4) Designed or modified for "data (message) switching" or those incorporating equipment, devices, or techniques, including software, microprogram control (firmware) and/or specialized logic control (hardware), for accepting, storing, processing and retransmitting data groups ("Data (message) switching" is the technique (including but not limited to store and forward or packet switching) for accepting data groups (including messages, packets or other digital or telegraphic information groups that are transmitted as a composite whole), storing (buffering) data groups as necessary, processing part or all of the data groups for control (routing, priority, formatting, code conversion, error control, retransmission or journaling), transmission or multiplexing purposes as necessary, and retransmitting (prccessed) data groups when transmission and/or receiving facilities are available); and

(5) Equipment or systems incorporating such computers;

(d) Digital computers with one or more of the following characteristics:

(1) Floating point operations are implemented by hardware or microprogram control (firmware);

(2) The computer is equipped with peripherals (other than those free from control under sub-entry (h) below);

(3) The computer is equipped with cathode-ray tube or other displays (other than those free from control under sub-entry (h) below), as follows:

(i) Used to display alphanumeric, graphic and/or similar data or information; or

(ii) With light gun or other graphic input devices;

(e) Other digital computers operated by one or more common control units and capable of all of the following:

(1) Accepting, storing, processing, and producing an output in numerical or alphabetical form;

(2) Storing in fixed or alterable (writable) storage devices more than 512 numerical and/or alphabetical characters or having an internal fixed or alterable memory of more than 2,048 bits;

(3) Performing a stored sequence of operations that are modifiable by means (including replacement of fixed storage devices) other than a physical change in wiring or interconnections; and

(4) Selecting a sequence from a pluality of stored operations based upon data or an internally computed result;

(f) Computers capable of operating both analog and digital modes and related equipment, as follows:

(1) Equipment whose analog portion meets the conditions of sub-entry (b) and whose digital portion meets the conditions of sub-entry (e) and which also provides facilities for processing in the digital section numeric data from the analog section and/or vice versa;

(2) Equipment for interconnecting the analog and digital portions of computers as defined in sub-entry (f)(1); and

(3) Digital or analog computers containing interconnecting equipment as defined in sub-entry (f)(2);

(g) Related equipment for the above (including that also described in entry Nos. 1572 and 1588), designed or modified as described in sub-entry (a) or (c), i.e. specialized parts, components, peripherals, displays, sub-assemblies, accessories, and spare parts; and

(h) Other related equipment for the above (including that also described in entry Nos. 1572 and 1588), i.e., specialized parts, components, peripherals, displays, sub-assemblies, accessories, and spare parts.

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of analog computers covered by sub-entry (b) above, and related equipment therefore covered by sub-entry (h) above, provided that:

(a) The equipment is primarily used in non-strategic applications;

(b) The equipment will be used primarily for the specific non-strategic applications for which the export would be approved and that the number, type and characteristics of such equipment are normal for the approved use;

(c) The computers and related equipment are not covered by and would not thereby become covered by sub-entry (a), (f), or (g) above, or exceed the limits of this Note:

(d) The analog computers are limited as follows:

(1) The rated errors for summers, inverters and integrators are not less than (i) Static: 0.01%; (ii) Total at 1 kHz: 0.15%.

(2) The rated errors for multipliers are not less than (i) Static: 0.025%; (ii) Total at 1 kHz: 0.25%.

(3) The rated error for fixed function generators (log x and sine/cosine) is not less than Static: 0.1%.

(4) No more than 350 operational amplifiers; and

(5) No more than four integrator time scales switchable during one program;

Technical Notes.—(1) The percentage for Note 1(d)(1)(i) above applies to the actual output voltage; all other percentages apply to full scale, that is from maximum negative to maximum positive reference voltages.

(2) Total errors at 1 kHz for Note 1(d) (1)(ii) and (2)(ii) above, are to be measured with those resistors incorporated in the inverter, summer or integrator which provide the least error.

(3) Total error measurements include all errors of the unit resulting from, for example, tolerances of resistors and capacitors, tolerances of input and output impedances of amplifiers, the effect of loading, the effects of phase shift, and the generating of functions.

2. Favorable consideration for export to satisfactory end-users of digital computers covered by sub-entry (c)(4) above will depend in part upon the degree of conformity with the following:

(a) The equipment is specially designed to meet the requirements of CCITT recommendation F–31 or ICAO recommendations for civilian aviation communication networks;

(b) The equipment will be used primarily for the specified civil application and will be operated by the civil authorities of the importing country for general civil traffic, or for traffic with links with Western countries, or for an international Service to fulfill a commitment to ITU, ICAO, or any other inter-governmental organization which includes Western countries;

(c) The computers are not covered by the remainder of sub-entry (c) above, or by sub-entries (f) or (g) above, or do not exceed the limits of this Note;

(d) The number, type and characteristics of such equipment are normal for the approved use and that the equipment will be limited as follows:

(1) Suitable combinations of circuits not exceeding:

(i) 250 circuits with "data signaling rates" of less than 150 bits per second;

(ii) 60 circuits with "data signaling rates" of 150 to 1,000 bits per second; and/or

(iii) 8 circuits with "data signaling rates" of greater than 1,000 to 4,800 bits per second;

(2) The maximum "data signaling rate" of any circuit does not exceed 4,800 bits per second;

(3) The sum of the "data signaling rates" of all circuits does not exceed 27,500 bits per second;

(4) The sum of the "data signaling rates" of all circuits with "data signaling rates" greater than 1,000 bits per second does not exceed 19,200 bits per second;

Technical Note.—"Data signaling rate" is as defined in ITU Recommendation 53–36, taking into account that, for non-binary modulation, "bauds" and "bits per second" are not equal. Bits for coding, checking and synchronization functions are to be included.

(e) The disclosure of software and technical information for the equipment exported is held to the minimum necessary for the application, operation and maintenance of the equipment in the stated civil end-use.

3. Favorable consideration for export to satisfactory end-users of digital computers covered by sub-entries (d) (1) or (2), or (e) above, and related equipment therefor covered by sub-entry (h) above, will depend in part upon the degree of conformity with the following:

(a) The equipment is primarily used in "telephone circuit switching" or "telegraph (telex) circuit switching" systems designed for fixed civil applications;

(b)(1) The equipment will be installed in "telephone circuit switching", or "telegraph (telex) circuit switching" systems designed for fixed civil applications;

(2) The equipment in total represents no more than 30 percent of the value of the switching system (during the initial installation of a partially-equipped system, this total may approach 50 percent); and

(3) The switching system will be either:

(i) Operated by civil authorities of the importing country for general civil traffic, or for traffic with links with Western countries, or for an international service to fulfill a commitment to ITU, ICAO or any other inter-governmental organization which includes Western countries; or

(ii) Used in a private exchange or private branch exchange (in each case of no more than 5,000 lines) which will be used in a civil installation situated in a densely-populated industrial area in a proscribed destination, and for which a responsible representative of the end-user or importing agency has furnished a signed statement describing the end-use and the location of the exchange and certifying that the equipment will only be used for that specific end-use;

(c) The computers and related equipment are not covered by and would not thereby become covered by sub-entires (c), (f), or (g) above, or exceed the limits of this Note;

(d) The number, type and characteristics of such equipment are normal for the approved use and that the equipment will be limited to the minimum system configuration necessary to control a 50,000 line exchange for the uses cited in sub-paragraph (b)(3)(i) above, or to control a 5,000 line exchange for the uses cited in sub-paragraph (b)(3)(ii) above;

(e) For the interface equipment with which the digital computer is equipped (to be provided only for administrative and control communications purposes):

(1) The "total effective bit transfer rate" of remote "terminal devices" does not exceed 2,400 bits per second;

(2) The "effective bit transfer rate" of any interfaced "communication channel" does not exceed 2,400 bits per second;

(3) The interface equipment is located within the "computer operating area" and limits the "effective bit transfer rate" to those specified in sub-paragraphs (1) and (2) above; and

(4) All interfaced "communication channels" are dedicated full time to the given application;

(f) The disclosure of software and technical information for the equipment exported is held to the minimum necessary for the application, operation and maintenance of the equipment in the stated civil end-use.

Technical Notes.—(1) "Telephone Circuit Switching" is the technique for establishing within an exchange, on demand and until released, an exclusive direct or PCM (CCITT Recommendations G–11, G–732 and G–733) connection between calling and called telephone circuits based solely on subscriber-type of telephone dialing information derived from the calling circuit. The telephone circuits may carry any type of signal, e.g. telephony, telegraph or telex, compatible with a voice channel bandwidth of 3,100 Hz. No information available on the circuit other than the subscriber dialing information is utilized for any other function.

(2) "Telegraph (Telex) Circuit Switching" utilizes techniques essentially identical to "Telephone Circuit Switching" for establishing connections between telegraph (telex) circuits based on the same type of dialing information. The telegraph (telex) circuits (which may be telephone circuits) may carry any telegraph (telex) signal compatible with a voice channel bandwidth of 3,100 Hz or less. No information available on the circuit other than the subscriber dialing information is utilized for any other function.

4. Licenses are likely to be approved for export to satisfactory end-users of digital computers and/or devices covered by sub-entries (d)(1) or (2) or (e) above, and related peripherals covered by sub-entry (h) above, provided that:

(a) The digital computers and/or devices have been designed for identifiable office and personal use and, by nature of design, software, microprogram control (firmware), specialized logic control (hardware) or performance, are substantially restricted to the particular application for which they have been designed;

(b) The digital computers and/or devices and the related peripherals and displays are not covered by sub-entries (c), (f) or (g) above, or do not exceed the limits of this Note;

(c) The digital computers and/or devices are limited as follows:

(1) The "CPU data handling rate" does not exceed 2 million bits per second;

(2) The "CPU numerical processing rate" for units capable of arithmetic operations does not exceed 0.1 million bits per second;

(3) The "total internal memory available to the user" does not exceed 32,768 bits;

(4) For peripheral devices with which the computer is equipped:

(i) No more than one magnetic tape transport which does not exceed:

(a) 1,600 bits per inch per track;

(b) 9 tracks per ½ inch (12.7mm) tape width;

(c) ½ inch (12.7mm) tape width; and

(d) 25 inches (65.6cm) per second tape read/write speed;

(ii) Cassette/cartridge tape drives described in sub-paragraph (d) below;

(iii) Digital computer peripherals and displays free from control under sub-entry (h) above; and

(iv) Digital recording and reproducing equipment specially designed to use magnetic card, tag, label or bank check recording media free from control under entry No. 1572 sub-entry (a)*(ii)*;

(d) The related peripherals are limited as follows:

Cassette/cartridge tape drives operating serially one track at a time, provided they have:

(i) No more than 800 bits per inch per track; and

(ii) No more than 6,000 bits per second maximum bit transfer rate.

Technical Notes.—(1) "CPU data handling rate" is defined as the maximum number of bits that can be accessed in parallel from an internal memory divided by the minimum time (including access time) for the execution of any instruction operating on this number of bits.

(2) "CPU numerical processing rate" is defined as the number of bits used to represent an arithmetic operand divided by the average time required for execution of a multiplication operation, assuming the most efficient arithmetic data coding and the fastest hardware, microprogram control (firmware) and/or software multiplication technique available to the user.

(3) "Total internal memory available to the user" is defined as the sum of the storage capacities of all user-alterable internal storage devices plus all user-replaceable fixed storage devices that may be incorporated in the equipment at one time and that may be used to store microprogram control (firmware) and/or software instructions and data.

5. Licenses are likely to be approved for export to satisfactory end-users of related specialized parts, components, sub-assemblies, accessories and spare parts covered by sub-entry (h) above, for equipment previously exported pursuant to Note 4, provided that:

(a) The related specialized parts, components, sub-assemblies, accessories and spare parts:

(1) Will not upgrade the equipment beyond the limits of Note 4;

(2) Are in reasonable quantities based on the quantity of equipment previously exported from the country; and

(3) Are only for equipment previously exported from the country;

(b) Advanced technology components (microprocessors, arithmetic logic units (ALUs), fixed or alterable storage devices,

programmed logic arrays (PLAs), etc.) covered by entry No. 1564 or 1588 are held to the minimum performance and quantity appropriate for the type and quantity of equipment they are intended for, assuming normal usage patterns.

6. Licenses are likely to be approved for export to satisfactory end-users of related specialized parts, components, sub-assemblies, accessories and spare parts covered by sub-entry (h) above, for tape drives previously exported pursuant to Note 4 (c)(4)(ii) and (d), provided that they will not upgrade the tape drives beyond the limits of Note 4.

7. Licenses are likely to be approved for export to satisfactory end-users of digital computers covered by sub-entries (d) (1) or (2) or (e) above, and related equipment therefor covered by sub-entry (h) above, provided that:

(a) The equipment is primarily used in non-strategic applications;

(b) The equipment will be used primarily for the specific non-strategic applications for which the export would be approved and that the number, type and characteristics of such equipment are normal for the approved use;

(c) The computers and related equipment are not covered by and would not thereby become covered by sub-entries (c), (f) or (g) above, or exceed the limits of this Note;

(d) The digital computers are limited, as follows:

(1) The sum of either the "I/O bus rate" or the "total effective bit transfer rate", whichever is less, and the "CPU bus rate" does not exceed 45 million bits per second;

(2) The "processing data rate" for CPUs which implement floating point operations by hardware or microprogram control (firmware) does not exceed 8 million bits per second;

(3) The internal memory total connected capacity (excluding parity, word marker and flag bits) does not exceed 2.36 million bits;

(4) For peripheral devices with which the computer is equipped:

(i) The "total effective bit transfer rate" (excluding data channels not equipped with peripheral memory units) does not exceed 8 million bits per second;

(ii) The "effective bit transfer rate" of any peripheral memory or data channel does not exceed 1.6 million bits per second;

(iii) No more than 12 magnetic tape transports;

(iv) Magnetic tape transports which do not exceed:

(a) 1,600 bits per inch per track;

(b) 9 tracks per ½ inch (12.7 mm.) tape width; and

(c) ½ inch (12.7 mm.) tape width;

(v) For peripheral memory devices other than magnetic tape transports:

(a) Total connected "net capacity" does not exceed 960 million bits;

(b) For each independent device with an "average access time" of less than 30 milliseconds, the "memory performance factor" does not exceed 8,000;

(c) For each independent device with an "average access time" of 30 milliseconds or greater, the "memory performance factor" does not exceed 43,000;

(d) "Total number of access" does not exceed 150 per second;

(5) The "effective bit transfer rate" of any "terminal device" located remote from the "computer operating area" does not exceed 2,400 bits per second;

(6) For interface equipment with which the computer is equipped:

(i) The "total effective bit transfer rate" (excluding parity, word marker and flag bits) of remote "terminal devices" does not exceed 4,800 bits per second;

(ii) The "effective bit transfer rate" of any interfaced "communication channel" does not exceed 1,200 bits per second;

(iii) The interface equipment is located within the "computer operating area" and limits the "effective bit transfer rates" to those specified in sub-paragraphs (i) and (ii) above; and

(iv) All interfaced "communication channels" are dedicated full time to the given application.

8. Licenses are likely to be approved for export to satisfactory end-users of additional internal memory or peripheral memory devices covered by sub-entry (h) above, for equipment previously exported pursuant to Note 7, provided that:

(a) Two years have elapsed since the initial installation of the equipment;

(b) The equipment would not thereby exceed the limits of Note 7(d) with the following modified limits on internal memory and peripheral memory devices:

(1) The internal memory total connected capacity (excluding parity, word marker and flag bits) does not exceed 4.72 million bits;

(2) For peripheral memory devices other than magnetic tape transports:

(i) Total connected "net capacity" does not exceed 1,400 million bits;

(ii) "Total number of accesses" does not exceed 200 per second;

(c) The conditions of Note 7 continue to be met.

9. Licenses are likely to be approved for export to satisfactory end-users of reasonable quantities of peripherals covered by sub-entry (h) above, as follows:

(a) Disc drives utilizing non-rigid magnetic media, provided they have:

(1) No more than a 7.88 in. (201 mm.) disc;

(2) No more than 3.2 million bit "net capacity";

(3) No more than 250,000 bits per second maximum bit transfer rate; and

(4) No less than 250 millisecond "average access time";

(b) Cassette/cartridge tape drives operating serially one track at a time, provided they have:

(1) No more than 1,600 bits per inch per track;

(2) No more than 48,000 bits per second maximum bit transfer rate;

(c) Non-impact line printers operating at 2,000 lines per minute or less and non-impact character printers operating at 300 characters per second or less;

(d) Graphic displays specially designed for signature security checking having an active display area not exceeding 150 sq.cm.

10. Licenses are likely to be approved for export to satisfactory end-users of additional internal memory and peripheral memory devices covered by sub-entry (h) above, for equipment previously exported, provided that the equipment would not thereby exceed the limits with the following additional limits on peripheral memory devices with which the computer is equipped:

(a) The "effective bit transfer rate" of any peripheral memory or data channel does not exceed 1.6 million bits per second;

(b) For peripheral memory devices other than magnetic tape transports:

(1) Total connected "net capacity" does not exceed 1,900 million bits;

(2) For each independent device with an "average access time" of 30 milliseconds or greater, the "memory performance factor" does not exceed 64,000.

1568A Equipment, as follows:

(a) * * *

(b) * * *

(c) * * *

(d) * * *

(e) * * *

(f) * * *

(g) Precision potentiometers, *except potentiometers using only switched elements* (for the purpose of this sub-entry, a precision potentiometer means one having a rated conformity better than 0.25 percent for a linear potentiometer; or 1 percent for a non-linear potentiometer), and special instruments rated to have the same characteristics as potentiometers in (1) and (2) below, such as Vernistats, as follows:

(1) Linear potentiometers having a constant resolution and a rated linearity of better than 0.05 percent absolute;

(2) Non-linear potentiometers having a variable resolution and a rated conformity of:

(i) 1 percent or less when the resolution is inferior to that obtained with a linear potentiometer of the same type and of the same track length; or

(ii) 0.5 percent or less when the resolution is better than or equal to that obtained with a linear potentiometer of the same type and of the same track length; or

(3) * * *

(h) * * *

(i) * * *

(j) * * *

(k) * * *

(l) * * *

(m) * * *

Note.—Licenses are likely to be approved for export to bona fide end-users of potentiometers covered by subentries (g) (1) and (2) above, provided they have been designed for civil use, and have been in use in civil equipment for a period of not less than five years.

1572A Recording and/or reproducing equipment as follows (for equipment which may be exported in conjunction with computer shipments, see entry No. 1565.):

(a) Using magnetic techniques, *except:*

(i) Those specifically designed for voice or music;

(ii) Those specifically designed to use magnetic card, tag, label or bank check recording media with a magnetic surface area not exceeding 10 sq. in. (65 sq. cm.); or

(iii) Digital recording and reproducing equipment operating serially with a packing density not exceeding 800 bits per inch per track specially designed for use with, and incorporated in, typewriter systems used for preparing, correcting and/or composing text;

(b) Using electron beam(s) operating in a vacuum, and/or laser-produced light beams (see also entry No. 1522) that produce patterns or images directly on the recording surface, and specialized equipment for image development, *except equipment specifically designed for television recording and/or reproducing on discs;*

(c) Graphic instruments capable of continuous direct recording of sinusoidal waves at frequencies exceeding 20 kHz; and

(d) Specialized parts and components for the above and recording media used in equipment covered by subentries (a) and (b). (The term "recording media" is intended to include all types and forms of specialized recording media used in such recording techiques, including but not limited to tapes, drums, discs and matrices.)

Notes.—1. Licenses are likely to be approved for export to satisfactory end-users of reasonable quantities of equipment covered by sub-entry (a) above, and specialized parts, components and recording media therefor covered by sub-entry (d) above, for use with the exported equipment, as follows:

(a) Video magnetic tape recorders, specially designed for television recording, using a signal registered with the C.C.I.R., or specifically designed or adapted for use with medical equipment, and having all of the following characteristics:

(1) 3 dB recording bandwidth not exceeding 6 MHz;

(2) Maximum length of time of a single scan not exceeding 20 milliseconds;

(3) Not ruggedized;

(b) Analog magnetic tape recorders having all of the following characteristics:

(1) Bandwidth capability at maximum design speed not exceeding 100kHz per track;

(2) Recording density not exceeding 5,000 magnetic flux sine waves per linear inch (25.4 mm) per track;

Technical Note.—Recording density is, for direct recorders, the recording band width divided by the tape speed; and, for FM recorders, the sum of the carrier frequency and the deviation divided by the tape speed;

(3) Not ruggedized;

(4) Not rated for continuous operation in ambient temperatures from below −20° C to above +55° C;

(5) Not specifically designed for underwater use;

(6) Not including recording and/or reproducing heads of the rotary or floating types or designed for use in equipment with characteristics superior to those designed in subparagraph (b) (1) and (2) above;

(7) Tape speed not exceeding 60 inches (152.4 cm) per second;

(8) Number of recording tracks (excluding audio voice track) not exceeding 16;

(9) Start-stop time not less than 25 milliseconds;

(10) Equipped with tape-derived (off-tape) servo speed control and with a time displacement (base) error of not less than ±25 microseconds at a tape speed of 60 inches (152.4 cm) per second and not less than ±50 microseconds at any lower tape speed measured in accordance with IRIG document 118–71, paragraph 5.2.2.5, or document EIA RS–413/ANSI C 83.94–1973;

(c) Systems for use in civil aircraft or helicopters to record flight data for safety and/or maintenance purposes, and having all of the following characteristics:

(i) In normal civil use for more than one year;

(ii) Not exceeding 100 input channels;

(iii) Sum of the individual channel recording bandwidths not exceeding 500 Hz;

(d) Recording equipment not intended for use in conjuction with equipment or materials covered by other items, provided that the capability of the recorder is limited to both:

(1) A tape width not exceeding ¼ inch (6.35 mm);

(2) Digital recording techniques in serial form with a packing density not exceeding 800 bits per inch.

Technical Note.—Packing density is, for digital recorders, the number of bits per second per track divided by the tape speed;

(e) Incremental recorders and/or reproducers (i.e. equipment designed for discontinuous sampling and/or collection of data in an incremental manner) having all of the following characteristics:

(1) The maximum tape speed, at the maximum stepping rate, does not exceed 2 inches (50.8 mm) per second;

(2) The equipment has all the characteristics specified in sub-paragraphs (3) to (6) inclusive in Note 1(b) above;

(f) Digital magnetic recorders specially designed for seismic/geophysical applications, operating in the frequency range of 5 to 800 Hz and limited to the following operational parameters:

(1) A maximum bit packing density of 1,600 bits per inch (63 bits per mm) per track;

(2) A maximum bit transfer rate of 0.96 million bits per second;

(3) A maximum tape read-write speed of 75 inches (190.5 cm) per second.

Technical Note.—Packing density is, for digital recorders, the number of bits per second per track divided by the tape speed.

2. Licenses are likely to be approved for export to satisfactory end-users of reasonable quantities of magnetic tape and flexible disc cartridge recording media covered by sub-entry (d) above, for use in civil television recording and reproducing applications or with computers as appropriate, provided that:

(a) The base material consists only of polyethylene terephthalate or cellulose acetate;

(b) The magnetic coating material consists only of undoped gamma-ferric (iron) oxide with a rated intrinsic coercitivity not exceeding 350 oersteds (video tape considered under subparagraph (c)(1) below, may also include chromium dioxide-coated tape with a rated intrinsic coercitivity not exceeding 500 oersteds and a width not exceeding 1 inch (25.4 mm)); and

(c) The magnetic recording media is limited to the following types and characteristics:

(1) Video tape designed for television recording and reproduction with a tape width not exceeding 2 inches (50.8 mm);

(2) Computer tape designed for digital longitudinal recording and reproduction and having all of the following characteristics:

(i) A magnetic coating certified for a maximum packing density of 6,250 bits per inch (9,042 flux changes per inch) along the length of the tape;

(ii) A magnetic coating thickness not less than 0.40 mil (10.2 microns);

(iii) A tape width not exceeding 1 inch (25.4 mm);

(iv) A tape length not exceeding 3,600 feet (1,097.3 meters);

(3) Computer tape in cassettes/cartridges designed for digital longitudinal recording and reproduction and having all of the following characteristics:

(i) A magnetic coating certified for a maximum packing density of 1,600 bits per inch (3,200 flux changes per inch) along the length of the tape;

(ii) A magnetic coating thickness not less than 0.17 mil (4.32 microns);

(iii) A tape width not exceeding ¼ inch (6.35 mm);

(iv) A tape length not exceeding 900 feet (274.3 meters);

(4) Computer flexible disc cartridges designed for digital recording and reproduction and having all of the following characteristics:

(i) A magnetic coating certified for a maximum packing density of 13,262 flux changes per radian (3,268 bits per inch at a radius of 2.029 inches (51.536 mm)) around the disc;

(ii) A magnetic coating thickness not less than 0.1 mil (2.54 microns);

(iii) A disc thickness not exceeding 0.003 inch (80 microns);

(iv) A disc outer diameter not exceeding 7.88 inches (201 mm);

(v) A disc inner diameter of 1.5 inch (38.1 mm).

3. Licenses are likely to be approved for export to satisfactory end-users of reasonable quantities of recording media covered by sub-entry (d) above, specially designed for digital recording and reproducing equipment operating serially with a packing density not exceeding 800 bits per inch per track specially designed for use with, and incorporated in, typewriter systems used for preparing, correcting and/or composing text. (The digital recording and reproducing equipment described in this Note is not covered by sub-entry (a) above.)

1584A Cathode-ray oscilloscopes and specialized parts therefor, including associated plug-in units and external amplifiers, preamplifiers, and sampling devices, having any of the following characteristics:

(a) An amplifier bandwidth greater than 100 MHz (defined as the band of frequencies over which the deflection on the cathode-ray tube does not fall below 70.7 percent of that at maximum point measured with a constant input voltage to the amplifier);

(b) Containing or designed for use with cathode-ray tubes covered by entry 1541 (b) or (c);

(c) * * *

(d) * * *

(e) * * *

(f) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of oscilloscopes (including mainframe/amplifier systems) and probes therefor, covered only by sub-entries (a) and (b) above, provided that:

(a) The oscilloscope or system bandwidth is not rated in excess of 200 MHz;

(b) In the case of systems, the characteristics of individual plug-ins or mainframes are not in excess of what is required for the overall system performance;

(c) The equipment is a reasonable requirement for the stated legitimate civil end-use; and

(d) The cathode-ray tube contains no electron multiplier.

1586A Acoustic wave devices and specialized parts therefor, as follows:

(a) Surface acoustic wave and surface skimming acoustic wave devices (*i.e.*, signal processing devices employing elastic waves in materials, including but not limited to, lithium niobate, lithium tantalate, bismuth germanium oxide, silicon, quartz, yttrium garnet, aluminum oxide and magnesium aluminum oxide) which permit direct processing of signals, including but not limited to, amplifiers, correlators (fixed, programmable and memory), oscillators, bandpass filters (transversal and resonator), multiplexers, dispersive expansion and compression filters, delay lines (fixed and tapped) and non-linear devices, having any of the following characteristics:

(1) A carrier frequency of greater than 400 MHz;

(2) * * *

(b) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of devices covered by sub-entry (a)(1) above, which are specially designed for use in civil television equipment and which operate at frequencies below 1 GHz.

1587A Quartz crystals and assemblies thereof in any stage of fabrication (i.e. worked, semi-finished or mounted), *except optical grade quartz crystals*, as follows:

(a) For use as filter elements, and having either of the following characteristics:

(1) Designed for operation over a temperature range wider than 125° C; or

(2) Crystals or assemblies of crystals which use the trapped energy phenomenon (i.e. those which have more than one series or parallel resonance on a single quartz element);

(b) * * *

(c) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of items covered by sub-entry (a) above, which have either of the following characteristics:

(a) Designed for operation as intermediate frequency filters operating from 10.5 to 11 MHz or from 21 to 22 MHz with 3 dB bandwidths not exceeding 40 kHz; or

(b) Designed for operation as single sideband filters operating at from 1 to 10 MHz with 3 dB bandwidths not exceeding 4kHz.

1588A Materials composed of crystals having spinel, hexagonal, orthorhombic or garnet crystal structures; thin film devices; assemblies of the foregoing; and devices containing them, as follows (for equipment which may be exported in conjunction with computer shipments, see entry No. 1565):

(a) * * *

(b) Single aperture forms possessing either of the following characteristics:

(1) Switching speed of 0.3 microsecond or faster at the minimum field strength required for switching at 104° F (40° C); or

(2) A maximum dimension less than 30 mils (0.76 mm);

(c) * * *

(d) * * *

(e) * * *

(f) * * *

(g) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of single aperture forms covered by sub-entry (b) above, provided they have a switching speed of slower than 0.3 microsecond and a maximum dimension of 14 mils (0.36 mm) or more.

1595A Gravity meters (gravimeters), and specialized parts therefor, designed or modified for airborne or marine use.

Note.—Licenses are likely to be approved for export to civil end-users for civil end-uses of marine gravimetric systems having a static accuracy of 1 milligal or above, or an in-service (operational) accuracy of 1 milligal or above with a time to steady-state registration of two minutes or greater under any combination of attendant corrective compensations and motional influences.

3604A Zirconium metal; alloys containing more than 50% zirconium by weight; and compounds in which the ratio of hafnium content to zirconium content is less than one part to five hundred parts by weight; manufacturers wholly thereof; *except*

(i) Zirconium metal and alloy in shipments of 5 kg or less;

(ii) Zirconium in the form of foil or strip having a thickness not exceeding 0.025 mm (0.00095 in.) and specially fabricated and intended for use in photo flash bulbs, in shipments of 200 kg or less.

Note.—Licenses are likely to be approved for export to satisfactory end-users of:

(a) Finished parts made of zirconium metal or alloys, specially designed for an identified civil research or power reactor, such as cladding tubes and plugs and separators therefor, liner tubes, thermal insulating tubes, pressure tubes and calandria tubes, provided that:

(1) None of the parts contains fissile materials; and

(2) The importing country has agreed to the application of the Safeguards of the International Atomic Energy Agency (IAEA) in connection with the nuclear reactor facility;

(b) Contained zirconium metal, or parts made therefrom, in individual shipments not exceeding 100 kg, when intended for use in, or in support of, an identified civil research or power reactor facility, in connection with which it is contemplated that IAEA Safeguards would be applied.

3605A Nickel powder and porous nickel metal, as follows:

(a) Powder with a nickel content of 99 percent or more, and a particle size of less than 100 micrometers; and

(b) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of:

(a) Nickel powder in uncompacted powder form not made by the carbonyl process; or

(b) Nickel powder in uncompacted powder form made by the carbonyl process, in quantities of 50 kg or less.

1673A Artificial graphite having an apparent relative density of 1.90 or greater when compared with water at 60° F (15.50° C), *except artificial graphite which has been impregnated or composited with inorganic materials for the purpose of improving only its electrical conductivity, its mechanical resistance or its mechanical friction properties; and electrical resistors, artificial loads for microwave applications, cable waveguide terminations, brush stock, special joints for electrodes, boats and crucibles and high density graphite optical elements.*

Note.—Licenses are likely to be approved for export to satisfactory end-users of the following:

(a) Pyrolitic graphite (e.g. graphite made by vapor deposition at temperatures exceeding 2,732° F. (1,500° C)) in crude or semi-fabricated forms, the dimension of any one of which does not exceed 4 inches (10. cm) in any direction, in individual shipments not exceeding 55 pounds (25 kg);

(b) Non-pyrolitic graphite, having a relative density of less than 1.95 which has not been coated or composited with other elements or compounds to improve its performance at elevated temperatures or reduce its permeability to gases.

1754A Fluorocarbon compounds and manufactures, as follows:

(a) Monomeric and polymeric materials, as follows:

(1) Polychlorotrifluoroethylene, oily and waxy modifications only;

(2) * * *

(3) * * *

(4) * * *

(5) * * *

(b) Greases, lubricants and dielectric, damping and flotation fluids made wholly of any of the materials in sub-entry (a) above;

(c) * * *

Note.—Licenses are likely to be approved for export to satisfactory end-users of up to 5 US gallons (18.9 liters) of polychlorotrifluoroethylene-based lubricating oils covered jointly by sub-entries (a)(1) and (b) above, for bona fide civil uses.

1755A Silicone fluids and greases, as follows:

(a) * * *

(b) Silicone lubricating grease capable of operating at temperatures of 356° F (180° C) or higher and having a drop point (method of test being ASTM or ITP) of 428° F (220° C) or higher.

Note.—Licenses are likely to be approved for export to satisfactory end-users of silicone lubricating greases covered by sub-entry (b) above, provided they are not capable of operating at temperatures of 400° F (205° C) or higher.

1763A Fibrous and filamentary materials which may be used in composite structures or laminates and manufactures thereof, as follows:

(a) Having both of the following characteristics:

(1) Specific modulus greater than 1.25×10^6, and

(2) Specific tensile strength greater than 3×10^6;

(b) Having both of the following characteristics:

(1) Specific modulus greater than 1×10^8, and

(2) Melting or sublimation point higher than 3,000° F (1,649° C) in an inert environment; *except carbon fibers having a specific modulus of less than 2×10^8 and a specific tensile strength of less than 1×10^6;*

(c) * * *

Note.—Licenses are likely to be approved for export for bona fide civil end-uses, of carbon fibers covered by sub-entries (a) and (b) above having both of the following characteristics:

(a) Specific modulus less than 4.5×10^8, and

(b) Specific tensile strength less than 4×10^6.

1767A Preforms of glass or any other material specially designed for the fabrication of optical transmission fibers intended for the manufacture of cable covered by entry No. 1526 II(c).

Note.—Licenses are likely to be approved for export to satisfactory end-users of the preforms described in this entry.

2. The authority citation for Part 399 is revised to read as follows:

Authority: Sec. 4, Pub. L. 96–72 (50 U.S.C. app. 2403); (E.O. 12214, 45 FR 29783, May 6, 1980), Department Organization Order 10–3, (45 FR 6141, January 25, 1980) and International Trade Administration Organization and Function Order 41–1 (45 FR 11862, January 30, 1980).

3. Section 399.1 is revised to read as set forth below. The Commodity Control List printed in the **Federal Register** of June 25, 1980 (45 FR 43060–43138) is reconfirmed and is designated Supplement 1 to § 399.1. Supplement 1 is amended by removing pages CCL–5, 10, 19, 21, 22, 23, 24, 28, 66, 70, 72, 77 and 79 printed at 45 FR 43064, 43069, 43078, 43080, 43081, 43082, 43083, 43087, 43125, 43129, 43131, 43136, and 43138, and inserting in their place replacement pages CCL–5, 10, 19, 21, 22, 23, 24, 28, 66, 70, 72, 77 and 79 set forth below.

§ 399.1 The commodity control list and how to use it.

(a) *Commodity Coverage.* The Commodity Control List (CCL) includes all commodities except those specifically controlled for export by another department or agency of the U.S. Government. For example, arms, ammunition, and implements of war are controlled for export by the Office of Munitions Control, U.S. Department of State. See § 370.10 for a listing of exports controlled by other U.S. Government departments and agencies.

(b) *Commodity Categories.* The commodities under OEA jurisdiction are grouped on the CCL under 10 general categories. Each CCL entry is preceded by a four-digit Export Control Commodity Number (ECCN). The first digit relates to the strategic level of control; the second digit identifies the Group to which the commodity belongs; and the remaining two digits identify related commodities within a Group.

Group	Types of commodities
0	Metal-working machinery
1	Chemical and petroleum equipment
2	Electrical and power-generating equipment
3	General industrial equipment
4	Transportation equipment
5	Electronics and precision instruments
6	Metals, minerals, and their manufactures
7	Chemicals, metalloids, petroleum products, and related materials
8	Rubber and rubber products
9	Miscellaneous

Within the ten general categories, specific CCL entries define the commodities under control to the destinations included in the country groups specified in the CCL column headed "Validated License Required." See Supplement No. 1 to Part 370 for a listing of the countries included in each country group.

(c) *Embargo Destinations.* Almost all CCL entries include Country Groups S and Z, embargo destinations, in the column headed "Validated License Required." Generally, the last entry in each commodity category is a "basket" entry asserting control over exports to destinations in Country Groups S and Z of commodities that are not elsewhere specified in that commodity category. In a few instances, however, certain entries are excepted from the general embargo policy and are specifically identified. The commodities so excepted may be exported under General License *G-DEST*. Certain other General Licenses may also apply, *e.g.*, General License *GIFT*. With these exceptions, no commodity may be exported or reexported to a destination in Country Group S or Z unless an export license application (Form ITA–622P) or request to reexport (Form ITA–699P) has been filed with the Office of Export Administration and a validated export license or reexport approval covering the proposed transaction has been issued to the exporter. See § 385.1 for general policy statements with respect to embargo destinations.

(d) *All Other Destinations, except Canada.* If a commodity is intended for export to a destination in Country Group P, Q, T, V, W, or Y and is covered by a CCL entry that includes P, Q, T, V, W, or Y, as appropriate, in the column headed "Validated License Required," an export license application or reexport request will generally have to be filed with the OEA and a validated export license or reexport authorization covering the proposed transaction will generally have to be issued prior to shipment. If a commodity is covered by a CCL entry but is intended for export to a country that is *not* included in a country group for which control is indicated, the commodity may be shipped under authority of General License *G-DEST*, provided none of the parties involved is currently denied export privileges (see Supplement No. 1 to Part 388) and the export is not restricted by the special licensing requirements summarized in (f)(3) below. A small value shipment of a commodity included in a CCL entry may be eligible for export to a destination in Country Group Q, T, or V under the authority of General License *GLV*. In addition, one of the other, more specialized, General Licenses set forth in Part 371 may be applicable. Exporters should review the General License provisions in Part 371 prior to filing an application to ascertain whether any apply to the proposed shipment or conversely require a validated license.

(e) *Canada.* Canada is not included in any of the Country Groups, and most commodities may be exported to Canada for consumption or use in that country without a validated export license. In the few instances where a validated license is required, Canada is specifically named. See § 385.6 for a general policy statement with respect to exports to Canada. Note also the special licensing requirements summarized in (f)(3) below.

(f) *How To Use the CCL.*—(1) *General categories.* The first step is to identify which CCL entry covers the commodity proposed for export. This can usually be determined by reviewing the appropriate general category within which the commodity is most likely to be included. If the exporter is uncertain of the proper CCL entry, he should consult the Office of Export Administration.

Once the CCL entry has been located, the Export Control Commodity Number (ECCN) should be noted. This consists of a four-digit number that must appear on your export license application or reexport request, if one is required. The four-digit number will be followed by a code letter. This code letter is a key to the documentation requirements of Part 375, and is used elsewhere in the Regulations to indicate the country group level of control for CCL entries. This code letter need not appear on the export license application or reexport request. The letters used and the respective country groups are:

Code letters	Country groups for which validated license is required
A	PQSTVWYZ (Multilaterally controlled to all destinations.) Only "A" commodities are subject to IC/DV procedure (see § 375.1).
B	PQSTVWYZ (Unilaterally controlled to all destinations.)
C	PQSWYZ and certain other countries.
D	PQSWYZ only.
E	PSWYZ.
F	SZ and certain other countries.
G	SZ only.
I	None.
M	Various (Country Group control level is governed by another entry on the CCL.)

(2) *Country of destination and value of shipment.* Having located the ECCN for a commodity that is to be exported, the next step is to determine if a validated export license is required for *the particular shipment* in question. This is determined by reference to the column of the CCL headed "Validated License Required" and, in certain cases, by the value of the shipment.

(i) If the code letter following the ECCN is A or B, and the country of destination is in Country Group T or V, a validated export license is required if the value of the shipment exceeds the value shown in the column of the CCL headed "GLV $ Value Limit." However, see § 371.5 for restrictions on the use of General License *GLV.*

(ii) If the code letter following the ECCN is A and the country of destination is in Country Group P, Q, S, W, Y, or Z, a validated export license is required *regardless of the value of the shipment.*

(iii) If the code letter following the ECCN is B, C, D, or E, and the country of destination is in Country Group P, S, W, Y or Z or specifically named in the column of the CCL headed "Validated License Required," a validated export license *is* required, regardless of the value of the shipment. If the country of destination is in Country Group Q, a validated export license is required unless the code letter is E, F, G or I, or there is a GLV $ value shown in a footnote to the entry and the value of the shipment does not exceed the GLV $ value. The GLV $ value limit for Country Group Q is "0" unless stated otherwise in a footnote for the entry. However, see § 371.5 for restrictions on the use of General License *GLV.*

(iv) If the code letter following the ECCN is F or G, and the country of destination is in Country Group S or Z or is specifically named in the column of the CCL headed "Validated License Required," a validated export license *is* required, regardless of the value of the shipment.

(3) *Special licensing requirements.* Under certain circumstances, a commodity may not be exported under a General License even though, from an examination of the CCL, it appears to meet the requirements for export under a General License. Exporters should review, in particular, Parts 376, 378, and 385. For example—

(i) The commodity is related to nuclear weapons, nuclear explosive devices, nuclear testing, the chemical processing of irradiated special nuclear or source materials, the production of heavy water, the separation of isotopes of source and special nuclear material, or the fabrication of nuclear reactor fuel containing plutonium, as described in § 378.3, or the technical data are related to any of these activities, as described in § 379.4(c)(1), unless the technical data may be exported under the provisions of General License *GTDA;*

(ii) An individual validated export license is required to export any commodity or technical data (except data meeting the conditions of General License *GTDA*) where the exporter knows or has reason to know that the commodity, the data, or any product of the data, will be sold to or used by or for military or policy entities in the Republic of South Africa or Namibia. See also § 385.4 with respect to controls over other commodities for export to the Republic of South Africa or Namibia.

(g) *Commodity Control List Headings.* The Commodity Control List contains two headings designed to inform applicants of information that must be included on an export license application or reexport request, and one heading to inform applicants of the reason for control of the commodity.

(1) *Unit of quantity.* The quantity classification given for each commodity in the "Unit" column of the CCL must be shown on the export license application. If dashes (——) are shown in this column, the license is issued in terms of dollar value, unless a specific unit of quantity is required by a footnote in this column. However, if another unit of quantity is commonly used in the trade, the application should show the quantity in terms of that unit. If a unit of weight or measure is listed in the unit column, a shipping tolerance is allowed. (See § 386.7.)

(2) *Processing code.* For each entry on the Commodity Control List, a processing code, *i.e.,* CD, EE, MG, or SS, appears in the "Processing Code" column. These processing codes must be shown on the application for export license or reexport request, since they are used to facilitate the routing and processing of export license applications within the Office of Export Administration. These processing codes stand for Computer Division (CD), Electronic Equipment Division (EE), Capital Goods and Production Material Division (MG), and Short Supply Division (SS). Only those entries on the CCL that have the same processing code may be entered on a single application for export license. (For complete information the inclusion of related commodities on a single application, see § 372.4 (d).)

(3) *Reason for control.* The reason for control for each entry is specified in the last column[1], using the following number code—

Code No.	Reason for control
1	National security [1]
2	Short supply [2]
3	Foreign policy [3]
4	Nuclear non-proliferation [4]
5	Crime control (foreign policy) [5]

[1] Export Administration Act of 1979, Section 5, Pub. L. 96–72, 93 Stat. 507, to be codified at 50 U.S.C. app. § 2404.
[2] Export Administration Act of 1979, Section 7, Pub. L. 96–72, 93 Stat. 515, to be codified at 50 U.S.C. app. § 2406. Other statutes controlling petroleum and other commodities include: Energy Policy and Conservation Act, Section 103, Pub. L. 94–163, 89 Stat. 877, 42 U.S.C. § 6212; Trans-Alaska Pipeline Authorization Act, Section 101, Pub. L. 93–153, 87 Stat. 576, amending 30 U.S.C. § 185; Naval Petroleum Reserve Production Act of 1976, Section 201(10), Pub. L. 94–258, 90 Stat. 309, amending 10 U.S.C. § 7430.
[3] Export Administration Act of 1979, Section 6, Pub. L. 96–72, 93 Stat. 513, to be codified at 50 U.S.C. app. § 2405.
[4] Export Administration Act of 1979, Sections 5, 6, and 17(d), Pub. L. 96–72, 93 Stat. 507, to be codified at 50 U.S.C. app. § 2416(d), Nuclear Non-Proliferation Act of 1978, Section 309(c), Pub. L. 95–242, 92 Stat. 141, to be codified at 42 U.S.C. § 2139a.
[5] Export Administration Act of 1979, Section 6(j), Pub. L. 96–72, 93 Stat. 515, to be codified at 50 U.S.C. app. § 2405(j).

In some cases, more than one reason for control is given for one entry. If an entry is controlled for more than one reason, but not to an identical list of countries, the lesser degree of control is explained in a footnote. Also, all entries (except those showing "none" in the "Validated License Required" column) are controlled for foreign policy reasons to Country Groups S and Z due to certain embargo programs, and all entries having both a "V" in the "Validated License Required" column and a "1" in the "Reason for Control" column are controlled for foreign policy reasons to Syria, Iraq, Libya, and the People's Democratic Republic of Yemen. In some cases, sub-entries of a CCL entry are controlled for different reasons. In these cases, a dash (—) will be shown in the first line of the entry, and the code number is shown in the "Reason for Control" column exactly opposite each sub-entry (a), (b), etc. (For example, see CCL entry No. 1110.)

(h) *The Abbreviation "n.e.s."* The abbreviation "n.e.s." appearing in various CCL entries means "not elsewhere specified." If a commodity intended for export appears to be covered by a CCL entry and the

[1] In accordance with section 5(c)(1) and 6(k) of the Export Administration Act of 1979.

commodity description carries the limitation "n.e.s.," that CCL entry should not be used until a check has been made to determine whether another CCL entry specifically covers the commodity.

(i) *Commodity Description on Applications or Reexport Requests.* Phrases such as "specify by name," "specify by name and model number," "give full specifications," etc., are included in various CCL entries. This information is required by the OEA on export license applications or reexport requests in order to evaluate the proposed export. Failure to provide the requested information may delay processing or result in the application or reexport request being returned without action.

(j) *Commodity Groups.* Export control commodity classifications are divided into major groups of related commodities. Below are the titles appearing on the Commodity Control List and initial page number of each group.

(k) *Control Over End Products.* Certain commodities that are under export control to all destinations for national security reasons may be used as components in end products that, because of their peaceful use, are under control only to embargo destinations. Where a controlled component is the principal element in such an end product, however, and can feasibly be removed or used for other purposes, the object of the control program is defeated unless the end product is subject to the same control as the component. This explains why, in some instances, commodities that do not appear to qualify for control for national security reasons are under validated license control to all destinations.

Note.—The foregoing portion of this § 399.1 is explanatory only and does not modify or supersede other Parts of the *Export Administration Regulations.*

BILLING CODE 3510-25-M

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits T&V	Processing Code	Reason for Control
4094B Mandrels and bellows forming dies, as follows:		PQSTVWYZ and Canada	0	MG	4
(a) Mandrels or forming dies, two piece cylindrical having a single indented circumferential convolution bisected by the two halves and having the following dimensions:					
(1) 3 in. to 16 in. outside diameter;					
(2) ½ in. or more in length; and					
(3) Single convolution depth more than 2 mm; and					
(b) Mandrels or forming dies, hollow two piece cylindrical having a single internal indented circumferential convolution bisected by the two halves and having the following dimensions:					
(1) 3 in. to 16 in. inside diameter;					
(2) ½ in. or more in length; and					
(3) Single convolution depth more than 2 mm.					
6098F Other machinery and equipment (including tools, fixtures, and jigs) specially designed or modified for the manufacture of equipment utilized in the exploration for, or production of, petroleum or natural gas, and specially designed parts and accessories therefor, as follows:		SZ, Afghanistan and the USSR [1, 2]	—	MG	3
Dowel hole drilling machines, Cone bit drilling machines, Cone bit milling machines, Bit-arm milling machines, Pipe perforating machines, Liner mills, Casing mills, Cone buster mills,					
Collar mills, Packer mills, and Machinery and equipment, n.e.s., specially designed or modified for the manufacture of equipment utilized in the exploration for, or production of, petroleum or natural gas.					
6099G [2,3] Other metal-working machinery, n.e.s.; and parts and accessories, n.e.s.		SZ [2, 3]	—	MG	3
GROUP 1—CHEMICAL AND PETROLEUM EQUIPMENT [4]					
1110A Gas liquefying equipment, as follows:	[5]	PQSTVWYZ	500	MG	—
(a) Equipment for the production of liquid hydrogen, *except plants with a capacity of less than 1½ tons per 24-hour day and not designed for, or capable of, the production of hydrogen slush;*					1
(b) Equipment for the production of liquid fluorine; and					1, 4 [6]
(c) Specially designed parts and acessories therefor.					1, 4 [6]

[1] Including Estonia, Latvia, and Lithuania.
[2] A validated license also is required for export to the Republic of South Africa and Namibia if intended for delivery to or for use by or for military or police entities in these destinations or for use in servicing equipment owned, controlled, or used by or for these entities. See §§ 371.2(c)(11) and 385.4(a).
[3] A validated license is also required for export or reexport to the U.S.S.R. if the exporter knows or has reason to know the commodity is for any use directly in preparation for, in conduct of, in support of, or visually identified with the 1980 Summer Olympic Games scheduled to commence in Moscow on July 19, 1980. These commodities are subject to controls under the authority of the foreign policy provisions contained in section 6 of the Export Administration Act of 1979. This commodity control list entry as well as the other entries in this Group are subject to controls on the basis of the above criteria.
[4] See § 370.10 for commodities which require export authorization from other U.S. Government Departments and Agencies.
[5] Report equipment in "number."
[6] The countries to which commodities in this entry are controlled for nuclear reasons are those *not* listed in Supp. No. 2 or Supp. No. 3 to Part 373.

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits T&V	Processing Code	Reason for Control
1206A Electric arc devices for generating a flow of ionized gas in which the arc column is constricted, *except devices wherein the flow of gas is for isolation purposes only and devices of less than 100 kW for cutting, welding, melting, plating, and/or spraying;* equipment incorporating such devices; and specially designed parts, accessories, and control or test equipment for such devices.		PQSTVWYZ	500	MG	4 [1]
3240A Now covered by entry No. 3261.					
4240B Now covered by entry No. 4261.					
3261A Neutron generator systems, including tubes, designed for operation without an external vacuum system, and utilizing electrostatic acceleration to induce a tritium-deuterium nuclear reaction; and specially designed parts therefor.	[2]	PQSTVWYZ	0	EE	1, 4
4261B Particle accelerators having *all* of the following specifications:	[3]	PQSTVWYZ	500	EE	4
(a) Peak beam power exceeding 500 MW;					
(b) Output energy exceeding 500 kV; and					
(c) An output beam intensity exceeding 2,000 amperes with a pulse width of 0.2 microsecond or less; and					
(d) Specially designed parts and accessories therefor.					
6299G [4,5] Other electrical and power generating equipment, n.e.s.; and parts and accessories, n.e.s.		SZ [4, 5]	—	MG	3
GROUP 3—GENERAL INDUSTRIAL EQUIPMENT [6,7]					
1305A Metal rolling mills, as follows:		PQSTVWYZ	1,000	MG	1
(a) Mills specially designed or re-designed for the rolling of metals and alloys with a melting point exceeding 1,900°C; and					
(b) Specialized controls, parts, and accessories for the above mills.					
1312A Presses and specialized controls, accessories, and parts therefor, as follows:	[8]	PQSTVWYZ	1,000	MG	—
(a) Presses specially designed or re-designed for the working or forming of metals, alloys, or other materials with a melting point exceeding 3,452°F (1,900°C);					1
(b) Hydraulic presses, as follows:					1
(1) Vertical presses having a total rated force of over 10,000 tons; or					
(2) Horizontal presses having a total rated force of over 5,000 tons;					
(c) Isostatic presses, as follows (isostatic presses are those capable of pressurizing a closed					1, 4

[1] The countries to which commodities in this entry are controlled for nuclear reasons are those *not* listed in Supp. No. 2 or Supp. No. 3 to Part 373.
[2] Report systems and tubes in "number."
[3] Report accelerators in "number."
[4] A validated license also is required for export to the Republic of South Africa and Namibia if intended for delivery to or for use by or for military or police entities in these destinations or for use in servicing equipment owned, controlled, or used by or for these entities. See § 371.2(c)(11) and § 385.4(a).
[5] A validated license is also required for export or reexport to the U.S.S.R. if the exporter knows or has reason to know the commodity is for any use directly in preparation for, in conduct of, in support of, or visually identified with the 1980 Summer Olympic Games scheduled to commence in Moscow on July 19, 1980. These commodities are subject to controls under the authority of the foreign policy provisions contained in section 6 of the Export Administration Act of 1979. This commodity control list entry as well as the other entries in this Group are subject to controls on the basis of the above criteria.
[6] See § 370.10 for commodities which require export authorization from other U.S. Government Departments and Agencies.
[7] For mechanical measuring instruments, see entry No. 1532.
[8] Report machines in "number."

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits T&V	Processing Code	Reason for Control
4563B Nuclear reactor and nuclear power plant related equipment as follows:	--------	PQSTVWYZ [1]	0	MG	4
(a) Reactor and power plant simulators, models or mock-ups;					
(b) Process control systems intended for use with nuclear reactors;					
(c) Generators, turbine-generator sets, steam turbines, heat exchangers, and heat exchanger type condensers designed or intended for use in a nuclear reactor; and					
(d) Commodities, parts and accessories specially designed or prepared for use with nuclear plants (*e.g.*, snubbers, airlocks, reactor inspection equipment) *except* items licensed by the NRC pursuant to 10 CFR 110.					
1370A Turning machines for generating optical quality surfaces using a single point cutting tool, and components and accessories therefor, as follows:	No.	PQSTVWYZ	500	MG	1, 4
(a) Turning machines having all of the following characteristics:					
(1) Slide positioning accuracy less (finer) than 0.0005 mm per 300 mm of travel, TIR (peak-to-peak);					
(2) Slide positioning repeatability less (finer) than 0.00025 mm per 300 mm of travel, TIR (peak-to-peak);					
(3) Spindle runout (radial and axial) less than 0.0004 mm TIR (peak-to-peak);					
(4) Angular deviation of the slide movement (yaw, pitch and roll) less (finer) than 2 seconds of arc (peak-to-peak) over full travel;					
(5) Slide perpendicularity less than 0.001 mm per 300 mm of travel, TIR (peak-to-peak); (Turning machines will be evaluated under the conditions yielding the most accurate values, including but not limited to the incorporation of control systems which permit mechanical, electronic and software compensation.)					
(b) Components, as follows:					
(1) Spindle assemblies, consisting of spindles and bearings as a minimal assembly, *except those assemblies with axial and radial axis motion measured along the spindle axis in one revolution of the spindle equal to or greater (coarser) than 0.0008 mm TIR (peak-to-peak);*					
(2) Linear induction motors used as drives for slides, having all of the following characteristics:					
(i) Stroke greater than 200 mm;					
(ii) Nominal force rating greater than 45 N; and					
(iii) Minimum controlled incremental movement less than 0.001 mm; or					
(c) Accessories, *i.e.*, single point diamond cutting tool inserts having all of the following characteristics:					
(1) Flawless and chip-free cutting edge when magnified 400 times in any direction;					
(2) Cutting radius between 0.1 and 5 mm; and					
(3) Cutting radius out-of-roundness less than 0.002 mm TIR (peak-to-peak); and					
(d) Specially designed parts and components therefor.					
1371A Anti-friction bearings, as follows:	--------	PQSTVWYZ	500	MG	1
(a) Ball and roller bearings having an inner bore diameter of 10 mm or less and tolerances of ABEC 5, RBEC 5 (or national equivalents) or better and either of the following characteristics:					
(1) Made of special materials, *i.e.*, with rings, balls or rollers made from any steel alloy or other material including, but not limited to high-speed tool steels, Monel metal, beryllium, metaloids, ceramic, and					

[1] A validated license is *not* required for export of these commodities [illegible] to Part 373.

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits T&V	Processing Code	Reason for Control
GROUP 4—TRANSPORTATION EQUIPMENT [1]					
2404A Rockets and missiles, guided or unguided, as follows:	--------	PQSTVWYZ	500	MG	1
(a) Meteorological sounding rockets;					
(b) Non-irritant smoke flares, canisters, grenades, and charges;					
(c) Other pyrotechnic articles having dual military and commercial use;					
(d) Rocket launching ramps, towers, and associated equipment for meteorological rockets; and					
(e) Specially designed parts for the above.					
2406A Vehicles specially designed for military purposes, as follows:	-------- [2]	PQSTVWYZ	0	MG	1, 3, 5
(a) Specially designed military vehicles, excluding vehicles listed in Supplement No. 2 to Part 370;					
(b) Pneumatic tire casings *(excluding tractor and farm implement types)*, of a kind specially constructed to be bullet proof or to run when deflated;					
(c) Engines for the propulsion of the vehicles enumerated above, specially designed or essentially modified for military use; and					
(d) Specially designed components and parts therefor.					
(See § 399.2, Interpretation 19, for aid in determining whether your commodity is covered by this entry.)					
5406D [3] Diesel engines, nonmagnetic, 50 brake horsepower and over, having a nonmagnetic content exceeding 50 percent, up to but not exceeding 75 percent of total weight; and parts and accessories, n.e.s. (Specify brake hp at rated rpm.)	-------- [4]	PQSWYZ [5] and Afghanistan	—[6]	MG	1
2409A Naval equipment as follows:	-------- [4]	PQSTVWYZ	1,000	MG	1
(a) Diesel engines of 1,500 hp and over with rotary speed of 700 rpm or over specially designed for submarines;					
(b) Electric motors specially designed for submarines, *i.e.*, over 1,000 hp, quick reversing type, liquid cooled, and totally enclosed;					
(c) Nonmagnetic diesel engines, 50 hp and over, specially designed for military purposes (An engine shall be presumed to be specially designed for military purposes if it has nonmagnetic parts other than crankcase, block, head, pistons, covers, end plates, valve facings, gaskets, and fuel, lubrication and other supply lines, or its nonmagnetic content exceeds 75 percent of total weight.);					
(d) Other magnetic, pressure, and acoustic underwater detection devices specially designed for military purposes; and controls and components thereof;					
(e) Marine boilers designed to have *any* of the following characteristics: (1) Heat release rate (at maximum rating) equal to or in excess of 190,000 BTU's per hour per cubic foot of furnace volume; or (2) Ratio of steam generated in pounds per hour (at maximum rating) to the dry weight of the boiler in pounds equal to or in excess of 0.83; and					
(f) Components, parts, accessories, and attachments for the above.					

[1] See § 370.10 for commodities which require export authorization from other U.S. Government Departments and Agencies.
[2] Report vehicles, and engines in number.
[3] A validated license also is required for export to the Republic of South Africa and Namibia if intended for delivery to or for use by or for military or police entities in these destinations or for use in servicing equipment owned, controlled, or used by or for these entities. See § 371.2(e)(11) and § 385.4(a).
[4] Report engines in number.
[5] The GLV $ value limit for Country Group Q is $100.
[6] Report engines and motors in number.

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits T&V	Processing Code	Reason for Control
4409B Water tube boilers, marine type, designed to have a heat release rate (at maximum rating) equal to 180,000 BTU, up to but not including 190,000 BTU per hour per cubic foot of furnace volume; boiler superheaters, feedwater heaters, and economizers therefor; and parts and accessories therefor.	----------	PQSTVWYZ	1,000	MG	1
2410A Pressure refuellers, pressure refuelling equipment, and equipment specially designed to facilitate operations in confined areas and ground equipment, not elsewhere specified, developed specially for aircraft and helicopters, and specially designed parts and accessories, n.e.s	----------	PQSTVWYZ	500	MG	1, 3
1416A Vessels, as follows:	-------[1]	PQSTVWYZ	1,000	MG	1
(a) Hydrofoil vessels with automatically controlled foil systems which are capable of speeds of above 40 knots in rough water (Sea State Five);					
(b) Vessels incorporating any item included in a CCL entry beginning with the numeral 2 or listed in Supplement No. 2 to Part 370, any item described in entry Nos. 1485, 1501, 1502, and 1510 (*except all types of fish-finding or whale-finding equipment*), or incorporating degaussing facilities; and					
(c) Specially designed parts and accessories for the above. (Also see §§ 370.10(a) and (f).)					
1418A Deep submergence vehicles, manned or unmanned, tethered or untethered, capable of operating at depths exceeding 1,000 meters, and specially designed equipment, components and materials therefor, including but not limited to pressure housings or pressure hulls specially designed for normal operating pressures of more than 101 bars. (For syntactic foam, see entry No. 1759.)	-------[1]	PQSTVWYZ	500	MG	1
1431A Gas turbine engines for marine propulsion of 3,500 rated shaft hp and above, whether originally designed as such or adapted for such use from aero-engines; and specially designed parts, n.e.s.	-------[2]	PQSTVWYZ	1,000	MG	1
4431B Other marine propulsion steam turbines specially designed for naval use; and parts and accessories, n.e.s. (Specify hp or kW.)	----------	PQSTVWYZ	1,000	MG	1
5431D[3] Compressors, fans, and blowers, any type, specially designed or modified for military or naval shipboard use; and parts and attachments, n.e.s. (Specify by name.)	----------	PQSWYZ[3] and Afghanistan	—[4]	MG	1
1460A Nonmilitary aircraft and helicopters, aero-engines, and aircraft and helicopter equipment, as follows:	-------[5]	PQSTVWYZ	1,000	MG	—
(a) Helicopters over 10,000 lbs. (4,530 kg) empty weight, and power transmission systems therefor (empty weight is understood to include normal installation and normal minimum crew, but does not include fuel or payload);					1, 3[6]
(b) Other nonmilitary aircraft and helicopters, *except those which do not contain equipment listed in Supplement No. 2 to Part 370 or entry No. 1485 or 1501 and which are of types which are in a bona fide normal civil use;* (specify make and model of aircraft and type of avionic equipment on aircraft) and					1, 3[7]

[1] Report vessels or vehicles in number.
[2] Report engines in number.
[3] A validated license also is required for export to the Republic of South Africa and Namibia if intended for delivery to or for use by or for military or police entities in these destinations or for use in servicing equipment owned, controlled, or used by or for these entities. See § 371.2(c)(11) and § 385.4(a).
[4] The GLV $ value limit for Country Group Q is $500.
[5] Report aircraft, helicopters, and engines in "number."
[6] Foreign policy controls apply to helicopters over 10,000 lbs. empty weight for Libya, Syria, Iraq, the People's Democratic Republic of Yemen, the Republic of South Africa, and Namibia.
[7] Foreign policy controls apply to the Republic of South Africa and Namibia, for both aircraft and helicopters regardless of value, and to Libya, Syria, Iraq, and the People's Democratic Republic of Yemen for fixed-wing aircraft valued at $3,000,000 or more. Foreign policy controls do not apply to parts or engines.

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits T&V	Processing Code	Reason for Control
Entry No. 1460 (cont.)					
(c) Aero-engines and specially designed parts and accessories, n.e.s., *except:*					1
(1) Piston engines;					
(2) Jet engines of less than 5,000 lbs. (2,265 kg) thrust; or					
(3) Turbo-prop or turbo-shaft engines of less than 2,500 hp or with a residual thrust of less than 1,000 lbs. (453 kg).					
(Specify make, model and pound thrust or horsepower.) (Also see § 399.2, Interpretation 20.)					
4460B Nonmilitary aircraft and helicopters, aero-engines, and aircraft and helicopter equipment, as follows:	-------[1]	PQSTVWYZ	1,000	MG	1
(a) Other jet, turbo-prop, turbo-shaft, and gas turbine aircraft engines, as follows:					
(1) Under development for nonmilitary use, experimental or non-certified; or					
(2) Certified engines which have been in civil use for 3 years or less; and					
(3) Parts and accessories, n.e.s., therefor;					
(Specify make, model and pound thrust or horsepower); and					
(b) Parts and accessories, n.e.s., specially designed for nonmilitary:					
(1) Helicopters over 10,000 pounds weight; or					
(2) Helicopters 10,000 pounds or less empty weight or fixed-wing aircraft, of types which have been in normal civil use and containing one or more of the items listed in entry No. 1485 or 1501, or Supplement No. 2 to Part 370.					
(Specify make and model of aircraft, and type of avionic equipment on aircraft.) (Also see § 399.2, Interpretation 20.)					
5460F[2] Other nonmilitary aircraft and demilitarized military aircraft valued at $3,000,000 each or more.	----------	SZ[2] and Syria, Iraq, Libya, People's Dem. Rep. of Yemen, Rep. of South Africa & Namibia	—	MG	3
6460F[2] Other aircraft and helicopters, as follows:	-------[1]	SZ[2] and the Rep. of South Africa & Namibia	—	MG	3
(a) Military aircraft, demilitarized (not specifically equipped or modified for military operations), *the following only:*					
(1) Cargo, "C-45 through C-118" inclusive, and "C-121",					
(2) Trainers, bearing a "T" designation and using piston engines,					
(3) Utility, bearing a "U" designation and using piston engines,					
(4) Liaison, bearing an "L" designation, and					
(5) Observation, bearing an "O" designation and using piston engines; and					
(b) Other nonmilitary helicopters and aircraft.					

[1] Report aircraft, helicopters and engines in number.
[2] A validated license is also required for export or reexport to the U.S.S.R. if the exporter knows or has reason to know the commodity is for any use directly in preparation for, in conduct of, in support of, or visually identified with the 1980 Summer Olympic Games scheduled to commence in Moscow on July 19, 1980. These commodities are subject to controls under the authority of the foreign policy provisions contained in section 6 of the Export Administration Act of 1979. This commodity control list entry as well as the other entries in this Group are subject to controls on the basis of the above criteria.

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits T&V	Processing Code	Reason for Control
Entry No. 6460 (cont.)					
(Specify make and model of aircraft and type of avionic equipment on aircraft. See § 399.2, Interpretation 20. Also see Supplement No. 2 to Part 370 or entry No. 1485 or 1501 for aircraft which are not covered under this entry.)					
5480B [1] Nonmilitary mobile crime science laboratories; and parts and accessories, n.e.s. (See § 376.14.)	--------	PQSTVWYZ [1]	0	MG	5
1485A Compasses, gyroscopes, accelerometers, and inertial equipment, as follows:	--------	PQSTVWYZ	1,000	MG	1
(a) Gyro compasses with provision for determining and transmitting ship's level reference data (roll, pitch) in addition to own ship's course data;					
(b) Integrated flight instrument systems for aircraft which include gyrostabilizers and/or automatic pilots (An integrated flight instrument system is a primary instrument display system of attitude and azimuth with facilities for giving maneuver guidance information to the pilot and often integrated with an autopilot to the extent of embodying a common unit for setting up the required demands.);					
(c) Gyro-astro compasses and other devices which derive position and/or orientation by means of automatically tracking celestial bodies;					
(d) Gyrostabilizers used for other purposes than aircraft control, *except those for stabilizing an entire surface vessel;*					
(e) Automatic pilots used for other purposes than aircraft control *except marine types for surface vessels;*					
(f) Accelerometers with a threshold of 0.005 g or less, or a linearity error within 0.25 percent of full scale output or both, which are designed for use in inertial navigation systems or in guidance systems of all types;					
(g) Gyros with a rated free directional drift rate (rated free precession) of less than 0.5 degree (1 Sigma or r.m.s.) per hour in a 1 g environment;					
(h) Inertial or other equipment using accelerometers described in sub-entry (f) above and/or gyros described in sub-entry (g) above, and systems incorporating such equipment; and					
(i) Specially designed parts and components, and test, calibration, and alignment equipment for the above.					
5485D Now covered by entry No. 6499.					
6490F [2,3] Off-highway wheel tractors of carriage capacity 10 tons or more; and parts and accessories, n.e.s.	-------- [4]	SZ [2,3] and Libya	—	MG	3
6499G [4] Other transportation equipment, n.e.s.; and parts and accessories, n.e.s.	--------	SZ [2, 4]	—	MG	3
9499M Vehicles mounted with telecommunications equipment (including radar). (See Group 5—Electronics and Precision Instruments.) (Specify mounted equipment.) (Report telecommunications equipment, including radar, exported as replacements or accessories under appropriate Export Control Commodity Number.)	No.	Export controls applicable to vehicles included in this entry are those which apply to the equipment mounted on the vehicle.		EE	— [5]

[1] A validated license *is not* required for export of these commodities to Australia, Belgium, Denmark, France, the Federal Republic of Germany (including West Berlin), Greece, Iceland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Turkey, and the United Kingdom.
[2] A validated license also is required for export to the Republic of South Africa and Namibia if intended for delivery to or for use by or for military or police entities in these destinations or for use in servicing equipment owned, controlled, or used by or for these entities. See § 371.2(c)(11) and § 385.4(a).
[3] A validated license is also required for export or reexport to the U.S.S.R. if the exporter knows or has reason to know the commodity is for any use directly in preparation for, in conduct of, in support of, or visually identified with the 1980 Summer Olympic Games scheduled to commence in Moscow on July 19, 1980. These commodities are subject to controls under the authority of the foreign policy provisions contained in section 6 of the Export Administration Act of 1979. This commodity control list entry as well as the other entries in this Group are subject to controls on the basis of the above criteria.
[4] Report tractors in number.
[5] The reasons for control applicable to vehicles included in this entry are those which apply to the equipment mounted on the vehicle.

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits T&V	Processing Code	Reason for Control
Entry No. 1510 (cont.)					
(1) Incorporating sensitive elements made of piezoelectric ceramics or crystal, and with a sensitivity no greater than −192 dB (reference 1 volt per micropascal);					
(2) Not designed for operation at depths greater than 100 meters;					
(3) Independently mounted or configured and not reasonably capable of assembly by the user into a towed hydrophone array;					
(ii) Terrestrial systems or equipment not reasonably capable of conversion by the user to underwater or marine applications as embargoed above.					
(Passive hydrophone sensitivities in this entry are based on sensitivity being defined as 20 times the logarithm to the base 10 of the ratio of rms output voltage to a 1 volt reference, when the hydrophone sensor is placed in a plane wave acoustic field having an rms pressure of 1 micropascal. For example, a hydrophone of −160 dB (reference 1 volt per micropascal) would yield an output voltage of 10^{-8} volts in such a field, while one of −180 dB sensitivity would yield only 10^{-9} volts ouptut.)					
5510D [1] Doppler sonar navigation equipment; and parts and accessories therefor.	--------	PQSWYZ [1] and Afghanistan	— [2]	MG	1
1514A Pulse modulators capable of providing electric impulses of peak power exceeding 6 MW or of a duration of less than 0.1 microsecond, or with a duty cycle in excess of 0.002; and pulse transformer, pulse-forming equipment or delay lines being specialized parts of such modulators; and specially designed parts and accessories therefor. (Specify by name and type number.)	-------- [3]	PQSTVWYZ	1,000	EE	1
1516A Receivers, and specialized parts and accessories therefor, as follows:	-------- [4]	PQSTVWYZ	0 [5]	EE	1, 5
(a) Panoramic radio receivers (which search or scan automatically a part of the electromagnetic spectrum and indicate or identify the received signals); *except ancillary equipment for commercial receivers with which the frequency spectrum searched does not exceed either ±20 percent of the intermediate frequency of the receiver or ±2 MHz;*					
(b) Digitally-controlled radio receivers, whether or not computer controlled, which search or scan automatically a part of the electromagnetic spectrum, in which the switching operation takes less than 10 milliseconds, and which indicate or identify the received signals, *except non-ruggedized digitally-controlled pre-set type radio receivers designed for use in civil communications which have 200 selective channels or fewer* (For digitally-controlled radio receivers using frequency synthesizers see also entry No. 1531.); or					
(c) Receivers for spread spectrum and frequency agile systems having a total transmitted bandwidth which is:					
(1) 100 or more times greater than the bandwidth of any one information channel; and					
(2) In excess of 50 kHz.					
("Spread spectrum" is defined as the technique whereby energy in a relatively narrow-band communications channel is spread over a much wider energy spectrum under the control of a random or pseudo-random bit stream. On receipt, the signal is correlated with the same bit stream to achieve the reverse process of					

[1] A validated license also is required for export to the Republic of South Africa and Namibia if intended for delivery to or for use by or for military or police entities in these destinations or for use in servicing equipment owned, controlled, or used by or for these entities. See § 371.2(c)(11) and § 385.4(a).
[2] The GLV $ value limit for Country Group Q is $500.
[3] Report modulators in "number."
[4] Report receivers in "number."
[5] The GLV $ value limit for the following countries is $500: Australia, Belgium, Denmark, France, the Federal Republic of Germany (including West Berlin), Greece, Iceland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Turkey and the United Kingdom.

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits T&V	Processing Code	Reason for Control
5597B [1] Polygraphs (except biomedical recorders designed for use in medical facilities for monitoring biological and neurophysical responses); fingerprint equipment and analyzers; fingerprint cameras and equipment; automated fingerprint and identification retrieval systems (whether or not computerized); psychological testing machines; infrared and ultraviolet film and plates and other photo anodized plates, sensitized and unexposed; and specially designed parts and accessories, n.e.s.	-------[2]	PQSTVWYZ [1]	0	EE	5
6598F Geophysical and mineral prospecting instruments; and other instruments and equipment specially designed or modified for the examination or testing of equipment utilized in the exploration for, or production of, petroleum or natural gas; and specially designed parts and accessories therefor. (See § 399.2, Interpretation 30 for illustrative list of commodities included in this entry.)	--------	SZ, Afghanistan and the USSR [3]	—	MG	3
6599C [4, 5] Other electronic and precision instruments, including photographic equipment and film, n.e.s.; and parts and accessories, n.e.s.	--------	SZ [4, 5]	—	EE	3
7599I Exposed and developed microfilm reproducing in whole or in part, the content of printed books, pamphlets, and miscellaneous publications including newspapers and periodicals, children's picture and painting books, music books, sheet music, and calendars; motion picture film and sound track, exposed and developed, and advertising printed matter exclusively related thereto.	--------	None	—	MG	—

GROUP 6—METALS, MINERALS, AND THEIR MANUFACTURES [6]

1601A Now covered by entry No. 1371.						
4601B Aircraft landing mats	Sq. ft.	PQSTVWYZ	1,000 [7]	MG	1
2603A Specifically designed components and parts for ammunition, *except cartridge cases, powder bags, bullets, jackets, cores, shells, projectiles, boosters, fuses and components, primers, and other detonating devices and ammunition belting and linking machines.* (Specify by name.)	--------	PQSTVWYZ	0 [8]	MG	1, 3, 5
3604A Zirconium metal; alloys containing more than 50 percent zirconium by weight; compounds in which the ratio of hafnium content to zirconium content is less than one part to five hundred parts by weight; manufactures wholly thereof; and waste and scrap; *except zirconium metal and alloy in shipments of 5 kilograms or less; and zirconium in the form of foil or strip having a thickness not exceeding 0.025 mm (0.00095 in.) and specially fabricated and intended for use in photo flash bulbs, in shipments of 200 kilograms or less.*	Lb.	PQSTVWYZ	500	MG	1, 4
3605A Nickel powder and porous nickel metal, as follows:	Lb.	PQSTVWYZ	100	MG	1, 4
(a) Powder with a nickel content of 99 percent or more, and a particle size of less than 100 micrometers; and					

[1] A validated license is *not* required for export of these commodities to Australia, Belgium, Denmark, France, the Federal Republic of Germany (including West Berlin), Greece, Iceland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Turkey and the United Kingdom.
[2] Report instruments and equipment in "number."
[3] Including Estonia, Latvia, and Lithuania.
[4] A validated license also is required for export to the Republic of South Africa and Namibia if intended for delivery to or for use by or for military or police entities in these destinations or for use in servicing equipment owned, controlled, or used by or for these entities. See § 371.2(c) (11) and § 385.4(a).
[5] A validated license is also required for export or reexport to the U.S.S.R. if the exporter knows or has reason to know the commodity is for any use directly in preparation for, in conduct of, in support of, or visually identified with the 1980 Summer Olympic Games scheduled to commence in Moscow on July 19, 1980. These commodities are subject to controls under the authority of the foreign policy provisions contained in section 6 of the Export Administration Act of 1979. This commodity control list entry as well as the other entries in this Group are subject to controls on the basis of the above criteria.
[6] See § 370.10 for commodities which require export authorization from other U.S. Government Departments and Agencies.
[7] The GLV $ value limit for Country Group Q is $500.
[8] The GLV $ value limit for the following countries is $500; Australia, Belgium, Denmark, France, the Federal Republic of Germany (including West Berlin), Greece, Iceland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Turkey and the United Kingdom.

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits T&V	Processing Code	Reason for Control
4676B Cylindrical rings, or single convolution bellows, made of high-strength steels having all of the following characteristics:	--------	PQSTVWYZ and Canada	0	MG	4
(a) Tensile strength of greater than or equal to 150,000 psi;					
(b) Wall thickness of 3 millimeters or less;					
(c) Diameter of 3 inches or more.					
4677B Cylindrical discs, in raw, semifabricated, or finished form, having all of the following characteristics:	--------	PQSTVWYZ and Canada	0	MG	4
(a) Having a ½ to 2 inch peripheral lip;					
(b) Having a diameter of 3 inches or more;					
(c) Made of maraging steel or aluminum alloy (7000 series).					
4678B Corrosion-resistant sensing elements of nickel, nickel alloys, phosphor bronze, stainless steel, or aluminum specially designed for use with equipment which measures pressures to 100 Torr or less.	--------	PQSTVWYZ [1]	0	MG	4
5680B [2] Nonmilitary protective vests, helmets, leg irons, shackles, handcuffs, thumbcuffs, thumbscrews, and saps.	--------	PQSTVWYZ [2]	0	MG	5
6699C [2,6,8] Other metals, minerals, and their manufactures, n.e.s.	--------	SZ [4, 6, 8]	—	MG	3

GROUP 7—CHEMICALS, METALLOIDS, PETROLEUM PRODUCTS AND RELATED MATERIALS [6]

1701A Lead azide and primary explosives or priming compositions (mixtures) containing azides and/or azide compounds or complexes (for example, orthofluorophenyl azide, silver chlorazide, cuprammonium azide).	Lb.	PQSTVWYZ	500	MG	1
1702A Hydraulic fluids which are or which contain as the principal ingredients petroleum (mineral) oils or synthetic hydrocarbon oils and which have all of the following characteristics:	Bbl.	PQSTVWYZ	500	MG	1
(a) A pour point of −30°F (−34°C) or lower;					
(b) A viscosity index of 75 or greater; and					
(c) Are thermally stable at +650°F (+343°C).					
(See § 377.6(d)(6) and § 377.6(e)(2) for special documentation requirements. Also see § 371.5(d) for special provisions regarding shipments under General License *GLV*.)					

[1] A validated license is not required for export of these commodities to the countries listed in Supps. No. 2 and No. 3 to Part 373.
[2] A validated license *is not* required for export of these commodities to Australia, Belgium, Denmark, France, the Federal Republic of Germany (including West Berlin), Greece, Iceland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Turkey and the United Kingdom.
[3] A validated license also is required for export to the Republic of South Africa and Namibia if intended for delivery to or for use by or for military or police entities in these destinations or for use in servicing equipment owned, controlled, or used by or for these entities. See § 371.2(c) (11) and § 385.4(a).
[4] A validated license is also required for export or reexport to the U.S.S.R. if the exporter knows or has reason to know the commodity is for any use directly in preparation for, in conduct of, in support of, or visually identified with the 1980 Summer Olympic Games scheduled to commence in Moscow on July 19, 1980. These commodities are subject to controls under the authority of the foreign policy provisions contained in section 6 of the Export Administration Act of 1979. This commodity control list entry as well as the other entries in this Group are subject to controls on the basis of the above criteria.
[5] Aluminum powder, or aluminum-magnesium alloy powder, atomized or spherical, with an average particle diameter of 100 microns or less with a purity of 97.0 percent or greater, and aluminum alloy plates, sheets, and other wrought forms of Temper H alloy and all 5083 alloys, *except "O" temper form*, require export authorization from the U.S. Department of State, Office of Munitions Control. See Supplement No. 2 to Part 370.
[6] See § 370.10 for commodities which require export authorization frrom other U.S. Government Departments or Agencies.

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Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits TAV	Processing Code	Reason for Control
3709A Beryllium oxide ceramic and refactory tubes, pipes, crucibles, and other shapes in semi-fabricated or fabricated form, *except forms specially designed for electronic component parts or as substrates for electronic circuits.*	Lb.	PQSTVWYZ	500	MG	1, 4 [1]
3711A Chlorine trifluoride, *except shipments of 5 kilograms or less.*	Lb.	PQSTVWYZ	50	MG	1, 4
4712B Now covered by entry No. 3709.					
1715A Boron, as follows:	Lb.	PQSTVWYZ	500	MG	1, 4 [2]
(a) Boron element, boron compounds and mixtures in which the boron–10 isotope comprises more than 20 percent of the total boron content;					
(b) Boron element (metal) all forms; and					
(c) Boron compounds, mixtures and composites containing 5 percent or more of boron, *except pharmaceutical specialties packaged for retail sale,* as follows:					
(1) Boron carbide, *except powder,* having a boron content of 70 percent or more by weight and composites thereof in crude or semi-fabricated forms;					
(2) Boron nitride (hexagonal close-packed structure, white form) and composites thereof in crude or semi-fabricated forms; other boron-nitrogen compounds (*e.g.*, borazanes, borazines, and boropyrazoyls);					
(3) Boron hydrides (*e.g.*, boranes), *except sodium boron hydride, potassium boron hydride, monoborane, diborane and triborane;*					
(4) Organoboron compounds; including metalloorganoboron compounds; and					
(5) Borides with purities above 98.5 percent and having melting points of 3,632°F (2,000°C) or higher and composites thereof in crude or semi-fabricated forms.					
3715A Now covered by entry No. 3711.					
4720B Radioisotopes, cyclotron-produced or naturally occurring, *except those having an atomic number 3 through 83,* and compounds and preparations thereof. (Specify by name and isotope number.)	MC	PQSTVWYZ	100 [3]	MG	4
4721B Helium isotopically enriched in the helium–3 isotope, in any form or quantity, and whether or not admixed with other materials, or contained in any equipment or device.	Liters	PQSTVWYZ and Canada	1,000	MG	1
1746A Polymeric substances and manufactures thereof, where the value of the polymeric component, either alone or in combination with other materials included on the Commodity Control List under an Export Control Commodity Number that is followed by the code letter "A", is 50 percent or more of the total value of the materials, as follows:	Lb.	PQSTVWYZ	100 [4]	MG	1

[1] The countries to which commodities are controlled for nuclear reasons are those *not* listed in Supp. No. 2 or Supp. No. 3 to Part 373.
[2] Nuclear controls apply to all of this entry except sub-entries (c)(2)(5), (4) and (5).
[3] The GLV $ value limit for Country Group Q is $100.
[4] For protective vests and devices manufactured of aromatic polyamides described in sub-entry (d), General License *GLV* applies only to exports to Australia, Belgium, Denmark, France, the Federal Republic of Germany (including West Berlin), Greece, Iceland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Turkey and the United Kingdom.

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	GLV $ Value Limits TAV	Processing Code	Reason for Control
4781B Petroleum, crude or partly refined, including tar sands, shale oil and topped crudes, listed in Supplement No. 2 to Part 377.	Bbl.	PQSTVWYZ and Canada	0 [1]	SS	2
4782B Other petroleum products listed in Supplement No. 2 to Part 377. (See §§ 371.16 and 371.5(d) for special provisions regarding shipments under General Licenses *G–NNR* and *GLV*.)		PQSTVWYZ and Canada	250 [2, 6]	SS	2
4783B Natural gas liquids and other natural gas derivatives listed in Supplement No. 2 to Part 377. (See §§ 371.16 and 371.5(d) for special provisions regarding shipments under General Licenses *G–NNR* and *GLV*.) [4]	Bbl.	PQSTVWYZ and Canada	250 [2]	SS	2
4784B Manufactured gas and synthetic natural gas (except when commingled with natural gas and thus subject to export authorization from the Department of Energy) listed in Supplement No. 2 to Part 377. (See §§ 371.16 and 371.5(d) for special provisions regarding shipments under General Licenses *G–NNR* and *GLV*.)	MCF	PQSTVWYZ and Canada	250 [2]	SS	2
6794F [5] Phosphate rock; phosphoric acid of all concentrations; and processed phosphatic fertilizers of all concentrations (as listed in § 399.2, Interpretation 27). [7]	[6]	SZ, Afghanistan and the USSR [5]	—	SS	3
4799B [8, 9] Chemical agents, including tear gas formulations containing 1 percent or less of ortho-chlorobenzalmalononitrile (CS), or 1 percent or less of chloracetophenone (CN), and smoke bombs; and fingerprint powders, dyes and inks. (Specify by name.) (See § 376.14.)		PQSTVWYZ [4, 9]	0	MG	5
5799D [10] Other chemicals, chemical materials and products, plastic materials, regenerated cellulose, artificial resins, and miscellaneous related materials and products, n.e.s., *except those listed in § 399.2, Interpretation 24.*		PQSWYZ [10] and Afghanistan	— [11]	MG	1
6799G [10, 12] Chemicals, chemical materials and products, plastic materials, regenerated cellulose, artificial resins, and miscellaneous related materials and products, n.e.s., listed in § 399.2, Interpretation 24.		SZ [10, 12]	—	MG	3
GROUP 8—RUBBER AND RUBBER PRODUCTS [13]					
1801A Synthetic rubber, as follows:	Lb.	PQSTVWYZ	500	MG	1

[1] The GLV $ value limit for exports to Canada is the same as the value limit for Country Groups T and V.
[2] The GLV $ value limit for exports to Canada and to Country Group Q is $250.
[3] The GLV dollar value limit for petroleum asphalt and paving mixtures is $5,000.
[4] Natural gas, and liquified natural gas (L.N.G.) and synthetic natural gas commingled with natural gas require export authorization from the U.S. Department of Energy. See § 370.10(g).
[5] Including Estonia, Latvia, and Lithuania.
[6] Report unit of quantity for each commodity as specified in Statistical Classification of Domestic and Foreign Commodities Exported from the United States, Schedule B.
[7] These commodities are subject to control under the authority of the foreign policy provisions contained in section 6 of the Export Administration Act of 1979.
[8] A validated license is *not* required for export of these commodities to Australia, Belgium, Denmark, France, the Federal Republic of Germany (including West Berlin), Greece, Iceland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Turkey, and the United Kingdom.
[9] All other forms of tear gas are controlled by the U.S. Department of State, Office of Munitions Control.
[10] A validated license also is required for export to the Republic of South Africa and Namibia if intended for delivery to or for use by or for military or police entities in those destinations or for use in servicing equipment owned, controlled, or used by or for these entities. See § 371.2(c)(11) and §385.4(a).
[11] The GLV $ value limit for Country Group Q is $100.
[12] A validated license is also required for export or reexport to the U.S.S.R. if the exporter knows or has reason to know the commodity, except medicine and medical supplies, is for any use directly in preparation for, in conduct of, in support of, or visually identified with the 1980 Summer Olympic Games scheduled to commence in Moscow on July 19, 1980. These commodities are subject to controls under the authority of the foreign policy provisions contained in section 6 of the Export Administration Act of 1979. This commodity control list entry as well as the other entries in this Group are subject to controls on the basis of the above criteria.
[13] See § 370.10 for commodities which require export authorization from other U.S. Government Departments and Agencies.

Export Control Commodity Number and Commodity Description	Unit	Validated License Required	G.L.V. $ Value Limits T&V	Processing Code	Reason for Control
6998F [1,4] Shotgun shells, and parts.		SZ [1, 2] and the Rep. of South Africa, Namibia, Botswana, Lesotho, and Swaziland	—	MG	3
4999B Horses for export by sea.		PQSTVWYZ and Canada	0	SS	2
5999B [3,4] Saps; straight jackets; bullet and blast resistant garments, helmets and shields; and parts and accessories, n.e.s.		PQSTVWYZ [3]	0	MG	5
6999G [1,3] Other commodities, n.e.s.; and parts and accessories, n.e.s.		SZ [1, 3]	—	MG	3
7999I Prerecorded phonograph records reproducing in whole or in part, the content of printed books, pamphlets, and miscellaneous publications, including newspapers and periodicals; printed books, pamphlets, and miscellaneous publications, including bound newspapers and periodicals; children's picture and painting books; newspapers and periodicals, unbound, excluding waste; music books; sheet music; calendars and calendar blocks, paper; maps, hydrographical charts, atlases, gazeteers, globe covers, and globes (terrestrial or celestial) and advertising printed matter exclusively related thereto.		NONE	—	MG	—
9999M Technical models for demonstration.		The validated export license control applicable to each model is the same as the control which is applicable to the full size commodity represented by the model as exercised by Commerce (OEA and/or Maritime Administration), State (OMC), or Nuclear Regulatory Commission.			—

[1] A validated license also is required for export to the Republic of South Africa and Namibia if intended for delivery to or for use by or for military or police entities in these destinations or for use in servicing equipment owned, controlled, or used by or for these entities. See § 371.2(c) (11) and § 385.4(a).

[2] A validated license is also required for export or reexport to the U.S.S.R. if the exporter knows or has reason to know the commodity, except medicine and medical supplies, is for any use directly in preparation for, in conduct of, in support of, or visually identified with the 1980 Summer Olympic Games scheduled to commence in Moscow on July 19, 1980. These commodities are subject to controls under the authority of the foreign policy provisions contained in section 5 of the Export Administration Act of 1979. This commodity control list entry as well as the other entries in this Group are subject to controls on the basis of the above criteria.

[3] A validated license is not required for export of these commodities to Australia, Belgium, Denmark, France, the Federal Republic of Germany (including West Berlin), Greece, Iceland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Turkey and the United Kingdom.

[4] Gas masks designed for protection against tear gas and other chemical agents are controlled by the Office of Munitions Control. See § 370.10.

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4. Section 399.2 and Supp. 1 to § 399.2 are revised to read as follows:

§ 399.2 Commodity Interpretations

The commodity interpretations set forth in Supplement No. 1 to this §399.2 are for use in determining (1) the appropriate Export Control Commodity Numbers under which certain commodities are classified, or (2) the validated license requirements for these commodities. They are intended to clarify the question of control where it has been demonstrated that such clarification may prove helpful to the export community, and where such control is not readily apparent from the Commodity Control List and the Export Administration Regulations.

Supplement No. 1 to § 399.2—Interpretations

Interpretation 1: Electronic Computers and Related Equipment (ECCN 1565)

The following equipment is subject to nuclear non-proliferation controls and requires a validated license for Country Groups P, Q, S, T, V, W, Y, and Z, and in the case of (a) (1) through (4) below to Canada:

(a) Electronic computers intended for ultimate consignees engaged directly or indirectly in any of the following activities:

(1) Designing, developing or fabricating nuclear weapons or nuclear explosive devices; or devising, carrying out, or evaluating nuclear weapons tests or nuclear explosions;

(2) Designing, assisting in the design of, constructing, fabricating or operating facilities for the chemical processing of irradiated special nuclear material, for the production of heavy water, for the separation of isotopes of any source or special nuclear material, or specially designed for the fabrication of nuclear reactor fuel containing plutonium;

(3) Designing, assisting in the design of, constructing, fabricating or furnishing equipment or components specially designed, modified or adapted for use in such facilities; or

(4) Training in any of the above activities; and

(b) Advanced electronic digital computers with a bus rate of 60 million bits per second or more, or a processing data rate of 20 million bits per second or more (including digital differential analyzers), *except*

(1) *Electronic computers that do not exceed either a CPU bus rate of 500 million bits per second or a processing data rate of 225 million bits per second are not subject to nuclear non-proliferation controls for destinations listed in Supplement No. 2 to Part 373 of the Export Administration Regulations unless the activities cited in (a) above are involved; or*

(2) *Electronic computers that do not exceed either a CPU bus rate of 200 million bits per second or a processing data rate of 60 million bits per second are not subject to nuclear non-proliferation controls for destinations listed in Supplement Nos. 2 and 3 to Part 373 of the Export Administration Regulations unless the activities cited in (a) above are involved.*

Interpretation 2: Ball and Roller Bearings and Specially Designed Parts

(a) A ball or roller bearing physically incorporated in a segment of a machine or in a complete machine prior to shipment loses its identify as a bearing and the machine or segment of machinery *containing the bearing* is the item subject to export license requirements.

(b) A ball or roller bearing *not* incorporated in a segment of a machine prior to shipment but shipped as a component of a complete unassembled (knocked-down) machine is considered a component of the machine, and the *complete machine* is the item subject to export license requirements.

(c) Ball or roller bearings shipped as spares or replacements are classified under ECCN 1371 and 6699 (ball, roller, or needle-roller bearings and parts). This applies to separate shipments of ball or roller bearings *and* ball or roller bearings shipped with machinery or equipment for which they are intended to be used as spares or replacement parts.

Interpretation 3: Gear Making and Finishing Machinery

Certain Types of gear-making and gear-finishing machines, Export Control Commodity No. 1088, require a validated license for shipments to all destinations except Canada if they are capable of producing gears finer than 48 diametral pitch. In order to clairfy the meaning of the term "diametral pitch finer than 48," examples are given of how diametral pitch is computed. In addition, there is also given below an explanation of how to distinguish between "geartooth grinding machines, generating types" and "nongenerating types of grinding machines."

(a) *Diametral pitch* of a gear is the ratio of the number of teeth to the number of inches in the pitch diameter. It indicates the number of teeth in the gear for each inch of pitch diameter. ("Pitch diameter" is the diameter of the pitch circle which is the circle through the pitch point having its center at the axis of the gear.) *Module* (British or metric) is the ratio of the pitch diameter in millimeters to the number of teeth. The larger the proportion of teeth to pitch diameter, the finer the diametral pitch. Example of diametral pitch: If a gear has a 1-inch pitch diameter and has 48 teeth, the ratio would be 48:1, or a 48 diametral pitch gear. Additional teeth in the same pitch diameter gear, *i.e.*, 49, would result in a finer diametral pitch; fewer teeth, *i.e.*, 47, would result in a gear of coarser diametral pitch. Examination of a gear making or finishing machine may not disclose whether it is capable of producing a gear of finer than 48 diametral pitch. If the exporter has no information on the ability of the machine to be exported for making gears of finer than 48 diametral pitch, he should obtain the information from the manufacturer or distributor.

(b) *Generating type geartooth grinding machines* are those in which the grinding wheel and the gear are both power-driven for continuous circular motion while grinding, rather than an intermittent or indexing operation as with the non-generating type.

Interpretation 4: Classification of "Parts" of Machinery, Equipment, or Other Items

(a) *Where an assembled machine or unit of equipment is being exported.* Where one or more assembled machines or units of equipment are being exported, the individual component parts which are physically incorporated into the machine or equipment do not require a separate validated export license. The validated license or the general license under which the complete machine or unit of equipment is exported will also cover its component parts, *provided* that the parts are normal and usual components of the machine or equipment being exported; or that the physical incorporation is not used as a device to evade the requirement for a validated export license.

(b) *Where parts are exported as spares, replacements, for resale, or for stock.* Where parts are exported as spares, replacements, for resale or for stock, a validated export license is required only if the appropriate entry for the part specifies that a validated license is required for the intended destination.

Interpretation 5: Wire or Cable Cut to Length

(a) Wire or cable may be included as a component of a system or piece of equipment, whether or not the wire or cable is cut to length and whether or not it is fitted with connectors at one or both ends so long as it is in normal quantity necessary to make the original installation of the equipment and is necessary to its operation.

(b) Wire or cable shipped as replacement or spares, or for further manufacture overseas, shall be reported under the applicable wire or cable classification only. This includes wire or cable, whether or not cut to length or fitted with connectors at one or both ends.

Interpretation 6

[Reserved]

Interpretation 7: Numerical Control Systems

(a) Numerical control systems for machine tools are systems in which actions are controlled by the direct insertion of numerical data at some point. The system must automatically interpret at least some portion of this data. Units defined in 1091 include:

(1) Units consisting of fixed and dedicated circuits of discrete logic elements and storage devices (referred to as hardwired units);

(2) Units consisting of and including stored instructions (routines and/or programs), defined as logic states of alterable and nondedicated logic elements which determine various control functions of the machine(s), such as slide movements, cutter compensation, readout, adaptive control, part program editing and tool offsets (softwired or stored program units);

(3) Hardwired unit—a numerical control system wherein fixed and dedicated circuit interconnections of discrete, decision elements are used for primary system control. These circuits may include, but not necessarily, freely programmable memory devices which would be limited to use for data files, part program storage, or output control of machine tool interfacing;

(4) Softwired Unit (Computer Numerical Control (CNC))—a numerical control system

which includes: (*a*) Computer—a dedicated stored program computer to perform some or all of the basic numerical control functions which include, but may not be limited to, velocity and path generation. A stored program computer is further defined as a computer processor controlled by stored instructions that can synthesize, store, and in some cases, alter instructions as though they were data and subsequently execute these instructions, (*b*) Software—a control program (routines and/or programs) stored in the read/write memory of the computer which implements the basic numerical control functions, (*c*) Interface—the means by which the data is transmitted between the stored program computer and the machine;

(5) Direct Numerical Control (DNC)—a system connecting a set of numerically controlled machines to a common memory within a computer for part program or machine program storage with provision for on-demand distribution of data to the machines. Direct Numerical Control systems typically have additional provisions for collection, display, or editing of part programs, operator instructions, or data related to the numerical control process;

(6) Software—control programs, used with CNC and DNC systems, which are stored in a read/write memory of a computer and implement numerical functions, including but not limited to, velocity and path generation, on-line adaptive control and special purpose data distribution, recall, and editing programs for DNC applications. Software used in part programming, *e.g.*, APT, EXAPT, IFAPT, post processors, and similar programs are not considered among these control programs used for CNC and DNC systems.

Where the system is shipped complete (machine and controls) it shall be reported as a complete machine under the appropriate Export Control Commodity Number for the machine. Where a control system for a machine tool is not shipped as part of the original installation of the machine it shall be reported under Export Control Commodity No. 1091.

Note.—When preparing an *export license application* for a numerical control system, the machine and the control unit are classified separately. If either the machine or the control unit requires a validated license, then the entire system requires a license. If either a machine or a control unit is exported separately from the system, it is classified on the export license application without regard to the other parts of a possible system.

When preparing the *Shipper's Export Declaration* (SED), however, a system being shipped complete (*i.e.*, machine and control unit), should be reported under the Schedule B number for the machine. When either a control unit or a machine is shipped separately, it should be reported under the Schedule B number appropriate for the individual item being exported.

(b) Units for numerically controlling machine tools and dimension inspection machines having *all* of the following characteristics:

(1) Hardwired (not softwired, *i.e.*, Computerized Numerical Control (CNC)),

(2) No more than 2 contouring interpolating axes can be simultaneously coordinated,

(3) Minimum programmable increment equal to or greater (coarser) than 0.001 mm, *and*

(4) Without interface to enable direct computer input.

(c) Boring mills, milling machines, and machining centers, having *all* of the following characteristics:

(1) Maximum slide travel in any axis equal to or less than 3,000 mm,

(2) Positioning accuracy of any axis equal to or greater than plus or minus 0.01 mm per 300 mm and 0.005 mm for each additional 300 mm,

(3) Spindle power equal to or less than 20 kw,

(4) Single working spindle,

(5) Axial and radial axis motion measured at the spindle axis in one revolution of the spindle equal to or greater than $D \times 2 \times 10^{-5}$ mm TIR (peak-to-peak) where D is the spindle diameter in millimeters, *and*

(6) Not more than 3 axes capable of simultaneously coordinated contouring motion regardless of the NC unit connected to the machine.

(d) Machine tools, other than the machines described in (c) above, and dimensional inspection machines, which according to the manufacturer's technical specifications can be equipped with controls covered by paragraph (b) above, having *all* of the following characteristics:

(1) Positioning accuracy of any axis equal to or greater than plus or minus 0.01 mm per 300 mm and 0.005 mm for each additional 300 mm,

(2) Radial axis motion measured at the spindle axis equal to or greater than 0.008 mm TIR (peak-to-peak) in one revolution of the spindle (for lathes and other turning machines), *and*

(3) Not more than 3 axes capable of simultaneously coordinated contouring motion regardless of the NC unit connected to the machine.

Interpretation 8

[Reserved]

Interpretation 9

[Reserved]

Interpretation 10: Parts, Accessories, and Equipment Exported as Scrap

Parts, accessories, or equipment which are being shipped as scrap should be described on the Shipper's Export Declaration in sufficient detail to be identified under the proper Commodity Control List Number. When commodities declared as parts, accessories, or equipment are shipped in bulk, or are otherwise not packaged, packed, or sorted in accordance with normal trade practices, the Customs Officer may require evidence that the shipment is not scrap. Such evidence may include, but is not limited to, bills of sale, orders and correspondence indicating whether the commodities are scrap or are being exported for use as parts, accessories, or equipment. Exporters should consult the Exporters' Service Staff, Office of Export Administration, Room 1623, U.S. Department of Commerce, Washington, D.C. 20230, when in doubt regarding the proper Commodity Control List Number of commodities, as parts, accessories, equipment or as scrap.

Interpretation 11

[Reserved]

Interpretation 12: Scrap Arms, Ammunition, and Implements of War

Arms, ammunition, and implements of war, as defined in the U.S. Munitions List (see Supplement No. 2 to Part 370), are under the jurisdiction of the U.S. Department of State, with the following exceptions:

(a) Cartridge and shell cases which have been rendered useless beyond the possibility or restoration to their original identity by means of excessive heating, flame treatment, mangling, crushing, cutting, or by any other method are "scrap" and under the jurisdiction of the U.S. Department of Commerce.

(b) Cartridge and shell cases which have been sold by the armed services as "scrap" are under the jurisdiction of the U.S. Department of Commerce, whether or not they have been heated, flame-treated, mangled, crushed, cut, or reduced to scrap by any other method.

(c) Other commodities on the Munitions List are "scrap" and under the jurisdiction of the U.S. Department of Commerce if they have been rendered useless beyond the possibility of restoration to their original identify *only* by means of mangling, crushing, or cutting. When in doubt as to whether a commodity covered by the Munitions List has been rendered useless, exporters should consult the Office of Munitions Control, U.S. Department of State, Washington, D.C. 20520, or the Exporter's Service Staff, Office of Export Administration, Room 1623, U.S. Department of Commerce, Washington, D.C. 20230, before reporting a shipment as metal scrap.

Interpretation 13–18

[Reserved]

Interpretation 19: Military Automotive Vehicles

(a) *Military automotive vehicles.* (1) For purposes of U.S. export controls, military automotive vehicles "possessing or built to current military specifications differing materially from normal commercial specifications" may include, but are not limited to, the following characteristics:

(i) Special fittings for mounting ordnance or military equipment,

(ii) Bullet-proof glass,

(iii) Armor plate,

(iv) Fungus preventive treatment,

(v) Twenty-four volt electrical systems,

(vi) Shielded electrical system (electronic emission suppression), or

(vii) Puncture-proof or run-flat tires.

(2) These automotive vehicles fall into two categories:

(i) *Military automotive vehicles on the Munitions List, new and used.* Automative vehicles in this category are primarily combat (fighting) vehicles, with or without armor and/or armament, "designed for specific fighting function." These automotive vehicles are licensed by the U.S. Department of State. See list with descriptions, Supplement No. 2 to Part 370, Category VII.

(ii) *Military automotive vehicles not on the U.S. Munitions List, new and used.* Automotive vehicles in this category are primarily transport vehicles designed for non-combat military purposes (transporting cargo, personnel and/or equipment, and/or for towing other vehicles and equipment over land and roads in close support of fighting vehicles and troops). These automotive vehicles are licensed by the U.S. Department of Commerce.

(b) *Parts for military automotive vehicles.* Functional parts are defined as those parts making up the power train of the vehicles, including the electrical system, the cooling system, the fuel system, and the control system (brake and steering mechanism), the front and rear axle assemblies including the wheels, the chassis frame, springs and shock absorbers.

Parts specifically designed for military automotive vehicles on the Munitions List are licensed for export by the U.S. Department of State.

(c) *General instructions.* Manufacturers of non-Munitions List automotive vehicles and/or parts will know whether their products meet the conditions described above. Merchant exporters and other parties who are not sure whether their products (automotive vehicles and/or parts) meet these conditions should check with their suppliers for the required information before making a shipment under general license or submitting an application to the Office of Export Administration for an export license.

Interpretation 20: Aircraft, Parts, Accessories and Components

(a) *Aircraft, and parts, accessories and components therefor.*[1]

Aircraft, parts, accessories, and components defined in Categories VIII and IX of the Munitions List (see supplement No. 2 to Part 370) are under the export licensing authority of the U.S. Department of State. All other aircraft, and parts, accessories and components therefor, are under the export licensing authority of the U.S. Department of Commerce.

The following aircraft, parts, accessories and components are under the licensing authority of the U.S. Department of Commerce:

(1) Any aircraft (except an aircraft that has been demilitarized, but including aircraft specified in paragraph (2) below) that conforms to a Federal Aviation Agency type certificate in the normal, utility, acrobatic, transport, or restricted category, provided such aircraft has not been equipped with or modified to include military equipment, such as gun mounts, turrets, rocket launchers, or similar equipment designed for military combat or military training purposes.

(2) Military aircraft, demilitarized (aircraft not specifically equipped, reequipped, or modified for military operations), *the following only:*

(i) Cargo, bearing designations "C–45 through C–118 inclusive, " and "C–121";

(ii) Trainers, bearing a "T" designation and using piston engines;

(iii) Utility, bearing a "U" designation and using piston engines;

(iv) Liaison, bearing an "L" designation; and

(v) Observation, bearing an "O" designation and using piston engines.

(3) All reciprocating engines.

(4) Other aircraft engines not specifically designed or modified for military aircraft.

(5) Parts, accessories, and components (including propellers), designed exclusively for aircraft and engines described in (1), (2), (3), and (4) above.

(6) General purpose parts, accessories, and components usable interchangeably on either military or civil aircraft.

(b) *Normal civil use.* Aircraft listed on the Commodity Control List under No. 1460 are those that are in normal civil use *and* contain one or more of the following:

(1) Any item on the Munitions List (see Supplement No. 2 to Part 370),

(2) Inertial navigation or other inertial equipment,

(3) Integrated flight instrument systems that have been in normal civil use for less than two years,

(4) Airborne communications equipment having *any* of the following characteristics:

(i) Designed to operate at frequencies greater than 156 MHz,

(ii) Incorporating facilities for (a) the rapid selection of more than 200 channels per equipment, *except equipment operating in frequency range 108–136 MHz with 720 or fewer channels at not less than 25 kHz spacing and which has been in normal civil use for at least one year,* or (b) using frequency synthesis techniques with a speed of switching from one selected output frequency to another selected output frequency less than 10 milliseconds,

(iii) Pressurized throughout,

(iv) Rated for continuous operation over a range of ambient temperatures extending from below minus 55° C to above plus 55° C, and/or

(v) Designed for modulating methods employing any form of digital modulation using time and frequency redundancy such as "Quantized Frequency Modulation" (QFM).

(5) Airborne navigation and direction finding equipment having *any* of the following characteristics:

(i) Pressurized throughout,

(ii) Rated for continuous operation over a range of ambient temperatures extending from below minus 55° C to above plus 55° C,

(iii) Frequency modulated radio altimeters which have been in normal civil use for less than one year,

(iv) Pulse modulated radio altimeters.

(v) Is not in conformity with ICAO standards or provides a function exceeding those resulting from such standards,

(vi) Is designed to make use of hyperbolic grids at frequencies greater than 3 MHz, and/or

(vii) Direction finding equipment operating at frequencies greater than 5 MHz, other than equipment designed for search and rescue.

(6) Airborne radar having *any* of the following:

(i) In normal commercial service for less than one year, and/or

(ii) Specially designed for use other than as a commercial weather radar,

(iii) Incorporating any digital signal processing technique used for automatic target tracking, or having a facility for electronic tracking.

Interpretations 21–23

[Reserved]

Interpretation 24: Chemicals

The commodities listed below require a validated license for export to Country Groups S and Z.

Organic chemicals

Acenapthene
Acenapthenequinone
Acetal
Acetaldehyde
Acetamide
3-Acetamido-4 hydroxybenzene-arsonic acid
2-Acetamidoethyl (p-chlorophenyl) (m-trifluoro methyl phenoxy) acetate
Acetanilide
Acetic acid
Acetic anhydride
Acetin
Acetoacetic acid
Acetobromopropyl lactate
Acetone
Acetone cyanohydrin
Acetonitrile
Acetonylacetone
Acetophenetidin
Acetophenone
Acetoxime
Acetylacetone
para-Acetylaminophenol
para-Acetylaminophenyl salicylate
Acetyl chloride
Acetylene tetrabromide
N-Acetyleneuraminic acid
Acetylhistamine
N-Acetyl-L-tyrosine
N-Acetyl-L-tyrosine ethyl ester
Acetylpyridine
Acetylsalicylic acid
Acetyl triallyl citrate
Acetyl tributyl citrate
Acetyl triethyl citrate
Acetyl tri-2-ethyl hexyl citrate
Aconitic acid
Acrolein
Acrylamide
Acrylic acid
Acrylonitrile
Actase
Adenine
Adenine sulfate
Adenosine
Adenosine-2,3-cyclophosphate
Adenosine-3,5-cyclophosphate
Adenosine-5-diphosphate
Adenosine-5-monophosphate
Adenosine-5-triphosphate disodium
Adenosine-5-triphosphate trihydrate
Adenosyl-L-methionine iodide
Adenylic acid
Adipic acid
Adiponitrile
Adrenalone
Adrenalone hydrochloride
Agarose
Alanine
beta-Alanine
Aldol
Alginic acid

[1] This interpretation does not refer to electronic communication and navigational commodities usable on aircraft.

Alkyl aryl phosphate diphenyl, 2-ethyl hexyl phosphate
Alkyl dicyclophosphate
Allantoin
Allene
Alloxane
Allylamine
Allyl bromide
Allyl chloride
Allyl iodide
Allyl isocyanate
Allyl isothiocyanate
N-Allyl-morpholine
Aluminum acetate
Aluminum dihydroxyaminoacetate
Aluminum ethylhexoate
Aluminum formate solutions
Aluminum isopropylate
Aluminum lactate
Aluminum octoate
Aluminum oxyquinolate
Aluminum stearate solution
Ambrettolide
Ambutonium bromide
N-Amidino 3,5-diamino-6-chlorophyazine carboxamide and its salts
Amino-acetophenone
Aminoanthraquinone
p-Aminobenzamidine HCl
Aminobenzoic acid
para-Aminobenzoic acid
2-Amino-1-butanol
Aminobutyric acid
Aminodiazine
para-Aminodiethylaniline
para-Aminodiethylaniline hydrochloride
para-Aminodimethylaniline
para-Aminodiphenylamine
2-Aminoethanethiol
PTH (PTC-S-Aminoethyl) cysteine
3-(2-Aminoethyl) indole hydrochloride
N-Aminoethylpiperazine
Aminoethylpyrimidine
L-Amino-beta-guanidinopropionic acid
4-Amino-5-imidazole carboxamide
5-Amino-4-imidazole carboxamide
Aminoisobutyric acid
2-Amino-2-methyl-1-propanol
Aminomethylpyrimidine
Aminonapthol sulfonic and disulfonic acids
O-Aminonitrobenzene
2-Amino-5-nitrothiazole
Aminopentamide
meta-Aminophenol
ortho-Aminophenol
para-Aminophenol
ortho-Aminophenol hydrochloride
para-Aminophenol hydrochloride
2-Amino-1-phenol-4-sulfonic acid
Aminophenylacetic acid
Aminophylline
beta-Aminopropionitrile
2-Aminopyrimidine
Aminopyrine
4-Aminosalicylic acid
5-Aminosalicylic acid
2-Aminothiazole
L-3-Aminotyrosine dihydrochloride
Ammonium acetate
Ammonium benzoate
Ammonium bitartrate
Ammonium ferric oxalate
Ammonium gluconate
Ammonium mandelate
Ammonium oxalate
Ammonium thioglycollate
Amprolium
Amyl acetate
Amyl alcohol
n-Amyl alcohol, primary
tert-Amyl alcohol
Amylase
n-Amyl bromide
tert-Amyl bromide
tert-Amyl chloride
alpha-Amyl cinnamic aldehyde
Amyl mercaptan
tert-Amyl mercaptan
Amyl nitrate
Amyl nitrite
Amyl salicylate
Amylopectin
Amylose
ortho-sec-Amylphenol
para-tert-Amylphenol
Amyl salicylate
n-Amyl sebacate
Amyl ziram
Anethole
Aniline hydrochloride
Aniline oil
Aniline salt
Aniline sulfate
Anisic acid
Anisic aldehyde
ortho-Anisidine
para-Anisidine
Anthracene
Anthranilic acid
Anthraquinone
Anthrone
Antimony lactate
Antimony potassium tartrate
Antimony triacetate
Antipyrine
Apiol
Apoferritin
Apolysin
Arabinose
Arachidic acid
Arachidonic acid
Arginine
Arginine hydrochloride
Arrhenal
Asparagine
Asparagine hydrate
Aspartic acid
Aubepine
Aurothioglucose
5-Azacytidine
8-Azaguanine
6-Azathymine
6-Azauracil
6-Azauridine
Azelaic acid
d-Azetidine-2 carboxylic acid
Azetylcholine chloride
1-Aziridineethanol
Azobenzene
Azocoll
Azosulfamide
Banana oil
Barbital
Barbital sodium
Barbituric acid
Barium styphnate
Behenic acid
Benzaldehyde
Benzalkonium chloride
Benzanthrone
Benzene
Benzenesulfonic acid
Benzhydrol
Benzhydroxylamine HCl
Benzidine
Benzidine sulfate
Benzil
Benzoguanamine
Benzoic acid
Benzonitrile
3,3',4,4'-Benzophenone tetracarboxylic dianhydride
Benzotriazole
Benzotrichloride
Benzotrifluoride
N-alpha-Benzoyl-L-arginine ether ester hydrochloride
Benzoyl chloride
Benzoyl peroxide
2-Benzoyl pyridine
4-Benzoyl pyridine
Benzthiazide
Benztropin mesylate
Benzyl acetate
Benzyl alcohol
Benzyl amine
N-Benzyl-para-amino phenol
Benzyl benzoate
Benzyl bromide
Benzyl chloride
Benzyl cinnamate
Benzyl cyanide
Benzyl formate
Benzylidene acetate
Benzyl salicylate
Benzyl succinate
Benzyltriphenylphosphonium chloride
Betaine
Betaine hydrochloride
Bilirubin
2-(4-Biphenyl)-6 phenyl benzoxazole
N,N-Bis-(3-aminopropyl) methylamine
2,5-Bis-2-(5-tert-butylbenzoxazolyl)-thiophene
Bis-(2-dimethylaminoethyl) ether
Bis (2-ethylhexyl) peroxydicarbonate
N,N-Bis-(2-hydroxyethyl) alkylamine
N,N-Bis-(2-hydroxyethyl) glycine sodium salt
N,N-Bis (2-hydroxypropyl) aniline
1,4-Bis [2-(4-methyl-5-phenyloxazolyl)] benzene (methyl POPOP)
Bismuth citrate
Bismuth subgallate
Bismuth tannate
Bisphenol A
1,4-Bis-2-(5-phenyloxazolyl) benzene
N-N-Bis (trimethylsilyl) acetamide
Bis (trimethylsilyl) trifluoroacetamide
Bis-triphenylsilyl chromate
Bithionol
Borneol
Bornyl acetate
Bornyl formate
Bromelain-Pure
N-Bromoacetamide
Bromoactic acid
Bromobenzene
sym-Bromochloroethane
Bromochloromethane
1-Bromo-3-chloropropane
5-Bromodeoxyuridine
N-(2-Bromoethyl) phthalimide
Bromomethylethyl ketone
Bromoform
Bromomonochlorodifluoromethane
alpha-Bromonapthalene
Bromosuccinic acid
N-Bromosuccinimide
Bromostyrol

Bromotrifluoromethane
Butabarbital acid
Butabarbital sodium salt
Butacaine sulfate
1.4 Butanediamine dihydrochloride
Butanediol succinate
2,3-Butanedione monoxime
1-Butoxyethoxy-2-propanol
Butoxytriglycol
Butyl acetate
Butyl acetyl ricinoleate
n-Butyl acrylate
tert-Butyl acrylate
N-Butyl alcohol
n-Butylamine
tert-Butylamine
(-)-1-(tert-Butylamino)-3-[(4-morpholino-1,2,5 thiadiazol-3yl)oxy]-2 propanol maleate (1:1) and its salts
Butylate hydroxyanisole
n-Butyl benzene
sec-Butyl benzene
tert-Butyl benzene
Butyl benzyl phthalate
n-Butyl Bromide
sec-Butyl bromide
tertiary Butyl bromide
p-tert-Butyl catechol
n-Butyl chloride
sec-Butyl chloride
tert-Butyl chloride
6-tert-Butyl-meta-cresol
Butyl-meta-cresol methyl ethers
n-Butyl diethyl malonate
Butylene glycol
1,2-Butylene oxide
2,3-Butylene oxide
Butyl ether
tert-Butyl hydroperoxide
Butyl isocyanate
n-Butyl lactate
Butyl methacrylate
n-Butyl myristate
Butyl octyl phthalate
tert-Butyl perbenzoate
di-tert-Butyl peroxide
di (sec-Butyl) peroxydicarbonate
Butylphenol
o-sec-Butyl phenol
tert-Butyl phenol 2,2,4-trimethyl dihydroquinoline
2-(4-t-Butylphenyl)-5-(4-biphenyl)-1,3,4-oxdiazole
Butyl phthalyl butyl glycollate
n-Butyl propionate
tert-Butylquinoline
Butyl stearate
Butyne diol
Butyraldehyde
Butyric acid
Butyrolactone
Cadmium acetate
Cadmium octoate
Cadmium salicylate
Caffeine
Caffeine sodium benzoate
Calcium acetate
Calcium benzoate
Calcium citrate
Calcium cyanamide
Calcium cyclamate
Calcium formate
Calcium gluconate
Calcium glycerophosphate
Calcium lactate
Calcium levulinate
Calcium linoleate
Calcium mandelate
Calcium phenosulfonate
Calcium propionate
Calcium salicylate
Calcium stearate
Calcium succinate
Calcium tannate
Calcium tartrate
Calcium undecylenate
Camphene
Camphor (natural or synthetic)
Camphor bromate
Camphoric acid
Camphorsulfonic acid
Camphosulfuric acid
Capric acid
Caproic acid
Caprolactam
epsilon-Caprolactone
Caprylic acid
Canavanine sulfate
N-Carbamoylarsanilic acid
Carazole
Carbinoxamie antihistamines
Carbodiimide (cyanamide)
Carbon tetrachloride
Carbonyl chloride (phosgene)
Carbonyl cyanide, m-chlorophenylhydrazone
Carbosine
Carboxylic acid anhydride
Carisoprodol (n-isopropyl-2-methyl-2-propyl-1,3-propanediol discarbamate)
Carvacrol
Carvone
Cedryl acetate
Cellulase
Cerotic acid
Cerous oxalate
Cetyl alcohol
Cetylpyridinium chloride
Chloral
Chloral formamide
Chlorbetamide
Chlorendic acid
Chlormrodrin
meta-Chloroaniline
ortho-Chloroaniline
para-Chloroaniline
Chloroacetic acid
Chlorobenzene
para-Chlorobenzhydrol
meta-Chlorobenzoic acid
ortho-Chlorobenzoic acid
para-Chlorobenzoic acid
Chlorobenzotriazole
otho-Chlorobenzotrichloride
para-Chlorobenzotrichloride
meta-Chlorobenzotrifluoride
ortho-Chlorobenzotrifluoride
para-Chlorobenzotrifluoride
1-(p-Chlorobenzoyl)-5-methoxy-2-methylindole-3-acetic acid
Chlorobiphenyl
Chlorobutanol
3'Chloro-4'-(p-chlorophenoxy)-3,5-diiodosalicyanilide
1-Chloro-2,4-dinitrobenzene
Chlorogenic acid
Chlorohydroquinone
p-Chloromercuribenzoate
2-Chloro-4-nitroaniline
4-Chloro-2-nitroaniline
4-Chloro-3-nitroaniline
meta-Chloronitrobenzene
ortho-Chloronitrobenzene
para-Chloronitrobenzene
2-Chloro-6-nitrotoluene
4-Chloro-2-nitrotoluene
Chloropentafluoroethane
meta-Chlorophenol
ortho-Chlorophenol
para-Chlorophenol
p-Chlorophenylalanine
Chlorophyll, dry
Chlorophyll, solution in oil
Chloroprene
Chloroquine base
Chloroquine phosphate
N-Chlorosuccinimide
6-Chloro-7-sulfamyl-1,2,4-benzothidiazine-1,1-dioxide
6-Chloro-7-sulfamyl-3,4-dihydro-1,2,4-benzothiadiazine-1,1-dioxide
Chlorothen citrate anti-histamines
Chlorothymol
alpha-Chlorotoluene
meta-Chlorotoluene
ortho-Chlorotoluene
para-Chlorotoluene
Chlorotrifluoromethane
Cholesterol
Cholic acid
Choline
Choline bitartrate
Choline chloride
Chondroitin sulfate
Chromic acetate
Chymar
Chymotripsin, pure
Cinnamic acid
Cinnamic alcohol
Cinnamic aldehyde
Citral
Citrazinic acid
Citric acid
Citronella
Cobalt salts, n.e.s.
Cobinamide cyanide phosphate 3'-ester with 5,6 dimethyl-1-a-D-ribofuranosylbenzimidazole inner salt
Cobinamide hydroxide phosphate 3'-ester with 5,6 dimethly-1-a-D-ribofuranosylbenzimidazole inner salt
Cocarboxylase
Colace
Colchicine
2,4,6-Collidine (2,4,6 trimethylpyridine)
Compound N (Conmel) granulation
Copper acetate
Corticosterone
Coumarin
Coumarone
Creatine
Creatinine
m-Cresol
o-Cresol
p-Cresol
Cresotic acid
Cresyl diphenyl phosphate
Cresylic acid
Crotonic acid
Crontonaldehyde
Cumene
Cumidine
Cyanacetamide
3-Cyanopyridine
4-Cyanopyridine
Cyanuric acid
Cyanuric chloride
Cyclizine antihistamines
Cyclocyamine

Cyclohexane
Cyclohexanol
Cyclohexanone
Cyclohexene
Cyclohexylamine
1-Cyclohexyl-3-(2-morpholinoethyl)-carbodiimide metho-p-toluene sulfonate
para-Cyclohexylphenol
N-Cyclohexyl para toluene sulfonamide
Cyclopentamine hydrochloride
Cyclopentane
Cyclopentanol
Cyclopentanone
Cyclopentene
Cyclopentyl bromide
Cymene
Cystathionine
Cysteic acid
Cysteine
Cystine
Cytidine
Cytidine-5-diphosphate trisodium
Cytidine-5-monophosphate
Cytidine-5-monophosphate hydrate
Cytidine-3,2-phosphoric
Cytidine-5-triphosphate
Cytidine-5-triphosphate hexahydrate
Cytidylic acid
Cytidylyl 3'-5' adenosine
Cytidylyl 3'-5'-cytidine
Cytidylyl 3'-5'-guanosine
Cytidylyl 3'-5'-uridine
Cytosine beta-d-arabinofuranoiside HCl
Cytosine hemihydrate
Decahydronapthalene
1-Decanol
Dehydroabietylamine
Dehydroabietylamine acetic acid salt
Dehydroabietylamine ethylene oxide
Dehydroacetic acid
trans-Dehydroandrosterone acetate semicarbazone
Dehydrocholic acid
Dehydrothio-para-toluidine
Deoxyadenosine
Deoxyadenosine-5-triphosphate
Deoxyadenylic acid
Deoxycytidine
Deoxycytidine-5-triphosphate
Deoxyguanosine
Deoxyguanosine monohydrate
Deoxyguanosine-5-triphosphate
Deoxyguanylic acid
Deoxyinosine
Deoxyribonucleic acid
Desoxyadenosine monohydrate
Diacetone alcohol
Diacetyl
Diallylbarbituric acid
Diallyl maleate
Diallyl phthalate
1,2-Diaminopropane
1,3-Diaminopropane
Diaminoazoxytoluene
L-2,4-Diaminobutyric acid hydrochloride
2,4-Diaminodiphenylamine
Diamthazole dihydrochloride
Diamylphenol
Dianisidine
ortho-Dianisidine dihydrochloride
Diastase
Diastatic enzymes
Diastefor
Diazoaminobenzene
Diazodinitrophenol
4-(5H-Dibenzo (a,d) cyclohepten-5-ylidene)-1-methylpiperidine and its salts
2,5-Debiphenyloxazole
Dibromodifluoromethane
1,3-Dibromo-5,5,-Dimethylhydantoin
Dibromoethylbenzene
Dibromomonochlorotrifluoroethane
alpha, beta-Dibromopropionic acid
Dibutylamine
Dibutylamine Pyrophosphate
4,6-Di-tert-butyl-meta-cresol
2,6-Di-tert-butyl-para-cresol
2,6-Di-tert-butyl-alpha-dimethyl-amino-para-cresol
Di-tert-butyl disulfide
Dibutyl fumarate
Dibutyl itaconate
Dibutyl maleate
Dibutyl phosphate
Dibutyl phthalate
Dibutyl sebacate
Dibutyl tetrachlorophthalate
Dibutylthiourea
Dibutyl tin compounds
Dibutyryladenosine
Dicapryl adipate
Dicapryl phthalate
Dicapryl sebacate
3,4-Dichloroaniline
Dichlorobenzene
meta-Dichlorobenzene
ortho-Dichlorobenzene
para-Dichlorobenzene
2,5-Dichlorobenzenesulfonic acid
3,3'-Dichlorobenzidine
3,3'-Dichlorobenzidine dihydrochloride
2,4-Dichlorobenzoic acid
3,4-Dichlorobenzoic acid
2,4-Dichlorobenzoyl peroxide
Dichlorodifluoromethane
Dichlorodiphenyl sulfone
Dichloroethylene
Dichloroethylether
Dichloroisocyanuric acid
Dichloroisopropyl ether
[2,3-Dichloro-4-(2-methylene-butyryl) phenoxy] acetic acid
2,3-Dichloro-1,4-napthoquinone
2,6-Dichloro-4-nitroaniline
2,4-Dichlorophenol
Dichloropropane
Dicumyl peroxide
Dicyanodiamide
Dicyclohexylamine
Dicyclohexyl phthalate
Dicyclomine hydrochloride
Dicyclopentadiene
Dienestrol
Diethanolamine
Diethylaluminum ethoxide
Diethylaluminum hydride
Diethylamine
Diethylaminoethanol
meta-Diethylaminophenol
N,N-Diethylaniline
Diethylbarbituric acid
Diethylbenzene
Di-(2-ethylbutyl) phthalate
Diethylcarbamazine
Diethylcarbamazine citrate
Diethyl carbonate
diethyl chromium (chromocene)
Diethylene dichloride
Diethylene glycol
Diethylene glycol adipate
Diethylene glycol bis (allyl carbonate)
Diethylene glycol-n-butyl ether
Diethylene glycol dibenzoate
Diethylene glycol dibutyl ether
Diethylene glycol diethyl ether
Diethylene glycol dimethyl ether
Diethylene glycol ethyl ether
Diethylene glycol mono-butyl ether
Diethylene glycol mono-butyl ether acetate
Diethylene glycol mono-ethyl ether acetate
Diethylene glycol mono-methyl ether
Diethylene glycol mono-methyl ether acetate
Diethylene glycol succinate
Diethylene triamine
Di (2-ethylhexyl) adipate
Di (2-ethylhexyl) isophthalate
Di (2-ethylhexyl) phosphoric acid
Di (2-ethylhexyl) phthalate
Di (2-ethylhexyl) sebacate
Diethyl ketone
Diethyl malonate
3,3-Diethyl-5-methyl-2,4-piperidinedione
Diethyl phosphate
O,O-Diethyl phosphorochloridothioate
Diethyl phthalate
Diethylstilbestrol
Difluoroethane
Digitalin
Dihydrocholic acid USP
10,11-Dihydro-N,N-dimethyl-5H-dibenzo (a,d) cycloheptene-delta-5-gamma-propylamine and its salts
Dihydrouracil
1,2-Dihydroxyanthraquinone
1,4-Dihydroxyanthraquinone
1,5-Dihydroxyanthraquinone
1,8-Dihydroxyanthraquinone
Dihydroxy diphenyl sulfone
dl-3,4-Dihydroxyphenylalanine levo-3-(3,4-Dihydroxyphenyl)-2-methylalanine and its salts and esters
Dihydroxyuridine-2,3,-monophosphate
Diiodo-tyrosine
Diisoamyl phthalate
Diisobutylcarbinol
Diisobutyl ketone
Diisobutyl phthalate
Diisodecyl adipate
Diisodecyl phthalate
Diisooctyl adipate
Diisooctyl phthalate
Diisooctyl sebacate
Diisopropanolamine
Diisopropylamine
Diisopropyl benzene
meta-Diisopropyl benzene
para-Diisopropyl benzene
Diisopropyl benzene hydroperoxide
Diisopropyl carbinol
Diisopropyl fluophosphates
Diketene
2,5-Dimethoxybenzaldehyde
2,6-Dimethoxybenzoic acid
Dimethoxytetraglycol
Dimethyl acetal
Dimethyl acetamide
Dimethyl adipimide dihydrochloride
Dimethylallylamine
Dimethyl aluminum chloride
Dimethyl aluminum hydride
Dimethyl amine
para-Dimethylaminobenzaldehyde
2-Dimethylaminoethanol
Dimethylaminomethylphenol
5-Dimethylamino-1-naphthalene sulfonyl chloride
Dimethylaminopropylamine
5-(3-Dimethylaminopropylidene)-dibenzo (a,d) (1,4) cycloheptadiene pamoate

6-Dimethylamino purine
2,4-Dimethylaniline
N,N-Dimethylaniline
Dimethylbenzenesulfonic acid
N,N-Dimethylbenzylamine
Dimethylbenzyl carbinol acetate
2,5-Dimethyl-2,5-bis, (tert-butyl peroxy) hexyne-3
2,5-Dimethyl-2,5-Di (tert-butyl peroxy) hexane
Dimethyl dioctadecyl ammonium bentonite
2,5-Dimethyl-2,5-Diperbenzoxyhexane
2,5-Dimethyl-2,5-Diperoctoxyhexene
Dimethyl ether
Dimethylformamide
Dimethyl glyoxime
Dimethyl isophthalate
Dimethyl itaconate
Dimethyl malonate
2,6-Dimethylmorpholine
Dimethyl-alpha-napthylamine
Dimethyl-beta-napthylamine
N,N-Dimethyl-para-nitrosoaniline
3,6-Dimethyl-3-octanol
3,7-Dimethyl-1-octanol
Dimethylolpropionic acid
Dimethylphenylbenzyl ammonium hydroxide
Dimethyl phthalate
Dimethyl stearamide
Dimethyl sulfate
Dimethyl sulfolane
Dimethyl sulfoxide
Dimethyl terephthalate
2,4-Dimethyl tetrahydrothiophene-1,1-Dioxide
Dinitrobenzene
4,4' Dinitrocarbanilide and 2-Hydroxy-4,6-Dimethyl pyrimidine complex
Dinitromethylbutylacetophenone
Dinitronapthalene
Dinitrophenol
3,5-Dinitro-o-toluamide (zoalene)
Dinitrotoluene
Dinonyl phthalate
Di (n-octyl, n-decyl) adipate
Di (n-octyl, n-decyl) phthalate
Dioctyl phthalate
Diorgano siloxanes
1,4-Dioxane
Dipentaerythritol acetate
Dipentaerythritol hexabutyrate
Dipentaerythritol hexapropionate
Diphemanil methyl sulfate
Diphenic acid
Diphenyl
Diphenylamine
Diphenyldichlorosilane
Diphenylhydantoin sodium
Diphenylmethane
Diphenylmethane 4,4'-Diisocyanate
2,5-Diphenyloxazole
Diphenyl oxide
Diphenyl phthalate
Diphenylsilanediol
4,4-Diphenylstilbene
Diphosphopyridine nucleotide
Dipropylene glycol
Dipropylene glycol dibenzoate
Dipropylene glycol methyl ether
p-(Dipropylsulfamyl) benzoic acid
alpha, alpha-Dipyridyl
2,2-Dipyridylamine
2,2'-Dithiodibenzoic acid
5,5-Dithio-bis-(2-nitrobenzoic acid)
Dithiothreitol (cleland's reagent)
Ditridecyl phthalate
Diundecyl phthalate
Divinyl benzene
Djenkolic acid
1-Dodecene
Dodecenylsuccinic acid
Dodecenylsuccinic anhydride
Dodecylaniline
Dodecylphenol
Dulcitol
Durene
1-Eicosanol
Elaidic acid
Epichlorhydrin
Epinephrine
Ergosterol
Erucic acid
Erythorbic acid
Erythrityl tetranitrate
Ethanolamine
Ethanolformamide
Ethoheptazine
Ethoheptazine citrate
P-[(p-Ethoxybenzylidene)-amino] benzonitrile
2-Ethoxy-3,4-dihydro-2H-pyran
Ethoxy triglycol
Ethyl acetate
Ethyl acetoacetate
Ethylacetylene
Ethylacrylate
Ethylalcohol
Ethyl aluminum dichloride
Ethyl aluminum sesquichloride
Ethyl amine
Ethyl amyl ketone
N-Ethyl aniline
ortho-Ethyl aniline
Ethyl benzene
Ethyl benzoate
Ethyl bromide
2-Ethylbutyl acetate
2-Ethylbutyl alcohol
Ethyl butyl ketone
2-Ethyl-2-butylpropanediol-1,3
2-Ethylbutyraldehyde
Ethylbutyrate
2-Ethylbutyric acid
Ethylchloride
Ethylchloroacetate
Ethylchlorocarbonate
Ethylcyanoacetate
Ethylene carbonate
Ethylene chlorohydrin
Ethylene cyanohydrin
Ethylenediamine
Ethylenediamine dihydroiodide
Ethylenediamine tetraacetic acid
Ethylene dibromide
Ethylene dichloride
Ethylene glycol
Ethylene glycol n-butyl ether
Ethylene glycol diacetate
Ethylene glycol dibutyl ether
Ethylene glycol ethyl ether
Ethylene glycol methyl ether
Ethylene glycol monoacetate
Ethylene glycol monobutyl ether
Ethylene glycol monobutyl ether acetate
Ethylene glycol monohexyl ether
Ethylene glycol monomethyl ether
Ethylene glycol monomethyl ether acetate
Ethylene glycol monoethyl ether acetate
Ethylene glycol phenyl ether
Ethylene glycol succinate
Ethylene glycol tetrachlorophthalate
Ethyleneimine
Ethylene maleic anhydride
Ethylene oxide
Ethylene thiourea
Ethyl estragole cinnamate
Ethy ether
1-Ethyl-2-[3(1-ethylnaptho[1,2d)-thiazolin-2-ylidene)-2-methyl-propenyl]naptho[1,2d] thiazolium bromide
Ethyl fluid
Ethyl formate
2-Ethyl-hexaldehyde
2,2'-(2-Ethylhexamido) diethyl Di(2-Ethyl hexoate)
2-Ethylhexanediol-1,3
2-Ethylhexoic acid
2-Ethylhexyl acetate
2-Ethylhexyl acrylate
2-Ethylhexyl alcohol
2-Ethylhexyl isodecyl phthalate
Ethyl Hydrogen sulfate
5-Ethylidene-2-norbornene
Ethyl iodoacetate
Ethyl lactate
Ethyl malonate
Ethyl mercaptan
N-Ethylmorpholine
Ethylnitrite
Ethyl orthoacetate
Ethyl phenylacetate
Ethyl phthalyl ethyl glycollate
Ethyl silicate
Ethyl sulfide
Ethyl stearate
Ethyl thioethanol
N-Ethyl para-toluenesulfonamide
Ethyl vanillin
Eucatropine hydrochloride
Eugenol
Exol
Fenchone
Ferric ammonium citrate
Ferric ammonium oxalate
Ferric glycerophosphate
Ferrous gluconate
Ferrous oxalate
Ferulic acid
Ficin, pure
Fluoranthene
Fluorescein
9-Fluoro-11 beta, 17,21-trihydroxy-16a-methylpregna—1,4-diene-3,20 dione and its salts and esters
dl-p-Fluorophenylalanine
5-Fluorotryptophan
6-Fluorotryptophan
5-Fluorouracil
Folic acid
Formaldehyde
Formamide
Formic acid
Fructose
Fructose-1,6-diphosphate sodium salt
Fructose-1-phosphate
D-Fucose
L-Fucose
Fumaric acid
Furan
Furazolidone
Furfural
Furfuryl alcohol
Furfuryl mercaptan
Galactose
Gallic Acid
Gentiobiose
Geranyl cinnamate
Gluconic acid
Glucono-delta-lactone
D-Glucosamine
Glucose, pharmaceutical

Glucose-6-phosphate, disodium salt
Glucuronic acid
Glucuronolactone
Glutamic acid
Glutamine
Glutaraldehyde
Glutaric acid
Glutaric anhydride
Glutaronitrile
Glutathione
Glycerin
Glycerol monooleate
Glycerophosphates
Glycerophosphoric acid and salts
Glyceryl monostearate
Glyceryl tri-(acetyl ricinoleate)
Glyceryl tributyrate (tributyrin)
Glycidyl acrylate
Glycine
Glycylglycine
Glycocholic acid (cholylglycine)
Glyoxal
Guaiacol
Guaiacol carbonate
Guaiacol glyceryl ether
Guaiamar
Guanidine
gamma-Guanidinobutyric acid
Guanidinopropionic acid
Guanine
Guanosine
Guanosine-2,3-cyclic
Guanosine-3,5-cyclic phosphate
Guanosine dihydrate
Guanosine-5-diphosphate
Guanosine-5-monophosphate
Guanosine-5-triphosphate
Guanosine-5'-triphosphate trilithium tetrahydrate
3-Guanylic acid
5-Guanylic acid
Guanylyl-3,5-adenosine
Guanylyl-3,5-cytidine
Guanylyl-3',-5'-guanosine
Guanylyl-3',5'-uridine
Heliotropine
Hemimellitene (1,2,3-trimethylbenzene)
Hemin (chlorohemin; hemin chloride)
Heparin sodium (heparin)
n-Heptadecanoic acid
n-Heptadecanol
Heptafluorobutyric acid (perfluorobutyric acid)
n-Heptanoic acid
1-Heptanol
Heptylic acid
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
n-Hexadecane
1-Hexadecanol
Hexa-2-ethylbutoxydisiloxane
Hexafluoroacetone
Hexahydrobenzoic acid
Hexahydrophthalic anhydride
Hexamethonium chloride
Hexamethylene diammonium adipate (nylon salt)
Hexamethylenediamine
Hexamethyleneimine
Hexamethylenetetramine
1-Hexanol
Hexestrol NNR
n-Hexyl bromide
n-Hexyl chloride
Hexylene glycol
Hexylresorcinol
Hippuric acid
Histamine
Histamine phosphate
Histidine
Histidine hydrochloride
Homatropine and its salts
Homocystine
Homoserine
Hyaluronidase
Hydantoin
(-)-l-a-Hydrazino-3,4-dihydroxy-a-methyl-hydrocinnamic acid monohydrate
Hydrazobenzene
Hydrindantin, including hydrated forms
Hydrocholin
Hydrolase powder
Hydroorotic acid
Hydroquinone
Hydroquinone monobenzyl ether
Hydroxyacetic acid
meta-Hydroxybenaldehyde
para-Hydroxybenzaldehyde
meta-Hydroxybenzoic acid
ortho-Hydroxybenzoic acid
para-Hydroxybenzoic acid
3-Hydroxy-2-butanone
dl-Hydroxybutyric acid sodium salt
p-Hydroxychlorobenzene
Hydroxycitronella
2-Hydroxy-4n dodecyloxybenzophenone
Hydroxyethyl cellulose
Hydroxyethylethylenediamine
N-Hydroxyethylpiperazine
N-2-Hydroxyethylpiperazine-N'-2'-ethanesulfonic acid
Hydroxylapatite
Hydroxylsine hydrochloride
Hydroxymethyl 6-(2-amino-2-phenylacetamido)-3,3-dimethyl-7-oxo-4-thia-l-azabicylo (3,2,0) heptane-2-carboxylate pivalate and its salts and esters
5-Hydroxymethylcytosine
5-Hydroxymethyl deoxyuridine
3-Hydroxy-2-napthoic acid
2-Hydroxyphenylmercuric chloride
Hydroxyproline
Hydroxyquinoline and oxyquinoline anti-infective agents
Hydroxystearic acid
5-Hydroxytryptophan
3-Hydroxytyramine hydrochloride
Hydroxyzine
Hypoxanthine
3-3'-Iminobispropylamine
Iminodiacetonitrile
Indene
Indole
3-Indoleacetic acid
3-Indolebutyric acid
Indolyl-3 acetyl-L-aspartic acid
Indomethacin
Inosine
Inosine-5'-diphosphate
Inosine-5'-monophosphate
Inosine-5'-triphosphate
Inosinic acid
alpha-Iodoacetamide
5-Iododeoxyuridine
Iodoform
Ionones
Irisone ketone
Iron protoxalate
Iron sodium oxalate
Isatoic anhydride
Isoamyl alcohol, primary
Isoamyl bromide
Isoamyl butyrate
Isoamyl chloride
Isoamyl phthalate
Isoamyl valerate
Isoborneol
Isobutene
Isobutyl acetate
Isobutyl acrylate
Isobutyl alcohol
Isobutyl allyl barbituric acid
Isobutylamine
Isobutyl benzene
Isobutyl benzoate
Isobutyl bromide
Isobutyl chloride
Isobutyl methacrylate
Isobutyl phenyl acetate
Isobutyl quinoline
N-Isobutylundecyleneamide
Isobutyraldehyde
Isobutyric acid
Isobutyronitrile
dl-Isocitrate trisodium
Isoctyl thioglycolate
Isodecanol
Isoeugenol
Isoleucine
Isoniazid
Isooctyl alcohol
Isooctyl isodecyl phthlate
Isopentanoic acid
Isophorone
Isophthalic acid
Isopropenyl acetate
Isopropyl acetate
Isopropyl alcohol (isopropanol)
Isopropyl ethyl thionocarbamate
Isopropylamine
Isopropyl bromide
Isopropyl chloride
Isopropyl ether
Isopropyl iodide
Isopropyl palmitate
Isopropyl phenol
Isopropyl 2-(4 thiazolyl)-5-benzimidazole carbamate
Isosafrole
Itaconic acid
beta-Ketoglutaric acid
Khellin
Kinetin-6-furfurylaminopurine
Kojic acid
Lactic acid and salt(s)
Lactonitrile
Lanthionine
Lauric acid
Lauroyl peroxide
Lauryl alcohol
Lauryl aldehyde
Lauryl chloride
Lauryl mercaptan
Lead acetate
Lead formate
Lead maleate tribasic
Lead stearate
Lead styphnate
Lead tetraacetate
Lecithin, n.e.c.
Leucine
Leucenol leucenine
Levulinic acid
Lignoceric acid
D-Limonene
Linalool

Linalyl acetate
Linoleic acid
Linolinic acid
Linalyl acetate
Lithium benzoate
Lithium salts
Lutidine
2,4-Lutidinic acid
Lysine
Lysine hydrochloride
Lysozyme
D-Lyxose
Magnesium benzoate
Magnesium citrate
Magnesium citrate, dibasic
Magnesium p-(dipropylsulfamoyl) benzoate
Magnesium glycerophosphate
Magnesium salicylate
Magnesium stearate
Magnesium sulfate
Magnesium oxyphenyl arsenate
Maleic acid
Maleic anhydride
Malic acid
Malonic acid
Malt diastase
Maltose
Mandelic acid
Manganese acetate
Manganese citrate
Manganese glycerophosphate
Mannitol
D-Mannose
Margaric acid
Meclizine
Melamine
Melissic acid
Menadione (2-methyl-1,4-naphthoquinone)
para-Menthane hydroperoxide
Menthol
Mephentermine
Mephentermine sulfate
Mercaptobenzothiazole
Mercaptoethanol
beta-Mercaptopropionic acid
6-Mercaptopurine
Mercuric acetate
Mercuric salicylate
Mesityl oxide
Mesitylene (1,3,3-trimethylbenzene)
Metamine (trolnitrate phosphate)
Metanilic acid
Methacrylic acid
Methacrylonitrile
Methallyl chloride
Methanesulfonyl chloride (mesyl chloride)
Methantheline bromide
Methapyralene antihistamines
Methenamine anti-infective agents
Methionine
Methionine hydroxy analogue
Methionine sulfone
Methoxyphenamine hydrochloride
Methoxytriglycol
Methoxytriglycol acetate
Methyl acetate
Methyl-4-acetamido-2-ethoxy benzoate
Methyl acetanilide
Methyl acetone
Methyl acetophenone
Methyl acetylene
Methyl acetyl ricinoleate
Methyl acrylate
Methyl alanine
Methylallyl alcohol
Methylaluminum sesquibromide
Methylaluminum sesquichloride
Methylamine
Methylamyl acetate
Methyl amyl alcohol
Methyl-n-amyl carbinol
Methyl amyl ketone
N/Methylaniline (monomethylaniline)
alpha-Methylanthracene
Methyl antranilate
Methyl anthraquinone
Methyl arachidate
alpha-Methylbenzyl alcohol
alpha-Methylbenzyl ether
Methyl-bicyclo (2,2,1) heptene-2,3-dicarboxylic anhydride isomers
2-Methyl-l-butanol
Methyl butynol
Methyl caproate (methyl hexanoate)
Methyl chavicol
Methyl chloride
Methyl cinnamate
Methylcyclohexane
Methylcyclohexanol
Methylcyclohexanol acetate
Methylcyclohexanone
Methylcyclopentane
N-Methyl-5H-dibenzo (a,d) cycloheptene-5-propyl-amine and its salts
Methyl dichloroacetate
Methyldiethanolamine
Methyl di-hydrogenated tallow tertiary amine
Methylelaidate
N,N-Methylene bisacrylamide
Methylene blue
Methylene bromide
Methylene chloride
Methylene iodide
N-Methylethanolamine
2-Methyl-2-ethyl-1,3-dioxolane
Methylethylketone
Methylethylketone and cyclohexanone peroxide
Methylethylketone peroxide
2-Methyl-5-ethylpyridine
N-Methylglucamine
Methyl glutamate
Methyl glycolate
Methyl heneicosanoate
Methyl heptine carbonate
Methyl hexyl ketone
Methyl histidine
Methyl alpha-hydroxy behenate
Methyl alpha-hydroxy eicosanoate
Methyl alpha-hydroxy-lignocerate
Methyl alpha-hydroxy myristate
Methyl alpha-hydroxy palmitate
Methyl alpha-hydroxy stearate
Methylinoacetaldehyde
Methyl iodide
Methyl ionone
Methyl isoamyl ketone
Methyl isobutyl ketone
Methyl isopropenyl ketone
Methyl laurate
Methyl linoleate
Methyl linolenate
Methyl mercaptan
Methyl methacrylate monomer
N-Methyl morpholine
Methyl myristate
alpha-Methylnapthalene
beta-Methylnapthalene
(1-Methyl-5-nitroimidazol-2-yl)methyl carbamate
Methyl nonadecanoate
Methyl oleate
Methyl palmitate
Methyl palmitoleate
Methylparaben
2-Methylpentaldehyde
2-Methyl-1-pentanol
3-Methyl-1-pentyn-3-ol
Methylphenyldichlorosilane
3-Methyl-1-phenyl-2-pyrazolin-5-one
n-Methyl-o-phenylenediamine dihydrochloride
Methyl phthalate
Methyl phthalyl ethylglycollate
N-Methylpiperazine
2-Methyl piperidine
Methyl propyl ketone
n-Methyl-2-pyrrolidine
Methyl salicylate
Methyl stearate
alpha Methyl styrene
N-Methyltaurine and aqueous solutions
N-Methyltaurine slurry
Methyl tricosanoate
Methyl tridecanoate
dl-5-Methyl-tryptophan-2,5-hydrate
beta-Methylumbelliferone
2-Methyl-5-vinylpyridine
Mimosine
Monobutylamine
Monochlorodifluoroethane
Monochlorodifluoromethane
Monoethanolamine
Monoethylamine
Monoisopropanolamine
Monopentaerythritol diacetate dibutyrate
Monopentaerythritol tetrabutyrate
Monosodium glutamate
Montanic acid
Morpholine
Musk ambrette
Musk ketone
Musk xylene
Myristic acid
Myristoleic acid
Myristyl alcohol
Myristyl bromide
Nalidixic acid
Naphazoline hydrochloride
Napthalene
Napthalenesulfonic and disulfonic acids
Napthionic acid
alpha-Napthol
beta-Napthol
Napthol sulfonic and disulfonic acids and salts
1,2-Napthoquinone
1,4-Napthoquinone
alpha-Napthylamine
beta-Napthylamine
Napthylamine sulfonic, disulfonic and trisulfonic acids
2-Napthyl benzoate
Napthyl ethyl ether
Napthyl methyl ether
2-(l-Napthyl)-5-phenyl oxazole
Neopentyl glycol
Neopentyl glycol adipate
Neopentyl glycol sebacate
Neopentyl glycol succinate
Neotridecanoic
Nerol
Nialamide
Nicarbazin
Nickel acetate
Nickel formate
Nikethamide
Ninhydrin

Nithiazide
meta-Nitroaniline
ortho-Nitroaniline
para-Nitroaniline
meta-Nitroanisole
ortho-Nitroanisole
para-Nitroanisole
3-Nitrobenzaldehyde
Nitrobenzene
n-Nitrobenzenesulfonyl chloride
p-Nitrobenzenesulfonamide
meta-Nitrobenzoic acid
ortho-Nitrobenzoic acid
para-Nitrobenzoic acid
meta-Nitrobenzoyl chloride
para-Nitrobenzoyl chloride
ortho-Nitrobiphenyl
meta-Nitrochlorobenzene
ortho-Nitrochlorobenzene
para-Nitrochlorobenzene
Nitroethane
Nitrofurantoin
Nitromersol
Nitromethane
l-Nitronapthalene
para-Nitrophenetole
Nitrophenide
meta-Nitrophenol
ortho-Nitrophenol
para-Nitrophenol
p-Nitrophenyl-B-D-glucuronide
p-Nitrophenyl phosphate
p-Nitrophenyl-thymidine-5-phosphate
N-Nitrosodiphenylamine
beta-Nitrostyrene
meta-Nitrotoluene
ortho-Nitrotoluene
para-Nitrotoluene
Nitroxylene
Nonadecylic acid
Nonanal
n-Nonyl alcohol
Nonyl bromide
l-Nonylene
Nonyl phenol
Nordihydroguaiaretic acid
Norleucine
Norvaline
Nucleosides
Nucleotides or mono nucleotides
l-Octadecanol
Octafluorocyclobutane
Octanoic acid
1-n-Octanol
2-n-Octanol
n-Octyl bromide
n-Octyl chloride
n-Octyl, n-decyl adipate
n-Octyl, n-decyl phthalate
Octylene glycol titanate
2 Octyl iodide
Octyl phenol
alpha-Olefins
Oleic acid
Olein (Triolein, Glyceryl trioleate)
Ornithine
Orotic acid (Uracil-6-carboxylic acid; 6-Carboxyuracil)
Oxalic acid
Oxamide
Oxphencyclimine
Oxyalkylated alkylene glycol
beta, beta'-Oxydipropionitrile
Pamaquine naphthoate
Palmitelaidic acid
Palmitic acid
Palmitoleic acid
Palmitoyl chloride
Pancreatin
Papain
Paradichlorobenzene
Paraffin, chlorinated
Paraformaldehyde
Paraldehyde
Pelargonic acid
dl-Penicillinamine acetone
Penicillinase
Pepsin
Pepsin, spongy
Pentachloroethane
Pentadecylic acid
Pentaerythritol
Pentaerythritol tetrastearate
Pentamethylene dibromide
Pentane diol
2,4-Pentane dione
Pentanol
2-Pentanol
3-Pentanol
Pentazocine
Pentobarbital sodium
Pentobarbituric acid
Peracetic acid
Perchloroethylene
Perchloropentacyclodecane
Perpinyl acetate
Phenacetin
Phenanthrene
Phenanthrenequinone
Phenazine
ortho-Phenetidine
para-Phenetidine
Phenetsal
Phenhydramine hydrochloride antihistamine
Pheniramine maleate antihistamines
Phenobarbital
Phenobarbital sodium
Phenol
Phenolphthalein
Phenolphthalein glucaronide
Phenolsulfonephthalein (phenol red)
Phenosulfonic acid
Phenyl acetate
Phenyl acetic acid
Phenyl aceticaldehyde
Phenylalanine
Phenyl-2-amino-5-napthol-7-sulfonic acid
Phenyl-2-amino-8-napthol-6-sulfonic acid
N-Phenylanthranilic acid
Phenylazo diamino pyridine
1,3,4-Phenyl-biphenyloxadiazole
Phenylbutazone
1-Phenyl-3-carbethoxy-pyrazolone-5
Phenyl carbinol
Phenyldiethanolamine
Phenyldimethylpyrazolomethyl amino methane
Phenylephrine hydrochloride
m-Phenylenediamine
o-Phenylenediamine
Phenylethanolamine
Phenylethyl acetate
Phenylethyl alcohol
Phenylethyl barbituric acid
Phenyl ethyl salicylate
N-Phenyl glycine
alpha-Phenyl glycine
Phenyl glycine
Phenyl isocyanate
Phenyl isothiocyanate
Phenyl magnesium bromide
Phenylmethyl sulfonyl fluoride
N-Phenyl-alpha-napthylamine
N-Phenyl-beta-napthylamine
Phenylneopentyl phosphite
Phenyl nerol
o-Phenyl phenol
N-Phenylpiperazine
Phenylpropanolamine
Phenyl propylacetate
Phenyl salicylate
Phenyl sulfide (diphenyl sulfide)
Phenyl sulfone (diphenyl sulfone)
Phenyl sulfoxide (diphenyl sulfoxide)
Phenyl trichlorosilane
alpha-Pinene
beta-Pinene
Phloroglucinol
Phosphatase, alkaline
Phosphate diethylacetal
Phosphatidyl inositol
Phosphatidyl serine
2-Phosphoenol pyruvic acid
2-Phosphoglyceric acid
o-Phospho-dl-serine
Phthalamide
Phthalic acid
Phthalic anhydride
ortho-Phthalimide
Phthalonitrile
Phthaloyl chloride
Phytol
alpha-Picoline
beta-Picoline
gamma-Picoline
Picramic acid
Picric acid
Pimelic acid
d-Pipecolic acid
dl-Pipecolic acid
l-Pipecolic acid
Pipecolic acid hydrochloride
d-Pipecolic anhydride
dl-Pipecolic anhydride
l-Pipecolic anhydride
Piperazine
Piperazine adipate
Piperazine calcium edetate
Piperazine citrate
Piperazine dihydrochloride
Piperazine hexahydrate
Piperidine
Piperonal
Pivaloyloxymethyl-D-a-aminobenzyl penicillinate
Polyadenylic acid
Polycytidylic acid
Polyethylene glycol dibenzoate
Polyethylene glycols
Polyethyleneimine
Polyglycerol
Polyglycol distearate
Polymeric isocyanate
Polymethylene polyphenylisocyanate
Polyoxypropylene triol
Polypropylene diols
Polypropylene glycol
Polytetramethylene ether glycol
Polythiazide
Polythiazide, non-sterile
Polyuridylic acid
Polyuridylic acid potassium
Pontalin granulation
Pontalin powder
Potassium acetate
Potassium amyl xanthate
Potassium biphthalate
Potassium bitartrate

Potassium chloride
Potassium citrate
Potassium dichloroisocyanurate
Potassium ethyl xanthate
Potassium hexyl xanthate
Potassium oxalate
Potassium oxichinolin sulfonate
Potassium salicylate
Potassium tetroxalate
Proline
Prominal
Propargyl alcohol
Propargyl bromide
Propenyl guaethol
Prophenpyridamine maleate
beta-Propiolactone
Propionaldehyde
Propionic acid
Propionic anhydride
Propionyl chloride
Propiophenone
d-Propoxyphene hydrochloride
n-Propyl acetate
n-Propyl alcohol
Propyl amine
n-Propyl bromide
n-Propyl chloride
Propylene carbonate
Propylene chlorohydrin
Propylene dichloride
1,2-Propylene glycol
Propylene glycol methyl ether
Propylene oxide
Propyl gallate
Propylhexadrine
n-Propyl iodide
Propylparaben
Protamine sulfate
Protoporphyrin
Pseudocumene (1,2,4-trimethylbenzene)
Pseudocumidine
Pseudouridine (salmine)
Purine
Pyramidon
Pyranisamine maleate
Pyrene
Pyridine (refined)
3,4-Pyridinecarboxylic acid
Pyridium
Pyrilamine maleate (benzal)
Pyrilamine maleate N.N.R.
Pyrocatechol
Pyrogallol acid
Pyroligneous acid
Pyromellitic acid and dianhydrides
Pyruvic acid
Pyruvic aldehyde
Quinacrine hydrochloride
Quinaldine
Quinhydrone
Quinic acid
Quinizarin
Quinoline
Quinone
N^1-(2-Quinoxalinyl) sulfanilamide
Racephedrine
Raffinose
Rennet
Rennin
Resorcinol
Resorcinol acetate
Resorcinol dimethyl ether
Resorcinol monobenzoate
alpha-Resorcylic acid
beta-Resorcyclic acid
Rhamnose
Rhodinol
Ricinoleic acid and salts
Ristocetin
Rochelle salts
Saccharin
Saffrole
Salicin
Salicylaldehyde
Salicylamide
Salicylic acid, technical grade
Salicylic acid, USP grade
Salol
Salophen
Santalol
Santonin
Sarcosine
Sebacic acid
Secobarbital sodium salicylate
Selenium diethylthiocarbonate
Serine
Serotonin
Serotonin creatinine sulfate
Serotonin creatin sulfate complex
Shikimic acid (3,4,5,–trihydroxyl;–1–carboxylic acid)
Silanes
Skatole
Sodium acetate
Sodium allyl arsenate
Sodium para-aminobenzoate
Sodium para-aminosalicylate
Sodium arsanilate
Sodium benzoate
Sodium bitartrate
Sodium biphthalate
Sodium-sec-butyl xanthate
Sodium chloride
Sodium-4-chlorophthalate
Sodium citrate
Sodium dehydroacetate
Sodium diacetate
Sodium dibutyl napthalene sulfonate
Sodium dichloro isocyanurate
Sodium dimethyl-S-sulfo isophthalate
Sodium dodecyl benzene sulfonate
Sodium erythorbate
Sodium formate
Sodium gentisate
Sodium gluconate
Sodium glycolate
Sodium isobutyl xanthate
Sodium isopropyl xanthate
Sodium lactate
Sodium N-lauroyl sarcosinate
Sodium lignosulfonate
Sodium methylate
Sodium methyl siliconate
Sodium oxalate
Sodium phenolsulfonate
Sodium potassium tartrate
Sodium proprionate
Sodium saccharin
Sodium saccharinate
Sodium salicylate
Sodium tetroxalate
Sodium undecylenate
Sodium zirconium lactate
Sorbic acid
Sorbitol
Sorbose
Spermidine trihydrochloride
Spermidine tetrahydrochloride
Sphingomyelin
Squalane
Squalene
Stannous 2-ethylhexoate
Stearic acid
Stearin
Stearyl alcohol
Stilbestrol
Strontium acetate
Strontium lactate
Strontium oxalate
Streptokinase
Styrene oxide
Suberic acid
Succinic acid
Succinic acid disodium salt
Succinic anhydride
Succinimide
Sucrose
Sucrose acetate butyrate
Sulfanilic acid
meta-Sulfobenzoic acid
ortho-Sulfobenzoic acid
Sulfonamide drugs
4,4-Sulfonyldianiline
4-Sulfophthalic acid
Tartar emetic
Tartaric acid
Taurine
Terephthalic acid
Terephthaloyl chloride
para-Terphenyl
Terpin hydrate
Terpineol
Terpinyl acetate
Tetrabutyl titanate
Tetrachlorodifluoroethane
sym-Trachloroethane
Tetrachlorophthalic acid
Tetrachlorophthalic anhydride
5-Tetradecenoic acid
1,1,3,3-Tetraethoxypropane
Tetraethylene glycol
Tetraethylene pentamine
Tetraethyl lead
Tetrafluoroethylene
Tetrafluoromethane
Tetrahydrofuran
Tetrahydrofurfuryl alcohol
Tetrahydrofurfuryl oleate
Tetrahydrolinalool
Tetrahydronapthalene
Tetrahydrophthalic anhydride
Tetrahydropyran-2-methanol
Tetrahydrothiophene 1,1-dioxide (sulfolane)
Tetrahydroxyethylethylenediamine
Tetrahydrozoline
Tetrahydrozoline hydrochloride
Tetraisopropyl titanate
N,N,N,N,-Tetramethyl-1,3-butane diamine
Tetramethyldiaminobenzhydrol
Tetramethyldiaminobenzophenone
Tetramethyldiaminodiphenylmethane
N,N,N,N,-Tetramethylene diamine
Tetramethyl lead
1,1,4,4,-Tetraphenylbutadiene
Tetraphenyltin
Tetrapropylene
Tetrazene
2-(4'-Thiazolyl) benzimidazole
beta-2-Thienylalanine
2-Thiobarbituric acid
Thiodiglycol
Thiodipropionic acid
Thioglycerol
Thioglycolic acid
Thiophene
alpha-Thiophenealdehyde
Thiophenol
Thiosalicylic acid

Thiothixene
2-Thiouracil
Thiourea
Threonine
Thrombin topical
Thromboplastin
Thymidine
Thymidine-3,5-diphosphate
Thymidine-5-diphosphate
Thymidine-5-monophosphate
Thymidine-5-triphosphate
Thymine (5-methyluracil)
Thymol
Thymol blue
Thymol iodide
Titanium potassium oxalate
Titanyl acetylacetonate
ortho-Tolidine
ortho-Tolidine dihydrochloride
Toluene
Toluene-2,4-diamine
Toluene diisocyanates, except the 2–4 isomer with 85 percent purity and above.
Toluene sulfonamide
ortho-Toluenesulfonamide
para-Toluenesulfonamide
ortho-Toluenesulfonic acid
para-Toluenesulfonic acid
p-Toluenesulfonylchloride
para-Toluene sulfonyl-L-arginine methyl ester, HCl
o-Toluidine
Tolyl acetate
ortho-Tolyl biguanide
para-Tolyl-1-napthyl-amine-8-sulfonic acid
Triacetin
N-Triacontane (Melissic acid)
Triallyl cyanurate
Tribromoacetic acid
Tribromoethanol
Tributoxyethyl phosphate
Tri-n-butyl aconitate
Tributyl citrate
Tributyl phosphate
Tributyl phosphite
Trichloroacetic acid
1,2,3-Trichlorobenzene
1,2,4-Trichlorobenzene
1,1,1-Trichloroethane
Trichloroethylene
Trichlorofluoromethane
Trichloroisocyanuric acid
Trichloromethane (chloroform)
Trichloromethyl chloroformate (diphosgene)
Trichloropropane
Tricresyl phosphate
Tridecyl alcohol
Tri-n-decylaluminum
Tridecylic acid
2,4,6-Tri(dimethylaminomethyl) phenol
Triethanolamine
Triethanolamine titanate
1,1,3-Triethoxyhexane
Triethyl aluminum
Triethylamine
Triethyl citrate
Tri-2-ethylhexyl phosphate
Triethyl phosphate
Triethylenediamine
Triethylene glycol
Triethylene glycol dibenzoate
Triethylene glycol di(2-ethylbutyrate)
Triethylene glycol di(2-ethylhexoate)
Triethylene glycol monobutyl ether phosphate
Triethylenetetramine
Trifluoroacetic acid
Trifluoromonochloroethylene
Tri-n-hexylaluminum
Triisobutylaluminum
Triisohexylaluminum
Triisopropanolamine
Trilinolein
Trimellitic acid and anhydrides
Trimethyl aluminum
3,4,5-Trimethylcyclohexanol-1
Trimethylene bromide
Trimethylene chlorohydrin
Trimethylene glycol
2,6,8-Trimethyl-4-nonanone
2,6,8-Trimethylnonyl-4-alcohol
Trimethylolethane
Trimethylolpropane
2,2,4-Trimethyl-1,3-pentanediol
2,2,4-Trimethyl-1,3-pentanediol di-isobutyrate
2,2,4-Trimethyl-1,3, pentanediol mono-isobutyrate
2,4,4-Trimethylpentene
Tri-2-methylpentylaluminum
2,4,6-Trinitrobenzene sulfonic acid
Trinonylphenyl phosphite
Tri-n-octylaluminum
Tripalmitin (Palmitin, glyceryl tripalmitate)
Tripelennamine anti-histamines
Triphenyl phosphate
Triphenyl phosphite
Triphenyl phosphorus
Triphosphopyridine nucleotide
Tripropylene
Tripropylene glycol methyl ether
Tris-B-chloroethyl phosphate
Tris (2,3-dibromopropyl) phosphate
Tris dichloropropyl phosphate
Tris (hydroxymethyl) aminomethane
Trixylenyl phosphate
Trypsin powder
Trypsin pure
Tryptar trypsin
Tryptophan
Tyramine
Tyrosine
Undecalactone
Undecanaldehyde
1-Undecanol
2-Undecanol
Undecylic acid
Undecylenic acid
Uracil
Uranine
Urea
Urease
Uric acid
Uridine
Uridine-5-diphosphate
Uridine-5-diphosphogalactose
Uridine-5-diphosphomannose
Uridine-5-monophosphate
Uridine-5-triphosphate
Uridylic acid
Uridylyl-3',5'-cytidine
Uridylyl-3',5'-uridine
n-Valeraldehyde
Valeric acid
Valine
d Valine
dl Valine
l Valine
Vanadium ethylate
Vannilin
Varidase streptokinase-streptodornase
Veratraldehyde
Vetivert acetate
Vinyl acetate
Vinyl benzene (styrene)
Vinyl bromide
Vinyl-n-butyl ether
Vinyl chloride
Vinyl-2-chloroethyl ether
Vinyl ether
Vinyl ethyl ether
Vinylidene chloride
Vinyl isobutyl ether
Vinyl methyl ether
Vinyl methyl ketone
Vinyl pyridine
1-Vinyl-2-pyrrolidone
Vinyltoluene
Wintodon granulation
Xanthine
Xanthophyll feed supplement
Xanthosine
Xanthosine-5-phosphate
Xanthydrol
Xylene
ortho-Xylene
para-Xylene
Xylenol
Xylidine
Xylenyl phosphate
Xylose
Yttrium salts
Zinc acetate
Zinc 1,4-phenosulfonate
Zinc stearate
Zinc undecylenate

Plastic Materials and Artificial Resins, as Follows:

Acetal resins
Acrylic acid esters
Acrylic polymers
Acrylonitrile-butadiene-styrene copolymer (ABS resin)
Alkyd resins
Amino resins
Ammonium alginate
Carboxy vinyl polymers, water soluble [1]
Cellulose, chemical derivatives
Cellulose, regenerated
Chlorendic alkyd resins
Chlorinated polyether resins
Composites or laminates n.e.s., containing polyimides, polybenzimidazoles, polyimidazopyrrolones, aromatic polyamides, polyparxylylenes, polyimide-polyamide, silica, quartz, carbon or graphite fibers, polytetrafluoroethylene, polyvinylfluoride, or solid forms of polychlorotrifluoroethylene
Copolymer of tetrafluoroethylene and perfluoroalkyl-vinyl ether
Coumarone-indene resins
Epoxy resins, n.e.s.
Ethylene oxide polymers, water soluble [1]
Ethylene maleic anhydride resins
Ethylene-propylene
Ethylene-vinyl acetate
Flocculating agents [1]
Floor tile and flooring, plastic or plastic composition
Furan resins
High styrene resins masterbatches
Hydroxyvinyl resins
Ion exchange liquids, membranes, and resins

[1] A validated license is required for export of these commodities to the USSR, Estonia, Latvia, and Lithuania.

Ionomer resins
Laminates (including metal-clad) composed of two or more products included in Commodity Interpretation 24
Melamine-formaldehyde resins
Methacrylic acid esters
Methyl methacrylate, n.e.s.
Modified natural resins, including ester gum
Natural rubber, chemical derivatives
Nylon 6, 66, 610, and 612
Pentaerythritol resins
Phenol-formaldehyde adhesive and resins
Phenolic resins, n.e.s.
Phenoxy resins
Pipe and tubing made of, or lined and covered with, fluororcarbon polymers or copolymers, n.e.s.[1]
Polyallomer resins
Polyamide resins, n.e.s.
Polybutadiene resins
Polybutene resins
Polycaprolactone resins
Polycarbonate film, n.e.s.
Polycarbonate resins, molding and extrusion forms
Polychlorotrifluoroethylenem, solid forms
Polydivinylbenzene
Polyester resins, n.e.s.
Polyester tapered filaments
Polyethylene film, sheeting, laminates or wax containing any boron
Polyethyleneimine
Polyethylene, n.e.s.
Polyethylene oxide-based resins
Polyethylene terephthalate film
Polyimide-polyamide resins
Fully cured polyimide or polyimide-based film, sheet, tape, or ribbon having a maximum thickness of 10 mils (0.010 inch or 0.254 mm) whether or not coated or laminated with heat- or pressure-sensitive resinous substances of an adhesive nature, which contain no fibrous reinforcing materials, and which have not been coated or laminated with carbon, graphite, metals, or magnetic substances
Polymethylpentene resins
Polypropylene
Polystyrene
Polysulfone resins, n.e.s.
Polyterpene resins
Polytetrafluoroethylene, coagulated dispersion grades only; polyvinylidenefluoride; the copolymers of tetrafluoroethylene and hexafluoropropylene; and dibromotetrafluorethane having a purity of 99.8 percent or less and containing at least 25 particles of 200 microns or larger in size per 100 ml; and damping, dielectric, or flotation fluids wholly made thereof
Polytetrafluoroethylene, nondispersion grades
Polyurethane resins
Polyvinyl acetal resins
Polyvinyl acetate resins
Polyvinyl alcohol
Polyvinyl butyral
Polyvinyl chloride
Polyvinylidine chloride resins
Polyvinyl ether resins
Polyvinylfluoride
Polyvinyl formal
Polyvinyl pyrrolidone
Potassium alginate
Products, n.e.s., made of flurorcarbon polymers or copolymers [1]
Proteins, hardened
Resorcinol-formaldehyde resins
Silicone diffusion pump fluids having the capacity for producing ultimate pressures of 10^{-8} torr and greater
Silicone rubber and compounds, n.e.s.
Sodium alginate
Styrene-acrylonitrile copolymers
Styrene-butadiene copolymers
Sulfonamide-formaldehyde resins
Urea-formaldehyde resins
Vinylidene chloride acrylonitrile copolymers
Vulcanized fiber

Chemical preparations and compounds, miscellaneous related materials and products, n.e.s., as follows:

Acetone oil
Acid cupric chromate solution
Activated carbon for petroleum or chemical processing
Activated natural mineral products
Additives for fuel oils
Adhesives or cements containing polyimides, polybenzimidazoles, polyimidazopyrrolones, aromatic polyamides, polyparaxylylenes, or polyimide-polyamide, n.e.s.
Albumins, albuminates, and other albumin derivatives
Alkane sulfonic acid; mixed
Alkyl aryl phosphate
Alkyl aryl phthalate blend with alkyl benzene
Alkyl benzenes (detergent alkylates) with straight-chain alkyl groups containing 8 or more carbon atoms
Animal black, except activated
Articles, finished, of artificial plastic materials, n.e.s.
Artificial graphite, n.e.s.
Aryl-modified butyl benzyl phthalate ester
Auxiliary preparations for soldering, brazing, or welding (fluxes, powders, pastes) containing metal and other constituents
Azeotropic mixture of trifluoromethane and monochlorotrifluoromethane (R–503)
Boiler feed water compounds
Boric acid esters
Brewers' tank coating compounds pH Buffer salt and solution mixtures
Calcium lignosulfate
Calcium naphthenate
Carnauba wax, micronized
Calcium sulfate impregnated silica gel adsorbent carbon or graphite fibers, n.e.s.
Casein
Catalysts, n.e.s.
Cementing preparations not of fish, animal or vegetable origin, *the following only:* cementing preparations for pyroxylin watch glasses; film cement with paraffin; floor cement; floor patch, concrete; iron cement; linoleum cement except rubber; linoleum paste except rubber; polishing wheel cement; roofing cement; running board cement; soil pipe cementing preparation; solder glue; automobile top sealer; wall board cementing preparation; thread lubricant and seal compound; acrylic based glues, adhesives, or cement; and tire cut filler
Charges for fire extinguishers
Chemical compounds for manufacturing ice cream
Chill proofing compounds
Chlorinated hydrocarbon wax preparations
Clarifier for beer or ale
Clarifying powder for wines
Collecting reagents (preparations) for concentration of ores, metals, or minerals
Compounds and mixtures of rare earth metals, yttrium, or scandium n.e.s.
Composite solvents, paint removers, thinners, and other similar products, n.e.c.
Concrete hardeners
Concrete plasticizer compounds
Concrete waterproofing compounds
Conversion coating compounds
Copper naphthenate
Corrosion-inhibiting compounds
Cyanoacrylate adhesives and glues
Dental impression compounds and modelling pastes in plates, sticks, and similar forms
Dental plasters and preparations
Dextrins
Diethyl chromium (Chromocene) in toluene
Digestive enzymes (Glycerol Red Bone Marrow)
Diphenyl and diphenyl oxide heat transfer mixtures
N,N-Diphenyl-meta-phenylene-diamine
N,N-Diphenyl-para-phenylene-diamine
Dyeing, tanning, and coloring materials, natural and synthetic, n.e.s.
pH Electrode electrolyte solution mixtures
Epoxy-based adhesives or cements
Essential oils and perfume materials
Esters of saturated aliphatic monohydric alcohols containing more than six carbon atoms with adipic or azelaic or sebacic acids
Esters of dibasic saturated aliphatic acids combined with polyglycols, where one or both of the two constituents contain six or more carbon atoms, or saturated monohydric alcohols with dibasic saturated aliphatic acids where both of the two constituents contain six or more carbon atoms
Esters of trimethylol propane or trimethylol ethane or pentaerythritol with saturated monobasic acids containing more than six carbon atoms
Explosives and pyrotechnic products, n.e.s.
Ferrocerium and other pyrophoric alloys
Film developers
Flocculating agents, n.e.s.[1]
Glues and adhesives of fish, animal, or vegetable origin
Gluten and gluten flour
Glyceride kit MDT
Glycerol stearate
Glyceryl tri-(12-hydroxystearate)
Graphite, artificial and colloidal, n.e.s.
Gum rosin
Gum turpentine
Hat finishing powders
Herbicidal or antiplant preparations, n.e.s.
Hydraulic fluids, oils, and lubricants, n.e.s.
Hydrocarbon N-paraffin mixes
Hydrogenated tallow primary amine
Indicating pastes
Ink conditioners or eradicators
Ink thinners for cellophane printing
Inorganic and organic insecticides, pesticides, defoliants, herbicides, fumigants,

[1] A validated license is required for export of these commodities to the USSR, Estonia, Latvia, and Lithuania.

agricultural chemicals [2] and similar products n.e.s. *except organic phosphate insecticides and pesticidal compounds containing more than 75 per cent by weight of organic phosphates.*
Inulin
Iron oxide suspension
Laundry sour
Lead naphthenate
Leather binding compounds
Lipstick bases and waxes
Magnesium silicate impregnated silica gel adsorbent
Manganese naphthenate
Manufactured fertilizers
Meat curing compounds
Medicinal and pharmaceutical products in bulk, in dosage form, or as preparations, mixtures, or compounds, for human or veterinarian use, n.e.s.
Melamine-formaldehyde or Resorcinol-formaldehyde adhesives and glues
Metal patch solvents
Metallic hardeners for cement floors
Metanephrine
Methyl ethyl ketone peroxide 60 percent solution in dimethyl phthalate
Mineral or vegetable waxes, modified
Mixture of isobutyl ethers of propylene glycol and its homologs
Mixture of n-ethyl ortho and paratoluene ethyl sulfonamide
Mixture of ortho and para toluene sulfonamides
Mixtures or solutions containing two or more of any product included in Commodity Interpretation 24
Molecular sieves, loaded
Molecular sieves, not loaded
Monoglycerides
Natural and man-made staple, tow, fibers, filaments, yarn, fabrics, and made-up articles, clothing, and related products, new, used or waste, n.e.s.
Nickel compound catalysts and other catalysts, n.e.s.
Noncyclic-phosphates (plasticizers) n.e.s.
Nonmetallic mineral manufactures, n.e.s.
Oil-field demulsifying agents [1]
Peptones
Petroleum and petroleum products natural or synthetic, n.e.s.
Photographic chemicals and paper, n.e.s.
Photoresist thinners and rinses, synthetic polymer
Phthalate plasticizer incorporating coesterified mixed alkyl alcohols in the range of $C_7C_9C_{11}$
Pickling preparations for metal surfaces
Pigments, inorganic n.e.s.
Pine oil, *except pine-needle oil*
Platinum plating solutions
Polyether triols of alkylene oxides
Polyethylene glycol plus nitro (STAP)
Polyethylene glycol reacted with 2-nitro terephthalic acid (FFAP)
Polyethylene glycol, solidified
Polonium metal, salts and compounds
Polyester of adipic acid and butylene glycol
Polyester of adipic acid and phthalic acids and propylene glycol
Polymeric isocyanate
Polymeric (modified)-adipic acid
Polysaccharides
Polyvinyl acetate emulsion glues and adhesives
Potassium or sodium soaps of rosins in liquid, paste, or powder form
Prepared additives for petroleum lubricants, n.e.s.
Prepared additives for synthetic lubricants
Prepared brighteners and addition agents used in the following electroplating systems: antimony, arsenic, copper and copper alloy, cadmium, chromium, gold, indium, iridium, iron, lead, and lead alloy, nickel, palladium, platinum, rhodium, ruthenium, silver, tin and tin alloy, and zinc.
Prepared culture media
Prepared anti-knock compounds, n.e.s.
Prepared glazings, dressings, mordants, and sizes
Prepared rubber accelerators and compounding agents
Protein substances, including edible and inedible gelatins
Putty powder
Radioisotopes, cyclotron-produced or naturally occurring, having an atomic number 3 through 83, and compounds and preparations thereof; and stable isotopes and their compounds, n.e.s.
Radium and radium salts, alloys, and compounds
Road binding compounds
Rodenticides, inorganic
Rosin and resin acid derivatives, except ester gums
Rubber compounding chemicals, preparations and compounds, n.e.s.
Rubber thread lubricating compounds
Rust-preventive compounds
Screening pastes
Shark deterrents
Shaving cream bases
Silanized diatomaceous earth
Silica-based refractory core coatings
Silk-stocking savers, tablet form
Silver nitrate impregnated silica gel adsorbent
Soda lime
Sodium biphenyl in dimethoxyethane
Solvents, compounds, cutting fluids, or mixtures, containing less than 95 per cent of Trichlorotrifluoroethane (R–113) or Dichlorotetrafloroethane (R–114)
Starches
Sulfite lye, concentrated
Talc paste
Tall oil
Tall oil resins
Terphenyl resin plasticizer, partially hydrogenated
Terpenic solvents, n.e.s.
Tetrapropylene
Toilet, polishing and cleansing preparations
Ultraviolet light absorbers
Urea formaldehyde adhesives and glues
Urine concentrate
Vegetable pitch and products based thereon or on rosin
Water purifiers
Water softeners
Waxes, greases, lubricants, and damping dielectric, or flotation fluids wholly made of polytetrafluoroethylene, coagulated dispersion grades only; polyvinylidenefluoride; the copolymers of tetrafluoreothylene and hexafluoropropylene; or dibromotetrafluoroethane having a purity of 99.8 percent or less and containing at least 25 particles of 200 microns or larger in size per 100 ml.
Weed killers, consisting primarily of boron compounds
Wood creosote
Wood naphtha
Wood rosins
Wood rosin liquid tire chain solution
Wood tar
Wood tar oils
Wood turpentine

Inorganic chemicals elements, acids, oxides, hydroxides, peroxides, and halogen salts, as follows:

Alumina, n.e.s.
Antimony pentoxide
Antimony trioxide
Argon, *except liquified*
Arsenic disulfide
Arsenic, metallic
Arsenic powder
Arsenic trichloride
Arsenic triiodide
Arsenic trioxide
Artificial corundum (fused aluminum oxide), n.e.s.
Barium hydroxide monohydrate
Barium hydroxide octahydrate
Barium hydroxide pentahydrate
Barium oxide
Barium peroxide
Bismuth trioxide
Boric acids, n.e.s.
Boron, n.e.s.
Cadmium oxide
Carbon black, all forms
Carbon disulfide
Cerium oxide
Chlorine
Chlorine dioxide
Chlorosulfonic acid
Chromic acid
Chromic anhydride
Chromium oxides, anhydrides, and hydroxides, n.e.s.
Copper hydroxide
Copper oxide, black
Copper oxide, red
Dihydrazine sulfate
Ferric hydroxide
Fluosilicic acid
Germanium oxides, hydroxides, and peroxides
Hafnium oxides, n.e.s.
Hexafluorophosphoric acid
Hydrazine hydrate
Hydrazine mixtures containing less than 70 percent of hydrazine equivalent
Hydriodic acid
Hydrobromic acid
Hydrochloric acid
Hydrocyanic acid
Hydrofluoric acid
Hydrogen bromide, anhydrous
Hydrogen chloride
Hydrogen sulfide
Hydroxylamine
Hydroxylamine hydrochloride

[2] A validated license is required for export of phosphate rock and processed phosphatic fertilizers of all concentrations to the U.S.S.R.

[1] A validated license is required for export of these commodities to the U.S.S.R., Estonia, Latvia, and Lithuania.

Hypophosphorous acid
Iodic acid and its salts
Iodine U.S.P. (resublimed)
Iron oxides and hydroxides, n.e.s.
Lead oxides, n.e.s.
Lithium, n.e.s.
Magnesium hydroxide
Magnesium oxide
Magnesium peroxide
Manganese oxides, n.e.s.
Manganic hydroxide
Mercuric oxide, red
Mercuric oxide, yellow
Mercury (quicksilver)
Molybdenum oxides
Monocrystalline gallium compounds, n.e.s.
Monocrystalline and polycrystalline forms of molybdenum or tungsten, n.e.s.
Muriatic acid
Neon, *except liquified*
Nickel oxides, hydroxides, and peroxides
Niobium, n.e.s.
Nitric acid, *except fuming nitric acid*
Nitric oxide
Nitrogen, *except liquified*
Nitrogen pentoxide
Nitrous oxide
Oleum
Oxygen, *except liquified*
Perchloric acid
Phosphomolybdic acid
Phosphoric acid [1]
Phosphoric anhydride
Phosphorus, elemental
Phosphorus oxychloride
Phosphorus pentasulfide
Phosphorus sesquisulfide
Phosphorus trichloride
Phosphorus trisulfide
Polyphosphoric acid
Potassium hydroxides
Potassium peroxide
Rhenium oxides, hydroxides, and peroxides
Rubidium hydroxide
Selenium
Selenium dioxide
Selenium oxychloride
Selenium sulfide
Selenous acid
Silanes
Silica aerogel
Silica, colloidal
Silica, gel
Silica, pyrogenic
Silicic acid
Silicon, n.e.s.
Silicon dioxide, hydrated
Silicon monoxide
Silicon tetrachloride
Silicotungstic acid
Sodium hydroxide, solid and liquid
Sodium peroxide
Strontium hydroxide
Strontium oxide
Strontium peroxide
Sulfamic acid
Sulfur, except crude sulfur
Sulfur dioxide
Sulfuric acid
Sulfur trioxide
Tantalum, n.e.s.
Tantalum-niobium, n.e.s.
Thallium monoxide
Thionyl chloride
Tin oxides
Titanium, n.e.s.
Tungsten trioxide
Tungstic acid
Tungstic oxide
Vanadium pentoxide
Vanadium tetraoxide
Vanadium trioxide
Yttrium metal and powders
Zinc oxides and peroxides, n.e.s.
Zirconium oxides, hydroxides, and peroxides, n.e.s.

Other inorganic chemicals n.e.s., as follows:

Alum, crystallized
Aluminum ammonium sulfate
Aluminum chloride, anhydrous
Aluminum chloride hydrate
Aluminum fluoride
Aluminum fluosilicate
Aluminum hydride
Aluminum nitrate
Aluminum phosphate
Aluminum silicate
Aluminum sulfate
Ammonia alum
Ammonium bicarbonate
Ammonium bifluoride
Ammonium borate
Ammonium bromide
Ammonium carbonate
Ammonium chloride
Ammonium chromate
Ammonium dichromate
Ammonium fluosilicate
Ammonium hexafluoroaluminate
Ammonium iodide
Ammonium metavanadate
Ammonium persulfate
Ammonium phosphate, dibasic
Ammonium phosphate, monobasic
Ammonium polyphosphate
Ammonium reineckate
Ammonium sulfate
Ammonium sulfide
Ammonium tungstate
Antimony pentachloride
Antimony pentafluoride
Antimony trichloride
Antimony trifluoride
Antimony trisulfide
Arsenic pentoxide
Arsenic trioxide
Barium chlorate
Barium carbonate
Barium chloride
Barium cyanide
Barium fluoride
Barium nitrate
Barium phosphate, dibasic or secondary
Barium silicate
Barium thiocyanate
Barium titanate
Bismuth chloride
Bismuth iodide
Bismuth nitrate
Bismuth oxychloride
Bismuth subcarbonate
Bismuth subnitrate
Bismuth sulfate
Bismuth tetraoxide
Bismuth trioxide
Borates, refined
Boron compounds and mixtures, n.e.s.
Cadmium bromide
Cadmium carbonate
Cadmium chloride
Cadmium iodide
Cadmium nitrate
Cadmium sulfate
Calcium bromide
Calcium carbide
Calcium carbonate
Calcium carbonate, precipitated
Calcium chloride
Calcium fluoride
Calcium hydride
Calcium hydroxide
Calcium hypochlorite
Calcium hypophosphite
Calcium iodide
Calcium peroxide
Calcium phosphate
Calcium polysulfide
Calcium pyrophosphate
Calcium silicate
Calcium sulfate
Calcium thiosulfate
Calcium tungstate
Carbic cake
Carbic carbide
Carbide powder, *except abrasive powders*
Cesium bromide
Cesium chloride
Cesium iodide
Cesium sulfate
Chalk, precipitated
Chloroplatinic acid
Chromic chloride
Chromic sulfate
Chromium ammonium sulfate
Chromium potassium sulfate
Cobalt compounds, n.e.s.
Copper alloy containing more than 8 percent phosphor
Copper chloride
Copper cyanide
Copper nitrate
Copper oxychloride
Copper sulfate
Copper sulfate, ammoniated
Cupric bromide
Cupric carbonate, basic
Cupric chloride
Cuprous chloride
Cuprous cyanide
Cuprous iodide
Cuprous sulfide
Cyanogen bromide
Cyanogen chloride
Dicalcium phosphate
Dihydroxyaluminum sodium carbonate
Disodium phosphate
Epsom salts
Ferric ammounium sulfate
Ferric bromide
Ferric hypophosphite
Ferric pyrophosphate
Ferrophosphorous containing 15 percent or more by weight of phosphorous
Ferrous ammonium sulfate
Ferrous carbonate
Ferrous chloride
Ferrous sulfate
Fluoroborates, n.e.s.
Gallium compounds, n.e.s.
Germanium compounds
Gold cyanide
Gold sodium thiosulfate
Gold trichloride
Hafnium compounds, n.e.s.

[1] A validated license is required for export of this commodity to the U.S.S.R.

Hydrogen peroxide, concentrations of less than 85 percent
Hydroxylapatite
Iron chloride
Iron phosphate
Iron sulfate
Iron sulfide, artificial
Lead antimonate
Lead arsenite
Lead iodide
Lead nitrate
Lead silicate
Lead silicate, basic
Lead sulfate
Lead sulfate, basic
Lead sulfate, blue basic
Lead sulfate, tribasic
Lead thiocyanate
Lime bisulfate
Lime, chlorinated
Lime phosphate
Lithium compounds, n.e.s.
Magnesium arsenide
Magnesium carbonate
Magnesium chloride
Magnesium fluosilicate
Magnesium hypophosphite
Magnesium perchlorate
Magnesium phosphate
Magnesium silicate
Magnesium silicofluoride
Magnesium sulfate
Magnesium thiosulfate
Magnesium trisilicate
Magnesium tungstate
Manganese acetate
Manganese carbonate
Manganese hypophosphite
Manganous chloride
Manganous nitrate
Manganous sulfate
Manganous sulfide
Mercuric bromide
Mercuric chloride
Mercuric cyanide
Mercuric iodide
Mercuric nitrate
Mercuric oxycyanide
Mercuric potassium iodide
Mercuric sulfate
Mercuric sulfide, black
Mercuric sulfide, red
Mercuric thiocyanate
Mercurous chloride
Mercurous nitrate, hydrated
Mercurous sulfate
Mercury, ammoniated
Mercury fulminate
Molybdenum salts and compounds
Monocalcium phosphate
Monocalcium sulphate
Nickel ammonium sulfate
Nickel carbonate
Nickel chloride
Nickel nitrate
Nickel phosphate
Nickel sulfate
Niobium (columbium) compounds, n.e.s.
Palladium chloride
Palladium salts and compounds
Pea carbide
Potash alum
Potash magnesia carbonate
Potassium alum
Potassium aluminum sulfate
Potassium arsenite
Potassium bicarbonate
Potassium bisulfate
Potassium bromate
Potassium bromide
Potassium carbonate
Potassium chlorate
Potassium chlorochromate
Potassium chromate
Potassium cyanide
Potassium dichromate
Potassium ferricyanide
Potassium ferrocyanide
Potassium fluoride
Potassium fluosilicate
Potassium gold cyanide
Potassium hypophosphite
Potassium iodate
Potassium iodide
Potassium metabisulfite
Potassium nitrate, particle size greater than 100 microns
Potassium perchlorate
Potassium periodate
Potassium permanganate
Potassium persulfate
Potassium phosphate, dibasic
Potassium phosphate, monobasic
Potassium phosphate, tribasic
Potassium pyrophosphate
Potassium silicate
Potassium stannate
Potassium sulfate
Potassium sulfide
Potassium thiocyanate
Potassium tripolyphosphate
Rhenium compounds
Rubidium iodide
Sal soda
Silanes
Silicon carbide, n.e.s.
Silver chloride
Silver cyanide, industrial
Silver iodide
Silver nitrate
Silver oxide
Silver sulfate
Silver sulfide
Soda alum
Sodium aluminate
Sodium ammonium phosphate
Sodium aluminum sulfate
Sodium aluminum phosphate
Sodium antimonate
Sodium arsenate
Sodium azide
Sodium bicarbonate
Sodium bifluoride
Sodium bisulfate
Sodium bisulfite
Sodium bromide
Sodium carbonate
Sodium carbonate peroxide
Sodium chlorate
Sodium chlorite
Sodium chromate
Sodium cyanide
Sodium dichromate
Sodium ferricyanide
Sodium ferrocyanate
Sodium fluorosilicate
Sodium gold cyanide
Sodium hexafluorosilicate
Sodium hexametaphosphate
Sodium hydride and dispersions
Sodium hydrosulfide
Sodium hydrosulfite
Sodium hypochlorite
Sodium hypophosphite
Sodium iodide
Sodium metabisulfite
Sodium metaphosphate
Sodium metasilicate
Sodium metavanadate
Sodium nitrate
Sodium nitrite
Sodium nitroferricyanide
Sodium orthosilicate
Sodium orthovanadate
Sodium paraperiodate
Sodium perborate
Sodium perchlorate
Sodium periodate
Sodium persulfate
Sodium phosphate
Sodium phosphate, dibasic
Sodium phosphate, monobasic
Sodium phosphate, tribasic
Sodium phosphite
Sodium polyphosphate
Sodium polysulfide
Sodium pyrophosphate
Sodium pyrophosphate, acid
Sodium pyrovanadate
Sodium selenite
Sodium sesquicarbonate
Sodium silicate
Sodium silico aluminate
Sodium stannate
Sodium sulfate
Sodium sulfide
Sodium sulfite
Sodium thiocyanate
Sodium thiosulfate
Sodium trimetaphosphate
Sodium tripolyphosphate
Sodium tungstate
Stannic chloride
Stannous chloride
Stannous sulfate
Strontium bromide
Strontium carbonate
Strontium chloride
Strontium iodide
Strontium nitrate
Strontium sulfate
Tantalum compounds, n.e.s.
Tantalum-niobium compounds, n.e.s.
Theophylline
Titanium carbide
Titanium sulfate
Titanium tetrachloride
Titanium trichloride
Tricalcium phosphate
Vanadium carbide
Vanadyl sulfate
Zinc ammonium chloride
Zinc carbonate
Zinc chloride
Zinc chromate
Zinc cyanide
Zinc hydrosulfite
Zinc nitrate
Zinc oxide, U.S.P.
Zinc phosphate
Zinc phosphide
Zinc silicate
Zinc sulfate
Zinc thiocyanate
Zirconium compounds containing one part or more of hafnium to 500 parts of zirconium by weight
Zirconium carbonate, basic

Zirconium phosphate
Zirconium silicate
Zirconium sulfate

Interpretations 25–26

[*Reserved*]

Interpretation 27: Phosphate Materials Subject to Validated Licensing to the U.S.S.R. and Afghanistan

The commodities described below are included in ECCN 6794F and are subject to the policy set forth in §§ 385.2(e) and 385.4(f).

Schedule B[1] No.	Commodity description
416.3000	Phosphoric acid, other than fertilizer grade
480.4500	Phosphates, crude and apatite
480.7015	Phosphoric acid, less than 65 percent available P_2O_5 equivalents
480.7025	Phosphoric Acid, 65 percent or more available P_2O_5 equivalents
480.7030	Normal and enriched superphosphates
480.7050	Concentrated superphosphates
480.7075	Other superphosphates
480.8005	Diammonium phosphates
480.8010	Monoammonium phosphates
480.8018	Other ammonium phosphates
480.8027, 480.8065.	Other mixed chemical fertilizers containing 1 percent or more P_2O_5

[1] Commodity description, not Schedule B Number, determines the commodity subject to validated licensing.

Interpretation 28: Commodities and Transactions Not Classified According to Kind

The commodities below require a validated license for export to **Country Groups S and Z.**

Bacteria and protozoa, as follows:
1. Bacteria, as follows:
(a) Attenuated or inactivated systems.
(b) Orders and Suborders, *the following only:*
Chlamydobacteiales
Hyphomicrobiales
Caryophanales
Beggiatoales
Myxobacterales
Rhodobacteriineae
(c) Families and Subfamilies, *the following only:*
Nitrobacteraceae
Methanomonadaeae
Thiobacteriaceae
Caulobacteraceae
Siderocapsaceae
Azatobacteraceae
Rhizobiaceae
Brevibacteriaceae
Propionibacteriaceae
Streptomycetaceae
Serratia
(d) Genera, *the following only:*
Acetobacter
Alginomonas
Azotomonas
Mycoplana
Photobacterium
Protaminobacter
Zymomonas
Achromobacter
Agarbacterium
Alcaligenes
Aerobacter
Alginobacter
Paracolobactrum
Methanococcus
Micrococcus
Peptococcus
Sarcina
Veillonella
Eubacterium
Lactobacillus
Leuconostoc
Pediococcus
Mycococcus
Saprospira
Spirochaeta
Grahamella
Anaplasma
Ehrlichia
Neorickettsiella
Symbiotes
Wolbachia
2. Protozoa, as follows:
(a) Classes, *the following only:*
Ciliata
Suctoria
(b) Orders, *the following only:*
Chrysomonadida
Cryptomonadida
Phytomonadida
Euglenoidida
Chloromonadida
Hypermastigida
Proteomyxida
Mycetomyxida
Testacida
Foraminiferida
Heliozoida
Radiolarida
Gregarinida
(c) Families, *the following only:*
Prorocentridae
Cystodiniidae
Pronoctilucidae
Pauchetiidae
Noctilucidae
Polykrikidae
Peridiniidae
Dinophysidae
Multiciliidae
Phalansteriidae
Cadosigidae
Bicosoecidae
Amphimonadidae
Trimastigidae
Streblomastigidae
Pyrsonymphidae
Devesconvinidae
Calonymphidae
Naegleriidae
Amoebidae
Paramoebidae
Selenococcidiidae
Aggregatidae
Dabelliidae
Adeleidae
Ceratomyxidae
Trilosporidae
Myxidiidae
Tetractionomyxidae
Sphaeractionomyxidae
Trisctionomyxidae
Heractionomyxidae
Coccosporidae
Mrazekiidae
Telomyxidae

Interpretation 29: General Industrial Equipment

The commodities listed below require a validated license for export to **Country Groups S and Z.**

General industrial equipment and parts therefor, n.e.s. *the following only:*
Abrasive circulators
Abrasive-coating
Accumulators, hydraulic
Aerators
Agricultural machines and applicances, n.e.s.
Air-conditioning machines, n.e.s.
Air or gas compressors, n.e.s.
Air heaters, portable, fuel, fired, n.e.s.
Armature winding
Assembling fixtures, production, *except for production of military equipment*
Basket-making
Battery-making
Binoculars and telescopes, including astronomical telescopes, n.e.s.
Bituminous pavers, finishers, and spreaders
Blenders
Boiler room specialty tools
Bottling, canning, cleaning, dishwashing, filling, packaging, and sealing machines, n.e.s.
Broom-making
Brush-making
Button covering
Button-making
Cable-making, n.e.s.
Cable spinning
Calendering machines and similar rolling machines, n.e.s.
Candle making
Carpet sweepers, hand
Cattle stunners
Centrifuges, filtering, and purifying machines for liquids, air, and gases, n.e.s.
Cigarette and cigar making and other tobacco processing
Clay guns
Cleaners, ultrasonic, n.e.s.
Cleaning equipment, n.e.s., for magnetic tape and other recording media
Cleaning units, sack
Coil winding for electrical components
Coiling, flexible casing or flexible tube
Color mixing and dispensing
Concrete pavers, finishers, and spreaders
Coolers, evaporative type
Cordage making
Cranes, n.e.s., nonmilitary
Creosoting, wood products
Dehumidifiers, non-freezing
Diving bells or suits, mechanically equipped
Drawing, marking out, calculating, drafting, measuring, and checking appliances and machines, mechanical, nonelectric, or non-electronic, n.e.s.
Environmental chambers, n.e.s.
Excavating, leveling, mining, oilwell drilling, well drilling, construction, and maintenance equipment, n.e.s.[1]
Fans and blowers, n.e.s.
Fermentors
Filament winding, n.e.s.
Filters, ferro-magnetic
Flame arrestors

[1] A validated license is required for export of oil well drilling equipment and oil field wire line and down hole equipment to the USSR, Estonia, Latvia, and Lithuania.

Floor finishers, sanders, scrubbers, and surfacers, industrial type
Flourescent disposal units
Food processing machines
Freeze dryers
Fumigation chambers
Fur-blowing
Fur-treating
Garbage grinders, commercial and industrial
Gas operated welding, cutting, brazing, and surface tempering machines and appliances, n.e.s.
Gas or liquid supply meters, n.e.s.
Gas turbine engines, n.e.s.
Glass working machines, n.e.s.
Grinders and crushers, laboratory
Hand tools, n.e.s.
Hat-blocking and hat-making
Homogenizers, laboratory
Humidifiers, air
Ice breakers
Ice-crusher slingers
Ice saw and drill, combination type, engine driven
Impregnators, non-centrifugal
Incinerators, commercial and industrial
Incubator shalkers
Industrial and laboratory nonelectric furnaces and ovens, n.e.s.
Internal combustion engines, reciprocating
Internal pneumatic line-up clamps for welding transmission line pipe
Lifting, loading, and conveying machines and equipment, n.e.s.
Line-travelling coating and wrapping for pipes and tubes
Linoleum-making
Lubricating
Machinery and equipment, n.e.s., for the manufacturing and assembling of electronic components, n.e.s.
Machines, n.e.s., for processing and working wood, cork, bone, ebonite, glass, plastics, cement products, stone, and similar mineral materials.
Machines, n.e.s., for treatment of a material involving a change in temperature.
Mattress filling
Measureograph for measuring cloth
Mechanical appliances for testing physical properties of industrial materials, n.e.s.
Mechanical instruments, n.e.s., for measurement, transmission, or control of temperature, pressure, or other variables of liquids or gases
Mechanical watches and clocks
Metal finishing, chemical
Metallurgical, mill, and foundry equipment, n.e.s.
Metering and mixing, n.e.s.
Microscopes, except electron and proton, n.e.s.
Nutters
Office machines, n.e.s.
Oil field wire line and downhole equipment [1]
Optical elements and appliances, n.e.s.
Paint markers and mixers
Paper making machinery
Photoprinters, n.e.s.
Pin ticketing (tag-to-product applying)
Pipe line cleaning
Plastic working, n.e.s.
Power sweepers
Power transmission equipment, n.e.s.
Presses, n.e.s.
Printed circuit board laminating presses and lead masters
Printing machines, n.e.s.
Proportioning, mixing, and dispensing resins
Pulsating dampeners
Pumps for liquids, n.e.s.
Reels, hose and cable, power operated
Refractory injection guns
Refrigerant charging apparatus, automatic
Refrigeration equipment, n.e.s.
Ribbon coiling
Roller coaters, n.e.s.
Rope-making
Rubber extruding and processing
Rubber products manufacturing, n.e.s.
Searchlights and spotlights
Shaking machines, laboratory
Shock absorbers, mechanical or hydraulic
Shoelace tipping
Smoke generators, *except military*
Snow throwers, self-propelled
Soldering, automotive wave and reflow type
Sonic sewing machines
Special purpose industrial vehicles, n.e.s., non-military, *e.g.*, cement mixers, street and airfield cleaning, asphalt mixers, seismograph thumper mounted trucks, mine shuttle vehicles, trucks with derrick assembly and similar equipment for drilling, mounted integral to truck frame, etc.
Spinning
Spraying machines, n.e.s.
Steam cleaning
Steam generating power boilers, engines, and turbines, n.e.s.
Stone products manufacturing
Surgical dressing making
Surveying, hydrographic, meteorological, hydrological, and geophysical instruments, n.e.s.
Sweepers, road
Tank-cleaning
Tanks with agitators
Taping machines for covering wire and cable
Textile and leather working machines, n.e.s.
Tire building, recapping, and repairing
Toothbrush manufacturing
Track press for repairing tractor crawlers or tracks
Transfer machines, nonmetalworking, *except for assembling, gauging, or packing of munitions*
Tube cleaners
Tube expanders, maintenance type
Typemaking and typesetting machines, n.e.s.
Vacuum cleaners
Valves, plumbing fixtures, cocks, and taps, n.e.s.
Vegetable oil mill
Vibrating paper joggers
Vibrators, hydraulic
Wall-board plaster core
Watch-cleaning
Water bath shakers
Watercraft controls, nonelectric, *except military* (for example, steering equipment excluding rudders and remote controls)
Water turbines, water engines, wind, and hot air engines
Wax molding
Waxing, industrial
Weed cutting, underwater
Weighing machines
Welders, plastic, ultrasonic
Welding machines, n.e.s.
Welding rod brushing and feeders
Wheel tractors, including garden, log skidders, and contractors earthmoving types, n.e.s.
Wind tunnels, subsonic
Winding, n.e.s.
Windshield wipers, nonelectric
Wire braiding, wire rope-making, wire stitching, and measuring, stripping, cutting, and terminal attaching
Zipper manufacturing

[1] A validated license is required for export of oil well drilling equipment and oil field wire line and down hole equipment to the U.S.S.R., Estonia, Latvia and Lithuania.

Interpretation 30: Petroleum and Natural Gas Exploration and Production Equipment

The following is an illustrative list of petroleum and natural gas exploration and production equipment subject to validated license control for export to the USSR, Estonia, Latvia, and Lithuania. This list is illustrative only. It does not include all commodities which are covered by CCL entry Nos. 6191, 6391, and 6598.

(1) All equipment related to off-shore floating or bottom-supported drilling and producing structures, including all gathering equipment.

(2) Production and pipeline equipment designed for use in Arctic regions and the Polar Seas.

(3) Rotary type well drilling rigs and derricks.

(4) Parts, accessories, and equipment for well drilling machines, including, but not limited to, drill bits, box and pin tool joints, drill pipe, drill collars, rotary tables, and blow-out preventors.

(5) Petroleum gas-lift equipment.

(6) Oil well and oil field pumps, including, but not limited to, high performance types of submersible or conventional pumping units.

(7) Pipeline valves for oil and gas pipelines and high pressure steel hoses, pipes, and connections.

(8) Wire line and down-hole equipment and accessories, including, but not limited to, collars, stabilizers, mandrels, packers, multicompletion equipment, gun perforators, and telemetry equipment.

(9) Optical, electrical, or electronic geophysical and mineral prospecting instruments, including magnetic, gravity, seismic, bore-hole logging and high-resolution remote sensing equipment.

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federal register

Tuesday
December 30, 1980

Part III

Department of Health and Human Services

Food and Drug Administration

Medical Devices; Classification

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 78N-2830]

Classification of Dental Devices; Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general rules applicable to the classification of all dental devices. The Medical Device Amendments of 1976 require FDA to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulations classifying individual dental devices, which are being published elsewhere in this issue of the **Federal Register.** The preamble also describes the activities of the Dental Device Section of the Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel, an FDA advisory committee, that makes recommendations to FDA concerning the classification of dental devices.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (Pub. L. 94-295, hereinafter called the amendments) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; and class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the Panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), FDA issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848).

Activities of Panel

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Dental Device Classification Panel (the Panel) was originally chartered on October 15, 1974, as the Panel on Review of Dental Devices. FDA placed a report of the Panel's tentative classification recommendations on file with the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and announced the availability of the report to the public by notice published in the **Federal Register** of June 25, 1976 (41 FR 26245). On August 9, 1976, the Panel and other preamendments device classification panels were recharterd to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA had referred to it to make certain that its recommendations were in accord with the amendments. Throughout the Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of dental devices. The Panel also invited experts to testify and sought information on many devices from the published literature.

In October 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and former Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and announced its availability to the public by notice published in the **Federal Register** of November 29, 1977 (42 FR 60792). Also available in the office of the Hearing Clerk are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual dental device proposed classification regulations.

On April 28, 1978, the agency terminated all of the device classification panels, and then reestablished them with new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The Dental Device Classification Panel was terminated, and its functions are now conducted by the Dental Device Section of the Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel.

Relationship Between the Device Names in the Device Registration and Listing Codes and the Device Names in Classification Regulations

Some manufacturers have become accustomed to identifying a device by

its registration and listing name and three-letter code and used for purposes of device listing under section 510 of the act (21 U.S.C. 360). However, FDA is still making changes in the names and identifications of generic types of devices in the classification regulations for all devices for which final regulations have not been published. Because FDA has not use the present device registration and listing names in the proposed and final classification regulations, FDA has prepared an index of names of generic types of medical divices used in classification regulations to aid a manufacturer in matching its device with the proper classification regulation. The index shows the device registration and listing product code for each device reviewed by a classification panel and the corresponding name of the generic type of device and classification panel in which the device classification will be published in the **Federal Register**. The Agency announced the availability of this index in the **Federal Register** of March 6, 1979 (44 FR 12269). If necessary, this index will be updated and the availability of the revised index will be reannounced in the **Federal Register**. FDA believes that, because this index is available, it is unnecessary to include or cross-reference the present device registration and listing name and product code in the classification regulations. In the future, following publication of most of the device classification regulations, the agency will revise and reissue the device registration and listing product code, so the device names to be used for registration and listing correspond to the device names in the final device classification regulations.

List of Dental Devices

In 1972, FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of dental devices. The Panel supplemented the list utilizing its members' knowledge of dental devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included.

FDA is proposing to establish a new Part 872 in Title 21 of the Code of Federal Regulations. Part 872 will consist of sections identifying each dental device with a brief narrative description and stating the classification of that device. A list of the dental devices appears elsewhere in this preamble.

Individual Dental Device Classification Regulations

Elsewhere in this issue of the **Federal Register**, FDA is issuing 185 individual proposed regulations to classify each dental device. FDA is proposing to classify 49 dental devices into class I (general controls), 122 dental devices into class II (performance standards), 13 dental devices into class III (premarket approval); and one dental device into either class I or class II, depending upon the construction of the device. The agency also is publishing the recommendations of the Panel regarding these devices, as required by section 513(c)(2) and (d)(1) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

Interaction Between the Bureau of Medical Devices and the Bureau of Radiological Health

In addition to its authority under the amendments, FDA has authority to regulate some medical devices under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602). Public Law 90–602 authorized FDA to establish and execute a program to control electronic product radiation that includes performance standards for electronic products and their related accessories. Radiation emission performance standards have been, and will continue to be, established for those medical devices that emit electronic product radiation. Performance standards have already been promulgated for diagnostic X-ray systems and their major components (21 CFR 1020.30); radiographic equipment (21 CFR 1020.31); fluoroscopic equipment (21 CFR 1020.32); laser products (whether or not for medical use) (21 CFR 1040.11), and ultrasonic therapy products (21 CFR 1050.10). The agency will continue to use its authority over radiation-emitting electronic medical products under both the amendments and the Radiation Control for Health and Safety Act of 1968, as appropriate.

Published Panel Recommendations

Each published Panel recommendation concerning a dental device includes the information described below.

1. *Identification.* Both the Panel recommendation and the proposed FDA classification regulation include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 872.1, any manufacturer of a newly offered device who files a premarket notification submission under section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 (21 CFR Part 807) of the regulations cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a newly offered device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendments device (or to a postamendments device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The agency believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls), class II (performance standards), or class III (premarket approval).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), the good manufacturing practice requirements). The Panel recommended that several devices be exempted from section 510, section 519, and section 520(f) of the act in the manufacture of these devices. The agency's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the

Panel's recommended priority ("high," "medium," or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and III Devices," the agency is not, however, proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, FDA is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C 360g(f)).

4. *Summary of date on which the recommendation is based.* In many cases, the Panel based its recommendations on Panel members' personal knowledge of, and clinical experience with, the devices under review. The Panel particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments provides that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H.R. Rept. No. 94–853, 94th Congress, 2d Session 40 (1976)). FDA has determined that clinical experience and judgment constitute valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the "Proposed Classification" section of the preambles to individual dental device regulations. The agency is adopting as its statement of the basis for issuing the regulation under section 517(f) of the act the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by dental devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the individual device. In some cases, FDA has identified risks to health presented by a device in addition to those listed by the Panel. These additional risks are set out in the section of the preamble concerning the "Proposed Classification" of a particular device.

In addition to those hazards explicitly mentioned, the Panel and FDA recognize that there are general hazards associated with certain types of devices. For example, trauma may be associated with moving or powered device components. In any diagnostic device, accurate results must be obtained in a usable form in order to avoid misdiagnosis and incorrect patient management or to avoid the additional radiation exposure necessitated by a repeat procedure. The absence of a discussion of these general hazards does not imply that they are insignificant or that they were not considered in determining a proposed classification.

Because the classification recommendations and FDA regulations may not identify all risks to health presented by dental devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed classification

Each proposed regulation to classify a dental device states whether FDA agrees with the Panel's recommendation, describes the agency's proposed classification of the device, and proposes a new section in Part 872 in which the device classification will be codified. FDA is proposing that 75 of the devices that the Dental Device Section of the Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel recommended for classification into class I be classified into class II. The agency has identified risks to health, such as lack of biocompatibility of materials used in the devices, that would be controlled by performance standards. The agency believes that general controls alone are insufficient to control the risks to health presented by these 75 devices. In March 1979, FDA sent a letter to each member of the Dental Device Section. The letter to the members of the Section explained the agency's proposed change in the classification of the 75 devices. A copy of the agency's letter to members of the Section is on file with the Hearing Clerk, at the address noted above (Ref. 1).

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Panel Definition of a Dental Implant

The Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel identified a dental implant as a device that is surgically placed into, or in opposition to, the maxilla or mandible and which protrudes through the mucosa of the oral cavity. According to this Panel definition, restorative materials placed in the teeth, such as amalgams, gold alloys, silicates, and cements, are not implants.

Priorities for Class II and Class III Devices

For a device that the Panel recommends classification into class II or class III, section 513(c)(2)(A) of the act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of performance standards or premarket approval requirements. In developing its advice concerning priorities ("high," "medium," or "low") of devices recommended for classification into class II or class III, the Panel compared the device with other dental devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panel recommended assignment of a "high priority" only to those class II or class III devices that the Panel believed should receive the agency's immediate attention.

FDA is not proposing at this time to establish priorities for development of performance standards for all class II devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. In the **Federal Register** of February 1, 1980 (45 FR 7489 and 45 FR 7493), FDA published notices identifying which class II devices the agency found to warrant a high priority for the development of performance standards. At a later date, the agency will establish priorities for the development of standards for the remaining class II devices. All priorities established by the agency are based on the classification panels' recommendations, available resources,

and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

The agency intends to proceed as quickly as the statute and panel resources permit to require premarket approval of devices classified into class III. Two factors affect the length of time before FDA requires submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a panel. For example, where FDA classifies into class III only a few devices within a Panel's specialty area, FDA may, at the same time, publish regulations under section 515(b) of the act requiring premarket approval for many of the class III devices considered by the Panel, regardless of whether of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification, during which 30 month period a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

Products That Have Both Medical and Nonmedical Uses

Some products have both medical and nonmedical uses. FDA will regulate a multipurpose product as a medical device if it is intended for a medical purpose, i.e., for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." Section 210(h) of the act (21 U.S.C. 321(h)). FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them.

Exemptions for Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: section 510 (21 U.S.C. 360), registration; section 519 (21 U.S.C. 360i), records and reports; and section 520(f) (21 U.S.C. 360j(f)), good manufacturing practice.

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding or processing of * * * a device or devices" must register with FDA (section 510 (b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See 21 CFR Part 807.) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510 of the act. Several device panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions for certain devices. Thus, the agency has proposed to exempt manufacturers of certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k) of the act. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) of the act will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation under Part 820 (21 CFR Part 820), published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations in accordance with section 519 of the act, incuding a regulation requiring reports to FDA of experiences with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will issue exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the **Federal Register** of July 21, 1978. At the time of the Panel's recommendations, the GMP regulation had not yet been promulgated, and the agency had not yet developed criteria for exempting manufacturers of a class I device from GMP requirements. The agency has now decided that, if any one of the following criteria is met, FDA will consider exempting from the GMP regulation manufacturers of a class I device that is not labeled or otherwise represented as sterile. The agency will not, however, exempt manufacturers of a device from general requirements concerning records or complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of the GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or routine testing before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. A sterile device must be subject to the entire GMP regulation to ensure that manufacturers adequately reduce the bioburden (number of microorganisms) on the device and its components during the manufacturing process. This reduction is accomplished through adherence to a comprehensive quality assurance program as is required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest and that compliance with these sections is not unduly burdensome for device manufacturers. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all manufacturers are required to comply with the complaint file requirements. All device manufacturers also are required to comply with the general requirements concerning records to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of devices from requirements under section 510 or 520(f) of the act, but has acted on the basis of exemption recommendations of the device classification panels. However, FDA has proposed occasionally to exempt manufacturers of certain devices classified into class I or class II from the requirements of certain sections of the GMP regulation, according to the above exemption criteria. Manufacturers and other interested persons may submit comments on the appropriateness of the proposed exemptions of manufacturers of devices, whether the exemptions are proposed in response to recommendations of the panels or on the agency's initiative. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation is consistent with the criteria discussed above.

Guidelines for Preparing Petitions Requesting Exemption or Variance From the Device GMP Regulation for Devices Classified Into Class I or Class II

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device GMP regulation. These petitions may be submitted in accordance with provisions of section 520(f)(2) opf the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)(2)). The agency announced the availability of the guidelines in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671).

List of Dental Devices

The following is a list of dental devices that FDA is proposing to classify, the section and subpart of Part 872 in the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section	Device	Docket No.	Class
	Subpart B—Dental Diagnostic Devices		
872.1500	Gingival fluid measurer	78N-2831	I
872.1720	Pulp tester	78N-2834	II
872.1730	Electrode gel for pulp tester	78N-2835	II
872.1800	Extraoral source X-ray system	78N-2836	II
872.1810	Intraoral source X-ray system	78N-2837	II
872.1820	Dental X-ray exposure alignment device	78N-2838	II
872.1830	Cephalometer	78N-2839	II
872.1840	Dental X-ray position indicating device	78N-2840	II
872.1850	Lead-lined position indicator	78N-2841	II
872.1905	Dental X-ray film holder	78N-2842	II
	Subpart D—Dental Prosthetic Devices		
872.3050	Amalgam alloy	78N-2843	II
872.3060	Gold-based alloy for clinical use	78N-2844	II
872.3070	Precious metal alloy for clinical use	78N-2845	II
872.3080	Mercury and alloy dispenser	78N-2846	II
872.3100	AC-powered dental amalgamator	78N-2847	II
872.3110	Dental amalgam capsule	78N-2848	II
872.3130	Preformed anchor	78N-2849	II
872.3140	Resin applicator	78N-3024	I
872.3150	Articulator	78N-2850	I
872.3165	Precision attachment	78N-2851	II
872.3175	Performed bar	78N-2852	II
872.3200	Resin tooth bonding agent	78N-2853	I
872.3220	Facebow	78N-2854	I
872.3240	Dental bur	78N-2855	II
872.3250	Calcium hydroxide cavity liner	78N-2856	II
872.3260	Cavity varnish	78N-2857	II
872.3275	Dental cement	78N-2858	II
872.3285	Preformed clasp	78N-2859	II
872.3295	Preformed wire clasp	78N-2860	II
872.3300	Hydrophilic resin coating for dentures	78N-2861	II
872.3310	Coating material for resin fillings	78N-2862	II
872.3330	Preformed crown	78N-2863	II
872.3350	Gold and stainless steel cusp	78N-2864	II
872.3360	Preformed cusp	78N-2865	II
872.3400	Acacia and karaya with sodium borate denture adhesive	78N-2866	III
872.3410	Carboxymethylcellulose sodium (40 to 100 percent) denture adhesive.	78N-2867	II
872.3420	Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.	78N-2868	III
872.3430	Carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesive.	78N-2869	II
872.3440	Carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesive.	78N-2870	II
872.3450	Karaya denture adhesive	78N-2871	II
872.3460	Karaya and ethylene oxide homopolymer denture adhesive	78N-2872	II
872.3470	Karaya with sodium borate denture adhesive	78N-2873	III
872.3480	Polyacrylamide polymer (modified cationic) denture adhesive	78N-2874	III
872.3490	Polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.	78N-2875	II

Section	Device	Docket No.	Class
	Subpart D—Dental Prosthetic Devices—Continued		
872.3500	Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer and carboxymethyl cellulose sodium (NACMC) denture adhesive.	78N-2876	III
872.3510	Polyvinylmethylether maleic acid calcium-sodium double salt and carboymehtylcellulose sodium denture adhesive.	78N-2877	II
872.3520	OTC Denture cleanser	78N-2878	II
872.3530	Mechanical denture cleaner	78N-2879	II
872.3540	Over-the-counter (OTC) denture cushion	78N-2880	III
872.3550	Over-the-counter (OTC) denture pad	78N-2881	III
872.3560	Over-the-counter (OTC) denture reliner	78N-2882	III
872.3570	Over-the-counter (OTC) denture repair kit	78N-2883	III
872.3580	Preformed gold denture teeth	78N-2884	II
872.3590	Preformed plastic denture teeth	78N-2885	II
872.3600	Partially fabricated denture kit	78N-2886	III
872.3640	Endosseous implant	78N-2887	III
872.3645	Titanium subperiosteal implant material	78N-2888	II
872.3650	Cobalt chrome molybdenum subperiosteal implant material	78N-2889	II
872.3660	Impression material	78N-2890	II
872.3670	Resin impression tray material	78N-2891	I
872.3680	Polytetrafluoroethylene (PTFE) vitreous carbon material	78N-2892	II
872.3690	Tooth shade resin material	78N-2893	II
872.3700	Dental mercury	78N-2894	II
872.3710	Base metal alloy	78N-2895	II
872.3730	Pantograph	78N-2897	I
872.3740	Retentive and splinting pin	78N-2898	II
872.3750	Bracket adhesive resin and tooth conditioner	78N-2899	II
872.3760	Denture relining, repairing, or rebasing resin	78N-2900	II
872.3765	Pit and fissure sealant and conditioner	78N-2901	II
872.3770	Temporary crown and bridge resin	78N-2902	II
872.3810	Root canal post	78N-2904	II
872.3820	Root canal filling resin	78N-2905	II
872.3830	Endodontic paper point	78N-2906	II
872.3840	Endodontic silver point	78N-2907	II
872.3850	Gutta percha	78N-2908	II
872.3890	Endodontic stabilizing splint	78N-2909	II
872.3900	Posterior artificial teeth with metal insert	78N-2910	II
872.3910	Backing and facing for artificial teeth	78N-2911	II
872.3920	Porcelain teeth	78N-2912	II
872.3980	Zinc oxide eugenol	78N-2913	II
	Subpart E—Dental Surgical Devices		
872.4040	Endodontic broach	78N-2927	II
872.4075	Dental wax carver	78N-2914	I
872.4120	Manual bone drill and wire dirver	78N-2915	II
872.4130	Intraoral dental drill	78N-2916	II
872.4140	Powered bone drill	78N-2917	II
872.4150	Endodontic pulp canal file	78N-3026	II
872.4200	Air-powered dental handpiece	78N-2918	II
872.4220	Belt-driven dental handpiece	78N-2919	II
872.4240	Rotary bone-cutting handpiece	78N-2920	II
872.4260	Contra angle handpiece attachment	78N-2921	II
872.4280	Direct drive handpiece	78N-2922	II
872.4300	Foot controller for handpiece	78N-2923	I
872.4320	Water-powered handpiece	78N-2924	II
872.4465	Gas-powered jet injector	78N-2925	II
872.4475	Spring-powered jet injector	78N-2926	II
872.4500	Hand instrument for calculus removal	78N-2927	II
872.4520	Dental depth gauge instrument	78N-2928	I
872.4535	Dental diamond instrument	78N-2929	II
872.4555	Plastic dental filling instrument	78N-2930	I
872.4565	Dental hand instruments	78N-2931	I
872.4575	Dental instrument handle	78N-2932	I
872.4600	Intraoral ligature and wire lock	78N-2933	II
872.4620	Fiber optic dental light	78N-2934	II
872.4630	Dental operating light	78N-2935	II
872.4640	Surgical headlight	78N-2936	II
872.4730	Dental injecting needle	78N-2937	II
872.4760	Bone plate	78N-2938	II
872.4820	AC-powered bone saw	78N-2941	II
872.4840	Rotary scaler	78N-2942	II
872.4850	Ultrasonic scaler	78N-2943	II
872.4875	Surgical tissue scissors	78N-2945	II
872.4880	Intraosseous fixation screw	78N-2946	II
872.4920	Dental electrosurgical unit and accessories	78N-2947	II
872.4950	Intraosseous fixation wire	78N-2948	II
	Subpart F—Dental Therapeutic Devices		
872.5400	Orthodontic elastic band	78N-2950	II
872.5410	Orthodontic preformed band	78N-2951	II
872.5420	Orthodontic band driver	78N-2952	I
872.5430	Orthodontic band material	78N-2953	II
872.5440	Orthodontic band pusher	78N-2954	I
872.5450	Orthodontic band setter	78N-2955	I
872.5460	Orthodontic metal bracket	78N-2956	II
872.5470	Orthodontic plastic bracket	78N-2957	II
872.5480	Orthodontic bracket aligner	78N-2958	I
872.5490	Orthodontic wire clamp	78N-2959	II
872.5500	Extraoral orthodontic headgear	78N-2960	II

Section	Device	Docket No.	Class
	Subpart B—Dental Diagnostic Devices—Continued		
872.5510	Preformed orthodontic space maintainer	78N-2961	II
872.5520	Orthodontic pliers	78N-2962	I
872.5525	Preformed tooth positioner	78N-3025	II
872.5530	Orthodontic expansion screw retainer	78N-2963	II
872.5540	Orthodontic spring	78N-2964	II
872.5550	Teething ring	78N-2965	I, II
872.5560	Orthodontic tube	78N-2966	II
872.5570	Orthodontic ligature tucking instrument	78N-2967	I
872.5580	Orthodontic wire	78N-2968	II
	Subpart G—Dental Miscellaneous Devices		
872.6010	Abrasive disk	78N-2969	II
872.6020	Abrasive point	78N-2970	II
8072.6030	Oral cavity abrasive polishing agent	78N-2971	II
872.6035	Polishing agent strip	78N-2972	I
872.6040	Polishing wheel	78N-2973	I
872.6050	Paper saliva absorber	78N-2974	I
872.6070	Ultraviolet activator for polymerization	78N-2975	II
872.6080	Airbrush	78N-2976	III
872.6100	Anesthetic warmer	78N-2977	I
872.6140	Articulation paper	78N-2978	I
872.6200	Base plate shellac	78N-2979	II
872.6250	Dental chair with operative unit	78N-2980	II
872.6260	Dental chair without operative unit	78N-2981	II
872.6280	Cotton roll	78N-2982	I
872.6290	Prophylaxis cup	78N-2983	I
872.6300	Rubber dam	78N-2984	I
872.6310	Rubber dam clamp	78N-2985	I
872.6320	Rubber dam frame	78N-2986	I
872.6350	Ultraviolet detector	78N-2987	II
872.6370	Oral cavity evacuator	78N-2988	I
872.6390	Dental floss	78N-2989	I
872.6400	Forceps for articulation paper	78N-2990	I
872.6410	Forceps for dental dressing	78N-2991	I
872.6420	Forceps for a rubber dam clamp	78N-2992	I
872.6465	Guard for an abrasive disk	78N-2993	I
872.6475	Heat source for bleaching teeth	78N-2994	II
872.6510	Oral irrigation unit	78N-2996	II
872.6550	Dental matrix band	78N-2997	I
872.6560	Matrix retainer	78N-2998	I
872.6570	Impression tube	78N-2999	I
872.6600	Mouth mirror	78N-3000	I
872.6620	Saliva ejector mouthpiece	78N-3001	I
872.6640	Dental operative unit	78N-3002	II
872.6645	Suction operative unit	78N-3003	II
872.6650	Massaging pick	78N-3004	II
872.04		78N-30	I
872.6660	Porcelain powder for clinical use	78N-3005	II
872.6670	Silicate protector	78N-3006	I
872.6680	Dental retractor (all types)	78N-3007	II
872.6690	Dental retractor accessories	78N-3008	II
872.6710	Boiling water sterilizer	78N-3009	II
872.6730	Endodontic dry heat sterilizer	78N-3011	III
872.6750	Air or water syringe unit	78N-3012	I
872.6770	Cartridge syringe	78N-3014	II
872.6800	Periodontic or endodontic irrigating syringe	78N-3016	I
872.6810	Restorative or impression material syringe	78N-3017	I
872.6850	Rubber tip for oral hygiene	78N-3018	I
872.6855	Manual toothbrush	78N-3019	I
872.6865	Powered toothbrush	78N-3020	II
872.6870	Disposable fluoride tray	78N-3021	I
872.6880	Preformed impression tray	78N-3022	I
872.6890	Intraoral dental wax	78N-3023	II

Devices Considered by Two or More Panels

The Dental Device Section of the Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel and the other panels listed below made classification recommendations concerning the following devices:

Device—Other Panels

X-ray film cassette—Obstetrics-Gynecology and Radiologic
Extra oral X-ray dental film—Obstetrics-Gynecology and Radiologic
Intra oral X-ray dental film—Obstetrics-Gynecology and Radiologic
Intensifying radiographic screen—Obstetrics-Gynecology and Radiologic
Automatic radiographic film processor—Obstetrics-Gynecology and Radiologic
Leaded apron—Obstetrics-Gynecology and Radiologic
Leaded operator radiation protector—Obstetrics-Gynecology and Radiologic
Anesthesia flowmeter—Respiratory and Nervous System
Compressed gas cyliner and valve—Respiratory and Nervous System
Analgesia/anesthesia gas machine—Respiratory and Nervous System
Resuscitation and emergency oxygen unit—Respiratory and Nervous System
Cotton applicator—General Medical
Autoclave—General Medical
Ethylene oxide gas sterilizer—General Medical

Luer-lock drug syringe—General Medical
Tongue depressor—General Medical
Gauze sponge—Surgical and Rehabilitation
Surgical knife—Surgical and Rehabilitation
Dental suture—Surgical and Rehabilitation
Iontophoresis device—Surgical and Rehabilitation

The agency is not at this time publishing the recommendations of the Dental Device Section of the Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel to classify the devices listed above. The agency has published, or will publish, these recommendations and proposed classification regulations along with the recommendations of other Panels that reviewed the devices. Some of these other Panels' recommendations have already been published in the **Federal Register.** The following table shows the current structure of the advisory committees involved with classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel/Section Name—Publication Date in Federal Register

Circulatory Systems Devices Panel—March 9, 1979 44 FR 13284–13434 (proposals); February 5, 1980, 45 FR 7904–7971 (final regulations)

Clinical Chemistry and Hematology Devices Panel

Clinical Chemistry Device Section
Clinical Toxicology Device Section
Hematology and Pathology Device Section—September 11, 1979, 44 FR 52950–53063 (proposals); September 12, 1980, (45 FR 760576–06051 (final regulations)

General Medical Devices Panel

General Hospital and Personal Use Device Section—August 24, 1979, 44 FR 49844–49954 (proposals); October 21, 1980, 45 FR 69678–69737 (final regulations)
Gastroenterology-Urology Device Section

Immunology and Mircrobiology Devices Panel

Immunology Device Section—April 22, 1980, 45 FR 27204–27359 (proposals)
Microbiology Device Section—April 22, 1980, 45 FR 27204–27359 (proposals)

Obstetrics-Gynecology and Radiologic Devices Panel

Obstetrics-Gynecology Device Section—April 3, 1979, 44 FR 19894–19971 (proposals); February 26, 1980, 45 FR 12682–12720 (final regulations).
Radiology Device Section

Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel

Ophthalmic Device Section
Ear, Nose, and Throat Device Section
Dental Device Section

Respiratory and Nervous System Devices Panel

Anesthesiology Device Section—November 2, 1979, 44 FR 63293–63426 (proposals)
Neurological Device Section—November 28, 1978, 43 FR 54640–55732 (proposals); September 4, 1979, 44 FR 51726–51778 (final regulations)

Surgical and Rehabilitation Devices Panel

Physical Medicine device section—August 28, 1979, 44 FR 50458–50537 (proposals)
Orthopedic Device Section
General and Plastic Surgery Device Section

FDA has determined that the following devices reviewed by the Ophthalmic Ear, Nose, Throat, and Dental Devices Panel are identical to devices that have been reviewed by the General Hospital and Personal Use Device Section of the General Medical Devices Panel and classified by regulations published with that Panel: Dry heat sterilizer; air or water bulb syringe; and irrigating syringe. FDA has also determined that these dental devices should be included in the generic types of devices that have already been classified in regulations published with the General Medical Devices Panel. However, because the proposed general hospital and personal use device classifictiaon regulations were published before FDA determined that the devices in question were identical, the agency did not publish the recommendations of the Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel at that time. Accordingly, the agency is publishing the recommendations of the Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel for these devices, as required by the amendments. Interested persons are invited to comment, in accordance with the procedure set forth at the end of this notice, on the Panels' recommendations and on the agency's determinations that the devices described below are identical to the general hospital and personal use devices.

1. The Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel recommends that the dry heat sterilizer be classified into class II because it believes that the dry heat sterilizer should be capable of sterilizing dental instruments properly. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified infection in the patient as a risk to health from use of this device.

FDA has determined that the dry heat sterilizer classified by the Ophthalmic; Ear. Nose, Throat; and Dental Devices Panel is identical to the device with the same name considered by the General Hospital and Personal Use Device Section of the General Medical Devices Panel. On August 24, 1979, FDA published in the **Federal Register** (44 FR 49947) a proposed regulation, based on that Panel recommendation, classifying the dry heat sterilizer into class II.

2. The Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel recommends that both the air or water bulb syringe and the irrigating syringe be classified into class I with exemptions from premarket notification procedures and the good manufacturing practice requirements because it believes that both the air or water bulb syringe and the irrigating syringe are simple devices that present no risks to health. The Panel based its recommendation on the Panel members' clinical experience with these devices.

The agency has determined that both the air or water bulb syringe and the irrigating syringe classified by the Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel are identical to the irrigating syringe considered by the General Hospital and Personal Use Device Section of the General Medical Devices Panel. On August 24, 1979, FDA published in the **Federal Register** (44 FR 49951) a proposed regulation based on that Panel recommendation classifying the irrigating syringe into class I.

Dental Products Regulated as Drugs

The Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel made classification recommendations concerning the following three dental products that FDA has determined will be regulated as drugs rather than as devices: plaque-disclosing kits, lingual ascorbic acid tests, and root canal cleansers. The agency is not publishing proposal classification regulations for these products.

Environmental Impact

The agency has determined under 21 CFR 25.24(b)(12) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, the agency has concluded that neither an environmental assessment nor an environmental impact statement is required.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. and 4 p.m., Monday through Friday.

1. Letter dated March 22, 1979 from D. Gregory Singleton, Executive Secretary, Dental Device Section of the Ophthalmic; Ear, Nose, Throat; and Dental Devices Panel to members of this Section.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21

U.S.C. 360c, 371(a))), and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes that Chapter I of Title 21 of the code of Federal Regulations be amended by adding new Part 872, Subpart A, to read as follows:

PART 872—DENTAL DEVICES

Subpart A—General Provisions

Sec.
871.1 Scope.

Authority: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c and 371(a)).

Subpart A—General Provisions

§ 872.1 Scope.

(a) This part sets forth the classification of dental devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a dental device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, as amended by Executive Order 12221, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: December 16, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39814 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2831]

Medical Devices; Classification of Gingival Fluid Measurers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gingival fluid measurers into class I § (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gingival fluid measurers:

1. Identification: A gingival fluid measurer is a gauge device used to measure the amount of fluid in the gingival sulcus (depression between the tooth and gums) in order to determine if there is a gingivitis condition.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that gingival fluid measurers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, gingival fluid measurers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gingival fluid measures be classified into class I (general controls). FDA believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of gingival fluid measures be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that that these manufacturers be subject to registration, device listing, and premarket notification under section 510(a) through 510(k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of gingival fluid measurers, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, and to conduct necessary

inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540.546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 by adding new Subpart B and new § 872.1500, to read a follows:

Subpart B—Dental Diagnostic Devices

§ 872.1500 Gingival fluid measurer.

(a) *Identification.* A gingival fluid measurer is a gauge device used to measure the amount of fluid in the gingival sulcus (depression between the tooth and gums) to determine if there is a gingivitis condition.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39815 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 872

[Docket No. 78N–2834]

Medical Devices; Classification of Pulp Testers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pulp testers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pulp testers:

1. Identification: A pulp tester is an A.C. or battery powered device used to evaluate the pulpal vitality of teeth, by employing high frequency current, transmitted by an electrode, to stimulate the nerve tissue in the dental pulp.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pulp testers be classified into class II because improper electrical design of the device could cause electrical shock to the patient or user. Moreover, the amount of power delivered by the device must be controlled, because insufficient voltage could cause erroneous evaluation and excessive voltage could cause burns to oral tissue. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Electrical shock: Improper electrical design or malfunction of the device could cause electrical shock to the patient or user. (b) Erroneous evaluation: Improper mechanical or electrical design of the device may result in erroneous evaluation and subsequent therapy that is inappropriate. (c) Tissue burns: If the voltage delivered by the device is excessive, burns to oral tissue may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pulp testers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.1720, to read as follows:

§ 872.1720 Pulp tester.

(a) *Identification.* A pulp tester is an A.C. or battery powered device used to evaluate the pulpal vitality of teeth, by employing high frequency current, transmitted by an electrode, to stimulate the nerve tissue in the dental pulp.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39816 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2835]

Medical Devices; Classification of Electrode Gel for Pulp Testers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrode gel for pulp testers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of electrode gel for pulp testers:

1. Identification: An electrode gel for pulp testers is a device that is applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that electrode gel for pulp testers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, electrode gel for pulp testers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that electrode gel for pulp testers be classified into class II (performance standards). This device comes into direct contact with oral tissue. It is essential that the materials used in the device be biocompatible. Changes in the composition of the device or contamination of the device with other materials may lead to adverse tissue reactions (painful burns or infections), thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that electrode gel for pulp testers should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 ad 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs

proposes to amend Part 872 in Subpart B by adding new § 872.1730, to read as follows:

§ 872.1730 Electrode gel for pulp testers.

(a) *Identification.* An electrode gel for pulp testers is a device that is applied to the surface of a tooth before use of a pulp tester to aid conduction of electrical current.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39817 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2836]

Medical Devices; Classification of Extraoral Source X–Ray Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying estraoral souce X-ray systems into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia, Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of extraoral source X-ray systems:

1. Identification: An extraoral source X-ray system is an AC-powered device that produces X-rays and is used for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The X-ray source (a tube) is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that estraoral X-ray source systems be classified into class II because the device directs radiation at the body, and malfunction could result in the patient's exposure to unsafe levels of radiation. Moreover, the electrical design of the device must be regulated to assure electrical safety. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Exposure to unsafe levels of radiation: Improper shielding of the patient, or improper design or malfunction of the device may result in the unnecessary exposure of the patient to radiation. (b) Electrical shock: Improper electrical design or malfunction of the device could cause electrical shock to the patient or operator.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that extraoral source X-ray sustems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. Any standards developed for the device must conform to the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 262 et seq.) and the regulations governing radiation safety promulgated under that act, as well as the electrical safety regulations promulgated under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.)

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.1800, to read as follows:

§ 872.1800 Extraoral source X-ray system.

(a) *Identification.* An extraoral source X-ray system is an AC-powered device that produces X-rays and is used for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The X-ray source (a tube) is located outside the mouth. This generic type of device may include patient and equipment supports and component parts.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m. Monday through Friday,

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39818 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2837]

Medical Devices; Classification of Intraoral Source X-Ray Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intraoral source X-ray systems into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of intraoral source X-ray systems:

1. Identification: An intraoral source X-ray system is an AC-powered device that produces X-rays and is used for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The X-ray source (a tube) is located inside the mouth. This generic type of device may include patient and equipment supports and component parts.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that intraoral source X-ray units be classified into class II because the device directs radiation at the body, and malfunction could result in the patient's exposure to unsafe levels of radiation. Moreover, the electrical design of the device must be regulated to assure electrical safety. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel also recommends that because the source of the X-rays is placed inside the mouth, systems should be required to bear special labeling which describes the risks involved in using the device without a radiation shield.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Exposure to unsafe levels of radiation: Improper shielding of the patient, improper design, or malfunction of the device may result in unnecessary exposure of the patient to radiation. (b) Electrical shock: Improper design or malfunction of the device could result in electrical shock to the patient or operator.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that intraoral source X-ray systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. Any standards developed for the device must conform to the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 262 et seq.) and the regulations governing radiation safety promulgated under the act, as well as the electrical safety regulations promulgated under the Occupational Safety and Health Act (29 U.S.C. 651 et seq.).

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.1810, to read as follows:

§ 872.1810 Intraoral source X-ray system.

(a) *Identification.* An intraoral source X-ray system is an electrically-powered device that produces X-ray and is used for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The X-ray source (a tube) is located inside the mouth. This generic type of device may include patient and equipment supports and component parts.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be

submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39819 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2838]

Medical Devices; Classification of Dental X-Ray Exposure Alignment Device

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental X-ray exposure alignment devices into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying the device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposal regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of a dental X-ray exposure alignment device:

1. Identification: A dental X-ray exposure alignment device is a device used to position and hold X-ray film and to align the examination site with the X-ray beam.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental X-ray exposure alignment devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because it is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental X-ray exposure alignment devices in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that dental X-ray exposure alignment devices be classified into class II (performance standards). The design and function of dental X-ray exposure alignment devices affect the amount of radiation to which patients are exposed. Alteration of the beam size or change in alignment of the beam, both of which could result from improper design or malfunction of the device, could have an adverse effect on the safety and effectiveness of the device. Also, the agency believes that improper design of the device, resulting in improper beam alignment, would require repeating the X-ray, thus exposing a patient to unnecessary radiation. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that dental X-ray exposure alignment devices should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.1820, to read as follows:

§ 872.1820 X-ray beam aligner.

(a) *Identification.* A dental X-ray exposure alignment device is a device used to position X-ray film and to align the examination site with the X-ray beam.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug

Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39820 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2839]

Medical Devices; Classification of Cephalometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cephalometers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cephalometers:

1. Identification: A cephalometer is a device used in dentistry during X-ray procedures. The device is used to place and to hold a patient's head in a standard position during dental X-rays.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cephalometers be classified into class II because a performance standard is necessary to assure that the measuring and positioning functions of the device are sufficiently accurate to prevent misdiagnosis. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Misdiagnosis: Improper design of the device may result in misdiagnosis and subsequent inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cephalometers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device to assure the accuracy of its measuring and positioning functions and because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.1830, to read as follows:

§ 872.1830 Cephalometer.

(a) *Identification.* A cephalometer is a device used in dentistry during X-ray procedures. The device is used to place and to hold a patient's head in a standard position during dental X-rays.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39821 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2840]

Medical Devices; Classification of Dental X-Ray Position Indicating Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental X-ray position indicating devices into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II

is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental X-ray position indicating devices.

1. Identification: A dental position indicating device is a device, such as a collimator, cone, or apertune, that is used in dental radiographic examination. The device aligns the examination site with the X-ray beam and also restricts the dimensions of the dental X-ray field by limiting the size of the primary X-ray beam.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The panel recommends that dental X-ray position indicating devices be classified into class II because improper design of the device may expose the patient and the operator unnecessarily to radiation. The panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry, and on a presentation by FDA's Bureau of Radiological Health which described the potential hazards associated with the device (Ref. *1*).

5. Risks to health: Exposure to unsafe levels of radiation: Improper design of the device may result in unnecessary exposure of the patient and the operator to radiation.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental X-ray position indicating devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed on file in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Transcript of Dental Device Classification Panel Meeting, Washington, DC, December 5, 1977.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.1840, to read as follows:

§ 872.1840 Dental X-ray position indicating device.

(a) *Identification.* A dental X-ray position indicating device is a device, such as a collimator, cane, or aperture, that is used in dental radiographic examination. The device aligns the examination site with the X-ray beam and also restricts the dimensions of the dental X-ray field by limiting the size of the primary X-ray beam.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identifeid with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39822 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2841]

Medical Devices; Classification of Lead-Lined Position Indicators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lead-lined position indicators into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lead-lined position indicators:

1. Identification: A lead-lined position indicator is a cone-shaped device that is attached to a dental X-ray tube and is used to aid in positioning the tube, to prevent the misfocusing of the X-rays by absorbing divergent radiation, and to prevent leakage of radiation by use of the lead lining.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that lead-lined position indicators be classified into class II because the Panel believes that performance standards are necessary to assure that the X-ray beam is properly controlled by the indicator and, thereby, protects the patient and operator. Faulty design of the cone could cause improper alignment of the X-ray beam at the tip of the cone and, as a result, proper collimation of the X-ray beam (elimination of the divergent portion of the beam) may not occur. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Misdiagnosis and inappropriate treatment: Improper design of the device may result in inaccurate X-rays and subsequent misdiagnosis and inappropriate treatment. (b) Overexposure to radiation: If the lining of the device has an insufficient lead content, the patient may be exposed to unnecessary radiation.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that lead-lined position indicators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.1850, to read as follows:

§ 872.1850 Lead-lined position indicator.

(a) *Identification.* A lead-lined position indicator is a cone-shaped device that is attached to a dental X-ray tube and is used to aid in positioning the tube, to prevent the misfocusing of the X-rays by absorbing divergent radiation, and to prevent leakage of radiation by use of the lead-lining.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39823 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2842]

Medical Devices; Classification of Dental X-Ray Film Holders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental X-ray film holders into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the

development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental X-ray film holders:

1. Identification: A dental X-ray film holder is a device used to position and to hold X-ray film inside the mouth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental X-ray film holders be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification notification procedures, records and reports requirements, and the good manufacturing practice regulation because the Panel believes that defects in this device are readily apparent to the user.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental X-ray film holders in the practice of dentistry.

5. Risks to health: Infection: If the materials used in the device cannot be properly sterilized, a patient may contract an infection.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that dental X-ray film holders be classified into class II (performance standards). This decision is based on the knowledge that a single dental X-ray film holder may be used for many patients and has the potential for transmitting microorganisms between patients. Therefore, these devices must be constructed of materials that can be properly sterilized. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that dental X-ray film holders should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel's recommendation that this device be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.1905, to read as follows:

§ 872.1905 X-ray film holder.

(a) *Identification.* A dental X-ray film holder is a device used to position and to hold X-ray film inside the mouth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39824 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2843]

Medical Devices; Classification of Amalgam Alloys

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying amalgam alloys into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of amalgam alloys:

1. Identification: An amalgam alloy is a device that consists of a metallic substance that is mixed with mercury to form filling material for dental caries.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a

performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that amalgam alloys be classified into class II because materials used in the device that contact the body should meet a generally accepted and satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Adverse gastric or respiratory response: Ingestion of the powdered alloy or the mixed amalgam may be harmful to the patient's digestive or respiratory tract. (b) Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that amalgam alloys be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the advice. A performance standard would provide reasonable assurances of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 by adding new Subpart C, which is reserved, and adding new Subpart D and § 872.3050, to read as follows:

Subpart C—Reserved

Subpart D—Prosthetic Devices

§ 872.305 Amalgam alloy.

(a) *Identification.* An amalgam alloy is a device that consists of a metallic substance that is to be mixed with mercury to form filling material for dental caries.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39825 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2844]

Medical Devices; Classification of Gold-Based Alloy for Clinical Use

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gold-based alloy for clinical use into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gold-based alloy for clinical use:

1. Identification: A gold-based alloy for clinical use is a mixture of metals, the major component of which is gold. It may also contain smaller quantities of silver, copper, platinum, or palladium. It is used to fabricate custom-made dental appliances, such as crowns and bridges.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for gold-based alloy for clinical use be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gold-based alloy for clinical use be classified into class II because the materials used in the device that contact the body should meet a generally accepted and satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Adverse tissue reaction: If materials used in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gold-based alloy for clinical use be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3060, to read as follows:

§ 872.3060 Gold-based alloy for clinical use.

(a) *Identification.* A gold-based alloy for clinical use is a mixture of metals, the major component of which is gold. It may also contain smaller quantities of silver, copper, platinum, or palladium. It is used to fabricate custom-made dental appliances, such as crowns and bridges.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39826 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2845]

Medical Devices; Classification of Precious Metal Alloys for Clinical Use

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying precious metal alloys for clinical use into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of the classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of precious metal alloys for clinical use:

1. Identification: A precious metal alloy for clinical use is a mixture of metals, the major components of which are silver and palladium. It may also contain smaller quantities of other metals, such as copper, gold, and platinum. It is used to fabricate dental applicances such as crowns and bridges.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for precious metal alloys for clinical use by a low priority.

3. Summary of reasons for recommendation: The Panel recommends that precious metal alloys for clinical use be classified into class II because the materials used in the device that contact the body should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Adverse tissue reaction: If the materials used in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that precious metal alloys for clinical use be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classfication regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the

general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3070, to read as follows:

§ 872.3070 Precious metal alloy for clinical use.

(a) *Identification.* A precious metal alloy for clinical use is a mixture of metals, the major components of which are silver and palladium. It may also contain smaller quantities of other metals, such as copper, gold, and platinum. It is used to fabricate dental appliances such as crowns and bridges.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 80–39827 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2846]

Medical Devices; Classification of Mercury and Alloy Dispensers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mercury and alloy dispensers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regualtion based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mercury and alloy dispensers:

1. Identification: A mercury and alloy dispenser is a device used to measure and dispense a predetermined amount of dental mercury in droplet form and a premeasured amount of alloy pellets. The device uses a spring-activated valve to deliver the materials into a mixing capsule.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that mercury and alloy dispensers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, mercury and alloy dispensers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that mercury and alloy dispensers be classified into class II (performance standards). Mercury is toxic to humans. For many years, spillage or leakage of mercury has been considered a hazard to dental patients, the dentist, and staff workers. Leakage of mercury from the device may cause acute or chronic mercury toxicity through inhalation of mercury vapors. Failure of the device to dispense an accurate amount of mercury could affect the physical properties of the carie filling material, resulting in early failure of the filling. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that mercury and alloy dispensers should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the

former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3080, to read as follows:

§ 872.3080 Mercury and alloy dispenser.

(a) *Identification.* A mercury and alloy dispenser is a device used to measure and dispense a predetermined amount of dental mercury in droplet form and a premeasured amount of alloy pellets. The device uses a spring-activated valve to deliver the materials into a mixing capsule.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39828 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2847]

Medical Devices; Classification of AC-Powered Dental Amalgamators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying AC-powered dental amalgamators into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered dental amalgamators:

1. Identification: An AC-powered dental amalgamator is an electrically-powered device used to mix, by shaking, amalgam capsules containing mercury and dental alloy particles, such as silver, tin, zinc, and copper. The resulting amalgam material is used for filling dental caries.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for AC-powered dental amalgamators be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered dental amalgamators be classified into class II because the electrical design of the device should be controlled to assure that the amalgam will be mixed properly and the assure the electrical safety of the device. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Adverse tissue reaction: Improper design of the device, resulting in improper mixing of the amalgam, could cause an adverse tissue reaction in the patient. (b) Electrical shock: Improper electrical design of the device could cause an electrical shock to users.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that AC-powered dental amalgamators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and restablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3100, to read as follows:

§ 872.3100 AC-powered dental amalgamator.

(a) *Identification.* An AC-powered dental amalgamator is an electrically-powered device used to mix, by shaking, amalgam capsules containing mercury and dental alloy particles, such as silver, tin, zinc, and copper. The resulting dental amalgam material is used for filling dental caries.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing

Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39829 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2848]

Medical Devices; Classification of Dental Amalgam Capsules

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental amalgam capsules into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become 78–2448 effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides backgound information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental amalgam capsules:

1. Identification: A dental amalgam capsule is a container device in which silver alloy is mixed with mercury to form dental amalgam.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental amalgam capsules be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with records and reports requirements and the good manufacturing practice regulation because it is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental amalgam capsules in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that dental amalgam capsules be classified into class II (performance standards). Dental amalgam capsules are used to mix amalgam materials, one component of which is mercury. Mercury is toxic to humans. For many years, spillage or leakage of mercury has been considered a hazard to dental patients, the dentist and staff workers. Leakage of mercury from the device may cause acute or chronic mercury toxicity through inhalation of mercury vapors. The agency believes that a performance standard is necessary to assure that dental amalgam capsules can safely be used to perform this mixing process without exposing patients and dental care workers to mercury vapors and because general controls alone are insufficent to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that dental amalgam capsules should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666,, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3110, to read as follows:

§ 872.3110 Dental amalgam capsule.

(a) *Identification.* A dental amalgam capsule is a container device in which silver alloy is mixed with mercury to form dental amalgam.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading

of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39830 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2849]

Medical Devices; Classification of Preformed Anchors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed anchors into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed anchors:

1. Identification: A preformed anchor is a prefabricated device made of metal, such as stainless steel or titanium, that is incorporated in to a dental appliance, such as a denture, to help stabilize the appliance in the patient's mouth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that preformed anchors be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, preformed anchors in the practice of dentisty.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that preformed anchors be classified into class II (performance standards). The properties of the materials used to form preformed anchors depend upon the proper composition of these materials. Moreover, preformed, anchors directly contact oral tissue. Altering the composition of the materials used in the device, or contamination of the materials with other substances, may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that preformed anchors should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3130, to read as follows:

§ 872.3130 Preformed anchor.

(a) *Identification.* A preformed anchor is a device made of metal, such as stainless steel or titanium, that is incorporated into a dental appliance, such as a denture, to help stabilize the appliance in the patient's mouth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received Comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39831 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3024]

Medical Devices; Classification of Resin Applicators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying resin applicatiors into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of resin applicators:

1. Identification: A resin applicator is a brushlike device that is used to spread dental resin on a tooth prior to application of tooth shade material.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends resin applicators be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, resin applicators in the practive of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that resin applicators be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872-3140, to read as follows:

§ 872.3140 Resin applicator.

(a) *Identification.* A resin applicator is a brushlike device that is used to spread dental resin on a tooth prior to application of tooth shade material.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39832 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2850]

Medical Devices; Classification of Articulators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying articulators into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of articulators:

1. Identification: An articulator is a mechanical device used to simulate

movements of a patient's upper and lower jaw. Plaster casts of the patient's teeth and gums are placed in the device to reproduce the occlusion (bite) and articulation of the patient's jaws. An articulator is used to fit dentures or provide orthodontic treatment.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that articulators be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purposes recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, articulators in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that articulators be classifed into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In respone to the Panel recommendation that manufacturers of articulators be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of articulators, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of articulators be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requriements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel's recommendation that manufacturers of articulators be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of articulators having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3150, to read as follows:

§ 872.3150 Articulator.

(a) *Identification.* An articulator is a mechanical device used to simulate movements of a patient's upper and lower jaw. Plaster casts of the patient's teeth and gums are placed in the device to reproduce the occlusion (bite) and articulation of the patient's jaws. An articulator is used to fit dentures or provide orthodontic treatment.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39833 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2851]

Medical Devices; Classification of Precision Attachments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying precision attachments into class II (performance standards). FDA is also publishing the recommendation of the Dental Service Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classfication of precision attachments:

1. Identification: A precision attachment is a device made of cast metal that is used in restorative dentistry in conjunction with removable partial dentures. Various forms of the device are used to connect a lower partial denture, with another lower partial denture to connect an upper partial denture with another upper partial denture, to connect either an upper or lower partial denture to a tooth or a crown, or to connect a fixed bridge to a partial denture.

2. Recommended classification: Class I (general controls). The Panel recommends that precision attachments be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that precision attachments be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, precision attachments in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that precision attachments be classified into class II (performance standards). The properties of the materials used to form precision attachments depend upon the proper composition of these materials. Moreover, precision attachments directly contact oral tissue. Altering the composition of the materials used in the device, or contamination of the materials with other substances, may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessay for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that precision attachments should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from records and reports requirements under section 519 and the good manufacturing practices regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue in the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3165, to read as follows:

§ 872.3165 Precision attachment.

(a) *Identification.* A precision attachment is a device made of cast metal that is used in restorative dentistry in conjunction with removable partial dentures. Various forms of the device are used to connect a lower partial denture with another lower partial denture, to connect an upper partial denture with another upper partial denture, to connect either an upper or lower partial denture to a tooth or a crown, or to connect a fixed bridge to a partial denture.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39834 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 872

[Docket No. 78N-2852]

Medical Devices; Classification of Preformed Bars

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed bars into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed bars:

1. Identification: A preformed bar is a prefabricated device made of metal, such as heavy wire, wrought metal, or cast metal, that is incorporated into a dental appliance, such as a denture, to connect the part of the dental appliance.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that preformed bars be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, preformed bars in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that preformed bars to be classified into class II (performance standards). The properties of the materials used to form preformed bars depend upon the proper composition of these materials. Moreover, preformed bars directly contact oral tissue. Altering the composition of the materials used in the device, or contamination of the materials with other substances, may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device beause general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that preformed bars should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation indentifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3175, to read as follows:

§ 872.3175 Preformed bar.

(a) *Identificaiton.* A preformed bar is a prefabricated device made of metal, such as heavy wire, wrought metal, or cast metal, incoporated into a dental appliance such as a denture, to connect the parts of a removable denture.

(c) *Classificaiton.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39835 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 872

[Docket No. 78-2853]

Medical Devices; Classification of Resin Tooth Bonding Agents

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying resin tooth bonding agents into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of resin tooth bonding agents:

1. Identification: A resin tooth bonding agent is a device, such as methyl methacrylate, that is painted on the interior of a prepared cavity of a tooth to improve retention of a restoration, such as a filling.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that resin tooth bonding agents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, resin tooth-bonding agents in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that resin tooth bonding agents be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

FDA disagrees with the Panel recommendation that manufacturers of resin tooth bonding agents be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820,198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel recommendation that manufacturers of resin tooth bonding agents be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of resin tooth bonding agents having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3200, to read as follows:

§ 872.3200 Resin tooth-bonding agent.

(a) *Identification.* A resin tooth bonding agent is a device, such as methyl methacrylate, that is painted on the interior of a prepared cavity of a tooth to improve retention of a restoration, such as a filling.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981, submit to the Hearing

Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39836 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78–2854]

Medical Devices; Classification of Facebows

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying facebows into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classifed into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of facebows:

1. Identification: A facebow is a device used in denture fabrication to determine the spatial relationship between the upper and lower jaws. This determination is used to place denture casts accurately into an articulator (a device that holds a set of plaster dental casts and reproduces jaw movements) and, thereby, to aid the correct placement of artificial teeth into the denture base.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that facebows be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel Members' personal knowledge of, and clinical experience with, facebows in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that facebows be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel recommendation that manufacturers of facebows be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510(a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer fom section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of facebows, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of facebows be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that included records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel recommendation that manufacturers of facebows be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation other than §§ 820.180 and 820.198, is

unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of facebows must be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of facebows must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 7012(a) 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3220, to read as follows:

§ 872.3220 Facebow.

(a) *Identification.* A facebow is a device used in denture fabrication to determine the spatial relationship between the upper and lower jaws. This determination is used to place denture casts accurately into an articulator (a device that holds a set of plaster dental casts and reproduces jaw movements) and, thereby, to aid the correct placement of artificial teeth into the denture base.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39837 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2855]

Medical Devices; Classification of Dental Burs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental burs into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFA–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification following recommendation regarding the classification of dental burs:

1. Identification: A dental bur is a rotary cutting device made from carbon steel or tungsten carbide used to cut hard mouth, such as teeth or bone. It is also used to cut hard metals, plastics, porcelains, and similar materials that are used in the fabrication of dental devices.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for dental burs be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that dental burs be classified into class II because materials used in the device should meet mechanical and structural performance standards to prevent breakage and possible tissue damage to patients. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Tissue damage: Breakage of the bur due to inadequate mechanical or structural properties may cause severe tissue damage to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental burs be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA

published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3240, to read as follows:

§ 872.3240 Dental bur.

(a) *Identification.* A dental bur is a rotary cutting device made from carbon steel or tungsten carbide that is used to cut hard structures in the mouth, such as teeth or bone. It is also used to cut hard metals, plastics, porcelains, and similar materials that are used in the fabrication of dental devices.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39838 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2856]

Medical Devices; Classification of Calcium Hydroxide Cavity Liners

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying calcium hydroxide cavity liners into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305, Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of calcium hydroxide cavity liners: 1. Identification: A calcium hydroxide cavity liner is a device material that is applied to the interior of a prepared cavity and provides protection for the pulp of the tooth. The device is applied to the area to be restored prior to the insertion of restorative material, such as amalgam.

2. Recommended classification: Class I (general controls). The panel recommends that calcium hydroxide cavity liners be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that calcium hydroxide cavity liners be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Dental Panel believes that manufacturers should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, calcium hydroxide cavity liners in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that calcium hydroxide cavity liners be classified into class II (performance standards). Calcium hydroxide cavity liners are constructed of a material with certain properties, properties that depend upon the correction composition and purity of the material. Moreover, calcium hydroxide cavity liners directly contact oral tissue. Altering the composition of the material used in the device or contamination of the material with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that calcium hydroxide cavity liners should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26,

1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3250, to read as follows.

§ 872.3250 Calcium hydroxide cavity liner.

(a) *Identification.* A calcium hydroxide cavity liner is a device material that is applied to the interior of a prepared cavity and provides protection for the pulp of the tooth. The device is applied to the area to be restored prior to the insertion of restorative material, such as amalgam.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 80–39839 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2857]

Medical Devices; Classification of Cavity Varnishes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cavity varnishes into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering publich comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cavity varnishes:

1. Identification: A cavity varnish is a device that consists of a compound used to coat a prepared cavity of a tooth prior to insertion of restorative materials. The varnish prevents penetration of the restorative materials, such as amalgam, into the dentinal tissue.

2. Recommended classification: Class I (general controls). The Panel recommends that cavity varnishes be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that cavity varnishes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, cavity varnishes in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that cavity varnishes be classified into class II (performance standards). Cavity varnishes are composed of materials with certain properties, properties that depend upon the correct composition and purity of these materials. Moreover, cavity varnishes directly contact oral tissues. Altering the composition of the materials used in the device, or contamination of the materials with other substances, may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that cavity varnishes should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names

may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3260, to read as follows:

§ 872.3260 Cavity varnish.

(a) *Identification.* A cavity varnish is a device that consists of a compound used to coat the prepared cavity of a tooth prior to insertion of restorative materials. The varnish prevents penetration of the restorative materials, such as amalgam, into the dentinal tissue.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39840 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2858]

Medical Devices; Classification of Dental Cement

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental cement into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classifed into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of dental cement:

1. Identification: Dental cement is a device used to affix dental filling materials and dental devices, such as crowns and bridges, to provide a restorative base for the protection of tooth pulp, and to serve as a temporary filling material for caries. The device is composed of materials such as zinc oxide-eugenol.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that dental cement be classified into class II because materials used in the device should meet a generally accepted and satisfactory level of tissue compatibility. Improper phosphoric acid content in the device may irritate or destroy dental pulp. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard. The Panel also recommends that the phosphoric acid content and the need for appropriate pulp protection be stated in the labeling.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members personal knowledge of, and clinical experience with, the device, and on two articles in the dental literature which suggest that dental cement containing polycarboxylate may irritate dental pulp (Refs. *1* and *2*).

5. Risks to health: (a) Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction. (b) Irritation or destruction of dental pulp: Dental pulp may be irritated or destroyed by improper amounts of phosphoric acid in the device.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental cement be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305) (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Plant, C. G., "The Effect of Polycarboxylate Containing Stannous Fluoride on the Pulp," *British Dental Journal*, 135:317, 1973.

2. Spangberg, L., H. Rodriguez, and K. Langeland, "Biologic Effect of Dental Materials," *Oral Surgery*, January, 1974, p. 113.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the

Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3275, to read as follows:

§ 872.3275 Dental cement.

(a) *Identification.* Dental cement is a device used to affix dental filling materials and dental devices, such as crowns and bridges, to provide a restorative base for the protection of tooth pulp, and to serve as a temporary filling material for caries. The device is composed of materials such as zinc oxide-eugenol.

(b) *Classification.* Class II (performance standards).

Interested persons, may on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39841 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2859]

Medical Devices; Classification of Preformed Clasps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed clasps into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed clasps:

1. Identification: A preformed clasp is a prefabricated device made of cast metal, such as chrome-cobalt, that is incorporated into a dental appliance, such as a partial denture, to help stabilize the appliance in the patient's mouth by fastening the clamp to an adjacent tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that preformed clasps be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, preformed clasps in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that preformed clasps be classified into class II (performance standards). The properties of the materials used to form preformed clasps depend upon the proper composition of these materials. Moreover, preformed clasps directly contact oral tissue. Altering the composition of the materials used in the device, or contamination of materials with other substances, may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard § is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that preformed clasps should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a) 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority

delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3285, to read as follows:

§ 872.3285 Preformed clasp.

(a) *Identification.* A preformed clasp is a prefabricated device made of cast metal, such as chrome-cobalt, that is incorporated into a dental appliance, such as a partial denture, to help stabilize the appliance in the patient's mouth by fastening the appliance to an adjacent tooth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39842 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2860]

Medical Devices; Classification of Preformed Wire Clasps

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed wire clasps into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed wire clasps:

1. Identification: A preformed wire clasp is a device made of bendable stainless steel wire that is incorporated into a dental appliance, such as an orthodontic retainer, and is used to anchor the applicance to a tooth.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for preformed wire clasps be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that preformed wire clasps be classified into class II because the materials used in the device that contact the body should meet a generally accepted level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Adverse tissue reaction: If the materials used in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that preformed wire clasps be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3295, to read as follows.

§ 872.3295 Preformed wire clasp.

(a) *Identification.* A preformed wire clasp is a device made of bendable stainless steel wire that is incorporated into a dental appliance, such as an orthodontic retainer, and is used to anchor the appliance to a tooth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 80–39843 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 872

[Docket No. 78N-2861]

Medical Devices; Classification of Hydrophilic Resin Coatings for Dentures

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hydrophilic resin coatings for dentures into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFA-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hydrophilic resin coatings for dentures:

1. Identification: A hydrophilic resin coating for dentures is a device used to improve denture retention and comfort. The device consists of a water-retaining polymer cream that is applied to the base of a denture before the denture is inserted into the patient's mouth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that hydrophilic resin coatings for dentures be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommend.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, hydrophilic resin coatings for dentures in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that hydrophilic resin coatings for dentures be classified into class II (performance standards). The properties of the materials used to form hydrophilic resin coatings for dentures depend upon the proper composition of these materials. Moreover, the device directly contacts oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that hydrophilic resin coatings for dentures should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3300, to read as follows:

§ 872.3300 Hydrophilic resin coating for dentures.

(a) *Identification.* A hydrophilic resin coating for dentures is a device used to improve denture retention and comfort. The device consists of a water-retaining polymer cream that is applied to the base of a denture before the denture is inserted into the patient's mouth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39844 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 872

[Docket No. 78N-2862]

Medical Devices; Classification of Coating Materials for Resin Fillings

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying coating materials for resin fillings into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of coating materials for resin fillings:

1. Identification: A coating material for resin fillings is a device that is applied to the surface of a restorative resin dental filling in order to attain a smooth glaze-like finish on the surface of the filling.

2. Recommended classification: Class I (general controls). The Panel recommends that coating materials for resin fillings be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that coating materials for resin fillings be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, coating materials for resin fillings in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that coating materials for resin fillings be classified into class II (performance standards). The properties of the materials used to form coating materials for resin fillings depend upon the proper composition of these materials. Moreover, the device directly contacts oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that coating materials for resin fillings should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3310, to read as follows:

§ 872.3310 Coating material for resin fillings.

(a) *Identification.* A coating material for resin fillings is a device that is applied to the surface of a restorative resin dental filing in order to attain a smooth glaze-like finish on the surface of the filling.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 10, 1980.

Willam F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39845 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 872

[Docket No. 78N-2863]

Medical Devices; Classification of Preformed Crowns

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed crowns into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 310-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed crowns:

1. Identification: A preformed crown is a prefabricated device made of plastic or metal that is affixed temporarily to a tooth after removal of, or breakage of, the natural crown (that portion of the tooth that normally protrudes above the gums). It is used as a functional restoration until a permanent crown is constructed. The device also is used as a functional restoration for a badly decayed deciduous (baby) tooth until the adult tooth erupts.

2. Recommended classification: Class I (general controls). The Panel recommends that preformed crowns be exempt from premarketed notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that preformed crowns be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be requried to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, preformed crowns in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that performed crowns be classified into class II (performance standards). The properties of the materials used to form preformed crowns depend upon the proper composition of these materials. Moreover, preformed crowns directly contact oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that preformed crowns should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from premarket notification procedures under section 510(k), records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsehwere in this issue in **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3330, to read as follows:

§ 872.3330 Preformed crown.

(a) *Identification.* A preformed crown is a prefabricated device made of plastic or metal that is affixed temporarily to a tooth after removal of, or breakage of, the natural crown (that portion of the tooth that normally protrudes above the gums). It is used as a functional restoration until a permanent crown is constructed. The device also is used to as a functional restoration for a badly decayed deciduous (baby) tooth until the adult tooth erupts.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39846 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 872

[Docket No. 78N-2864]

Medical devices; Classification of Gold and Stainless Steel Cusps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gold and stainless steel cusps into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendations regarding the classification of gold and stainless steel cusps:

1. Identification: A gold and stainless steel cusp is a prefabricated device made of gold and stainless steel that provides a permanent cusp (a projection on the chewing surface of a prosthetic tooth of a denture) and is used to ac occlusal harmony (a proper bite) between the teeth and a removable denture.

2. Recommended classification: Class I (general controls). The Panel recommends that gold and stainless steel cusps be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that gold and stainless steel cusps be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, gold and stainless steel cusps in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that gold and stainless steel cusps be classified into class II (performance standards). The properties of the materials used to form gold and stainless steel cusps depend upon the proper composition of these materials. Moreover, gold and stainless steel cusps directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that gold and stainless steel cusps should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(K), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3350, to read as follows:

§ 872.3350 Gold and stainless steel cusp.

(a) *Identification.* A gold and stainless steel cusp is a prefabricated device made of gold and stainless steel that provides a permanent cusp (a project on the chewing surface of a prosthetic tooth of a denture) and is used to achieve occlusal harmony (a proper bite) between the teeth and a removable denture.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading

of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39847 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 872

[Docket No. 78N-2865]

Medical Devices; Classification of Preformed Cusps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed cusps into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed cusps:

1. Identification: A preformed cusp is a prefabricated device made of plastic that is used as a temporary cusp (a projection on the chewing surface of a tooth) to achieve occlusal harmony (a proper bite) prior to permanent restoration of the tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notificaiton procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that preformed cusps be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no unreasonable risks to health. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, preformed cusps in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that preformed cusps be classified into class II (performance standards). The properties of the materials used to form preformed cusps are dependent upon the proper composition of these materials. Moreover, the device directly contacts oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a preformance standard for this device.

Because the agency has determined that performed cusps should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3360, to read as follows:

§ 872.3360 Preformed cusp.

(a) *Identification.* A preformed cusp is a prefabricated device made of plastic that is used as a temporary cusp (a projection on the chewing surface of a tooth) to achieve occlusal harmony (a proper bite) prior to permanent restoration of the tooth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing

Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39848 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2866]

Medical Devices; Classification of Acacia and Karaya With Sodium Borate Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying acacia and karaya with sodium borate denture adhesives into class III (premarket approval). FDA is also publishing § the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA Proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classfication of acacia and karaya with sodium borate denture adhesives:

1. Identification: A acacia and karaya with sodium borate denture adhesive is a device composed of acacia, karaya, and sodium borate that is applied to the base of denture before the denture is inserted into the patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that acacia and karaya with sodium borate be classified into class III because the device presents a potential unreasonable risk of illness or injury. Long-term exposure to the borate in the device may cause chronic toxicity in denture wearers. The The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel also believes that sufficient data do not exist to establish an adequate performance standard to assure the safety and effectiveness of the device. Premarket approval is necessary for this device to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry and on a report of the Bureau of Drugs OTC Panel on Dentifrices and Dental Care Agents (Ref. 1). This report states that there is a lack of information concerning the safety of adhesives containing sodium borate and a lack of information concerning the effectiveness of acacia in denture adhesives. The report states that the sodium borate concentration of 12 to 20 percent of the adhesive's total weight is equivalent to 2.6 to 5.3 percent boron. Because at least a portion of a denture adhesive is ingested, this amount of boron could cause chronic toxicity in denture wearers (Ref. 2). The Panel agrees that there is a lack of data concerning the safety and effectiveness of acacia and karaya with sodium borate.

5. Risks to health: (A) Chronic toxicity: The boron in this device may cause chronic toxicity to users. (b) Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that acacia and karaya with sodium borate be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness or injury because the boron in the device may cause toxicity, and because there is a lack of information available to determine the safety and effectiveness of acacia and karaya with sodium borate as a denture adhesive. A review of the literature confirmed that little is known about the possible effects of sodium borate in denture adhesives and no effectiveness data are available for acacia. In addition, the device is purported or represented to be for a use (affixing dentures to the gums) that is of substantial importance in preventing impairment of human health. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device, and that insufficient information exists to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Summary Report on Denture Aids and Plaque Disclosants Transferred to the Bureau of Medical Devices," by the OTC Panel on Dentifrices and Dental Care Agents, March 11–12, 1978.

2. Blacow, N. W. (ed.), "Martindale: The Extra Pharmacopeia," The Pharmaceutical Press, London, 1972, pp. 1084–1085.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory

committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3400, to read as follows:

§ 872.3400 Acacia and karaya with sodium borate denture adhesive.

(a) *Identification.* An acacia and karaya with sodium borate denture adhesive is a device composed of acacia, karaya, and sodium borate that is applied to the base of a denture before the denture is inserted into the patients mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39849 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2867]

Medical Devices; Classification of Carboxymethylcellulose Sodium (40 to 100 Percent) Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carboxymethylcellulose sodium (40 to 100 percent) denture adhesives into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carboxymethylcellulose sodium (40 to 100 percent) denture adhesives:

1. Identification: A carboxymethylcellulose sodium (40 to 100 percent) denture adhesive is a device containing 40 to 100 percent of carboxymethylcellulose sodium—that is applied to the base of a denture before the denture is inserted in the patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class I (general controls). The Panel recommends that carboxymethylcellulose sodium (40 to 100 percent) denture adhesives be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that carboxymethylcellulose sodium (40 to 100 percent) denture adhesives be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The device materials that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Sumamry of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, carboxymethylcellulose sodium denture adhesives in the practice of dentistry.

5. Risks to health: Patient discomfort and poor dental health: If the adhesive fails to anchor the denture in its proper position, the patient may experience discomfort and poor dental health.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that carboxymethylcellulose sodium (40 to 100 percent) denture adhesives be classified into class II (performance standards). The properties of the materials used to form carboxymethylcellulose sodium denture adhesives depend upon the proper composition of these materials. Moreover, carboxymethylcellulose sodium denture adhesives directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. FDA believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that carboxymethylcellulose sodium (40 to 100 percent) denture adhesive should be classified into class II rather than

class I, the agency is not required to publish a regulation adopting or rejecing the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3410, to read as follows:

§ 872.3410 Carboxymethylcellulose sodium (40 to 100 percent) denture adhesives.

(a) *Identification.* A carboxymethylcellulose sodium (40 to 100 percent) denture adhesive is a device containing 40 to 100 percent of carboxymethylcellulose sodium that is applied to the base of a denture before the denture is inserted in the patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39850 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N–2868]

Medical Devices; Classification of Carboxymethylcellulose Sodium and Cationic Polyacrylamide Polymer Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesives into class III (premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device to be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesives:

1. Identification: A carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive is a device composed of carboxymethylcellulose sodium and cationic polyacrylamide polymer that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesives be classified into class III. If the device fails to anchor the denture adequately in its proper position, a change in the distance between the upper and lower jaws occurs which may lead to gum irritation and bone loss due to alteration of biting pressures. Therefore, the device presents a potential unreasonable risk of illness or injury. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel also believes that insufficient data exist to establish adequate performance standards to assure the safety and effectiveness of this device, and therefore, premarket approval is necessary for this device.

4. Summary of data on which the recommendation was based: The Panel based its recommendation on the lack of information available to demonstrate the effectiveness of carboxymethylcellulose sodium and cationic polyacrylamide in dental adhesives and on a report of the Bureau of Drugs OTC Panel on Dentifrices and Dental Care Agents. According to the report, the belief that carboxymethylcellulose sodium is safe is based, in part, on its widespread use in food products such as milk and ice cream (Ref. 2). Tests of cationic polyacrylamide acute oral toxicity, eye irritation, dermal and inhalation toxicity, and subacute and chronic feeding experiments in animals have been negative. (Ref. 1). Human patch tests also have been negative (Ref. 2). However, no data were submitted to the Panel to demonstrate, and the literature did not establish, the effectiveness of carboxymethylcellulose sodium and cationic polyacrylamide polymer as a denture adhesive.

5. Risks to health: Bone loss from lack of effectiveness: If the adhesive fails to anchor the denture in its proper position,

a change in the distance between the upper and lower jaws may occur which may lead to gum irritation and bone loss due to alteration of biting forces.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesives be classified into class III (premarket approval). The agency believes the device presents a potential unreasonable risk of illness or injury because failure of the device to anchor the denture in place may cause a change in the distance between the upper and lower jaw, causing gum irritation and bone loss. Additionally, there is a lack of information necessary to determine the effective of this device as a denture adhesive. In addition, the device is purported or represented to be for a use (affixing dentures to the gums) that is of substantial importance in preventing impairment of human health. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the effectiveness of the device, and that insufficent information exists to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Summary Report on Denture Aids and Plaque Disclosants Transferred to the Bureau of Medical Devices," by the OTC Panel on Dentifrices and Dental Care Agents, 1978.

2. "GRAS (Generally Recognized as Safe) Food Ingredients—Cellulose and Derivatives," Prepared for the Food and Drug Administration by Informatics, Inc., National Technical Information Service, U.S. Dept. of Commerce, PB 221228, 1972, OTC Volume 080090.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsehwere in this issue in **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3420, to read as follows:

§ 872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive.

(a) *Identification.* A carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive is a device composed of carboxymethylcellulose sodium and cationic polyacrylamide polymer that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39851 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2869]

Medical Devices; Classification of Carboxymethylcellulose Sodium (32 percent) and Ethylene Oxide Homopolymer (13 Percent) Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesives into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administraton, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesives:

1. Identification: a Carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesive is a device composed of carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class I (general controls). The Panel recommends that this denture adhesive device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) dental adhesives be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials use in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesives in the practice of dentistry.

5. Risks to health: Patient discomfort and poor dental health: If the adhesive fails to anchor the denture in its proper position, the patient may experience discomfort and poor dental health.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing the carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesives be classified into class II (performance standards). The properties of the materials used to form carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesive depend upon the correct composition of these materials. Moreover, this denture adhesive directly contacts oral tissues. Altering the composition of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesives should be be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3430, to read as follows:

§ 872.3430 Carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesive.

(a) *Identification.* A carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) denture adhesive is a device composed of carboxymethylcellulose sodium (32 percent) and ethylene oxide homopolymer (13 percent) that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39852 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2870]

Medical Devices; Classification of Carboxymethylcellulose Sodium (49 Percent) and Ethylene Oxide Homopolymer (21 Percent) Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesives into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesives:

1. Identification: A carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesive is a device composed of carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) that is applied to the base of a denture before the denture is inserted in the patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class I (general controls). The Panel recommends that this denture adhesivs device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesives be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesives in the practice of dentistry.

5. Risks to health: Patient discomfort and poor dental health: If the adhesive fails to anchor the denture in its proper position, the patient may experience discomfort and poor dental health.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesives be classified into class II (performance standards). The properties of the materials used to form carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesives depend upon the proper composition of these materials. Moreover, carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesives directly contact oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesives should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3440, to read as follows:

§ 872.3440 Carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesive.

(a) *Identification.* A carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) denture adhesive is a device composed of carboxymethylcellulose sodium (49 percent) and ethylene oxide homopolymer (21 percent) that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class II (performance standards).

Interested persons, may on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39853 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2871]

Medical Devices; Classification of Karaya Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying karaya denture adhesives

into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of karaya denture adhesives:

1. Identification: A karaya denture adhesive is a device composed of karaya (a gum from the bark of a tree of the genus *astragolus*) that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class I (general controls). The Panel recommends that this karaya denture adhesive device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that karaya denture adhesives be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, karaya denture adhesives in the practice of dentistry.

5. Risks to health: Patient discomfort and poor dental health: If the adhesive fails to anchor the denture in its proper position, the patient may experience discomfort and poor dental health.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that karaya denture adhesives be classified into class II (performance standards). The properties of the materials used to form karaya denture adhesives depend upon the correct composition of these materials. Moreover, karaya denture adhesives directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that karaya denture adhesives should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3450, to read as follows:

§ 872.3450 Karaya denture adhesive.

(a) *Identification.* A karaya denture adhesive is a device composed of karaya (a gum from the bark of a tree of the genus *astragolus*) that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to the submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39854 Filed 12–29–80; 8:45 am]

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21 CFR Part 872

[Docket No. 78N–2872]

Medical Devices; Classification of Karaya and Ethylene Oxide Homopolymer Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying karaya and ethylene oxide homopolymer denture adhesives into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of karaya and ethylene oxide homopolymer denture adhesives:

1. Identification: A karaya and ethylene oxide homopolymer denture adhesives is a device composed of karaya (a gum from the bark of a tree of the genus *astragalus*) and ethylene oxide homopolymer that is applied to the base of a denture before the denture is inserted in the patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class I (general controls). The Panel recommends that karaya and ethylene oxide homopolymer denture adhesives be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that karaya and ethylene oxide homopolymer denture adhesives be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, karaya and ethylene oxide homopolymer denture adhesives in the practice of dentistry.

5. Risks to health: Patient discomfort and poor dental health: If the adhesive fails to anchor the denture in its proper position, the patient may experience discomfort and poor dental health.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that karaya and ethylene oxide homopolymer denture adhesives be classified into class II (performance standards). The properties of the materials used to form karaya and ethylene oxide homopolymer denture adhesives depend upon the correct composition of these materials. Moreover, karaya and ethylene oxide homopolymer denture adhesives directly contact oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that karaya and ethylene oxide homopolymer denture adhesives should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3460, to read as follows:

§ 872.3460 Karaya and ethylene oxide homopolymer denture adhesive.

(a) *Identification.* A karaya and ethylene oxide homopolymer denture adhesive is a device composed of karaya (a gum from the bark of a tree of the genus *astragalus*) and ethylene oxide homopolymer that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments

may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39855 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M §

21 CFR Part 872

[Docket No. 78N-2873]

Medical Devices; Classification of Karaya With Sodium Borate Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying karaya with sodium borate denture adhesives into class III (premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFA-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of karaya with sodium borate denture adhesives:

1. Identification: A karaya with sodium borate denture adhesive is a device composed of karaya (a gum from the bark of a tree of the genus *astragalus*) and sodium borate that is applied to the base of a denture before the denture is inserted in the patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that karaya with sodium borate denture adhesives be classified into class III because the device presents a potential unreasonable risk of illness or injury. Long-term exposure to borate may cause chronic toxicity in denture wearers. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel also believes that sufficient data do not exist to establish an adequate performance standard to assure the safety and effectiveness of this device because satisfactory performance has never been demonstrated. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device, and thus, assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry and on a report of the Bureau of Drugs OTC Panel on Dentifrices and Dental Care Agents (Ref. *1*). This report states that sodium borate concentration of 12 to 20 percent of the adhesive's total weight is equivalent to 2.6 to 5.3 percent boron (Ref. *2*). Because at least a portion of a denture adhesive is ingested, this amount of boron could cause chronic toxicity in denture wearers.

5. Risks to health: (a) Toxicity: The boron in this device may cause chronic toxicity to users. (b) Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that karaya with sodium borate denture adhesives be classified into class III (premarket approval). The agency believes the device presents a potential unreasonable risk of illness or injury because the boron in the device may cause toxicity, and because there is a lack of information available to determine the safety and effectiveness of karaya with sodium borate as a denture adhesive. A review of the literature confirmed that little is known about the possible effects of sodium borate in denture adhesives. In addition, the device is purported or represented to be for a use (affixing dentures to the gums) that is of substantial importance in preventing impairment of human health. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device, and that insufficient information exists to establish a peformance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Summary Report on Denture Aids and Plaque Disclosants Transferred to the Bureau of Medical Devices," by the OTC Panel on Dentrifices and Dental Care Agents.

2. Blacow, N.W. (ed.), "Martindale: The Extra Pharmacopeia," The Pharmaceutical Press, London, 1972, p. 1084-1085.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, § 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3470, to read as follows:

§ 872.3470 Karaya with sodium borate denture adhesive.

(a) *Identification.* A karaya with sodium borate denture adhesive is a device composed of karaya (a gum from the bark of a tree of the genus *astralagus*) and sodium borate that is

applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner, Regulatory Affairs.

[FR Doc. 80-39856 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2874]

Medical Devices; Classification of Polyacrylamide Polymer (Modified Cationic Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying polyacrylamide polymer (modified cationic) denture adhesives into class III (premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device to be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of polyacrylamide polymer (modified cationic) denture adhesives:

1. Identification: A polyacrylamide polymer (modified cationic) denture adhesive is a device composed of polyacrylamide polymer (modified cationic) that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that polyacrylamide polymer (modified cationic) be classified into class III because the device presents a potential unreasonable risk of illness or injury. If the device fails to anchor a denture in its proper position, a change in the distance the upper and lower jaws may occur which may lead to irritation of the gums and bone loss due to alteration of biting forces. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel also believes that sufficient data do not exist to establish an adequate performance standard to assure the safety and effectiveness of this device because satisfactory performance has never been demonstrated. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus, assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device, and on a report of the Bureau of Drugs' OTC Panel on Dentifrices and Dental Care agents. Tests of polyacrylamide polymer (modified cationic) for acute oral toxicity, eye irritation, and dermal and inhalation toxicity in subacute and chronic feeding experiments in animals have been negative (Ref. *1*). Human patch tests also have been negative (Ref. *2*). However, no data were submitted to the Panel to demonstrate, and the literature did not establish, the effectiveness of polyacrylamide polymer as the sole ingredient of a denture adhesive.

5. Risks to health: (a) Bone loss: If the adhesive fails to anchor the denture in its proper position, and the distance between the upper and lower jaw is changed, then bone loss and gum irritation may occur.

(b) Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that polyacrylamide polymer (modified cationic) denture adhesives be classified into class III (premarket approval). The agency believes the device presents a potential unreasonable risk of illness or injury because failure of the device to anchor the denture in place may result in bone loss, and because there is a lack of information to determine the effectiveness of polyacrylamide polymer as the sole ingredient of a denture adhesive. In addition, the device is purported or represented to be for a use (affixing dentures to the gums) that is of substantial importance in preventing impairment of human health. The agency believes that insufficient information exists to determine that general controls provide reasonable assurance of the safety and effectiveness of the device, and that in sufficient information exists to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Summary Report on Denture Aids and Plaque Disclosants Transferred to the Bureau of Medical Devices" by the OTC Panel on Dentifrices and Dental Care Agents, 1978.

2. "GRAS (Generally Recognized as Safe) Food Ingredients—Cellulose and Derivatives," Prepared for the Food and Drug Administration by Informatics, Inc., National Technical Information Service, U.S. Dept. of Commerce, PB 221228, 1972 OTC Vol. 080090.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA

published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3480, to read as follows:

§ 872.3480 Polyacrylamide polymer (modified cationic) denture adhesive.

(a) *Identification.* A polyacrylamide polymer (modified cationic) denture adhesive is a device composed of polyacrylamide polymer (modified cationic) to be applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 80–39857 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2875]

Medical Devices; Classification of Polyvinylmethylether Maleic Acid Calcium-Sodium Double Salt Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of polyvinylmethylether maleic acid calcium-sodium double salt denture adhesives:

1. Identification: A polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive is a device composed of polyvinylmethylether maleic acid calcium-sodium double salt that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

2. Recommendated classification: Class I (general controls). The Panel recommends that this adhesive be exempt from premarket notification precedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that polyvinylmethylether maleic acid calcium-sodium double salt denture adhesives be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, polyvinylmethylether maleic acid calcium-sodium double salt denture adhesives in the practice of dentistry.

5. Risks to health: Patient discomfort and poor dental health: If the adhesive fails to anchor the denture in its proper position, the patient may experience discomfort and poor dental health.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that polyvinylmethylether maleic acid calcium-sodium double salt denture adhesives be classified into class II (performance standards). The properties of the materials used to form polyvinylmethylether maleic acid calcium-sodium double salt denture adhesives depend upon the proper composition of these materials. Moreover, polyvinylmethylether maleic acid calcium-sodium double salt denture adhesives directly contact oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the

device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3490, to read as follows:

§ 872.3490 Polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive.

(a) *Identification.* A polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive is a device composed of polyvinylmethylether maleic acid calcium-sodium double salt that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39858 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2876]

Medical Devices; Classification of Polyvinylmethylether Maleic Anhydride (PVM–MA), Acid Copolymer and Carboxymethylcellulose Sodium (NACMC) Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesives into class III (premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesives:

1. Identification: A polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive is a device composed of polyvinylmethylether maleic anhydride, acid copolymer, and carboxymethylcellulose sodium that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer and carboxymethylcellulose sodium (NACMC) be classified into class III because the device presents a potential unreasonable risk of illness or injury. The materials used in the device are toxic if ingested; the possible acidity of the device may also cause tissue burns. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel also believes that sufficient data do not exist to establish an adequate performance standard to assure the safety and effectivness of this device. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus, assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a report of the Bureau of Drugs' OTC Panel on Dentifrices and Dental Care Agents. The report states that sufficient data are not available to demonstrate the safety and effectiveness of a combination of PVM–MA and NACMC used as a denture adhesive. (Ref. *1*). The Panel also based its recommendation on a publication by Blacow (Ref. *2*) which states that the pH and stability of the anhydride and diacid forms may be hazardous due to the possible presence

of an acid pH of 2 to 3, which can burn the tissues in the mouth.

5. Risks to health: (a) Toxicity: Ingestion of the materials in this device may cause chronic toxicity to users. (b) Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction. Acidity of the adhesive may burn tissues in the mouth.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesives be classified into class III (premarket approval). The agency believes the device presents a potential unreasonable risk of illness or injury because the materials in the device may cause chronic toxicity or oral tissue burns, and because there is a lack of information to determine the safety and effectiveness of the PVM–MA and NACMC combination as a denture adhesive. The literature confirms that little is known about possible effects of long-term use of this material. In addition, the device is purported or represented for a use (affixing dentures to the gums) that is of substantial importance in preventing impairment of human health. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Summary Report on Denture Aids and Plaque Disclosants Transferred to the Bureau of Medical Devices," by the OTC Panel on Dentifrices and Dental Care Agents, 1978.

2. Blacow, N. W. (ed.), "The Extra Pharmacopeia," The Pharmaceutical Press, London, pp. 1084–1085, 1972.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3500, to read as follows:

§ 872.3500 Polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive.

(a) *Identification.* polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive is a device composed of polyvinylmethylether maleic anhydride, acid copolymer, and carboxymethylcellulose sodium that is applied to the base of a denture before the denture is inserted in a patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class III (premarket approval).

Interested persons, may on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39859 Filed 12–29–80; 8:45 am]

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21 CFR Part 872

[Docket No. 78N–2877]

Medical Devices; Classification of Polyvinylmethylether Maleic Acid Calcium-Sodium Double Salt and Carboxymethylcellulose Sodium Denture Adhesives

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesives into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesives

1. Identification: A polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesives is a device composed of polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium that is applied to the base of a denture before the denture is inserted into a patient's mouth. The device is used to improve denture retention and comfort.

2. Recommended classification: Class I (general controls). The Panel recommends that this adhesive be

exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesives be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because it is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesives in the practice of dentistry.

5. Risks to health: Patient discomfort and poor dental health: If the adhesive fails to anchor the denture in its proper position, the patient may experience discomfort and poor dental health.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesives be classified into class II (performance standards). The properties of the materials used to form polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesives depend upon the proper composition of these materials. Polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose denture adhesives also directly contact oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesives should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3510, to read as follows:

§ 872.3510 Polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesive.

(a) *Identification.* A polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium denture adhesive is a device composed of polyvinylmethylether maleic acid calcium-sodium double salt and carboxymethylcellulose sodium that is applied to the base of a denture before the denture is inserted into a patient's mouth. The device is used to improve denture retention and comfort.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39860 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2878]

Medical Devices; Classification of OTC Denture Cleansers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying OTC denture cleansers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of OTC denture cleansers:

1. Identification: An OTC denture cleanser is a device that consists of material in the form of a powder, tablet, or paste, that is used to remove debris from removable prosthetic dental appliances, such as bridges or dentures. The dental appliance is removed from the patient's mouth when the appliance is cleaned.

2. Recommended classification: Class I (general controls). The Panel recommends that OTC denture cleansers be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that OTC denture cleansers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, denture cleansers in the practice of dentistry.

5. Risks to health: Oral tissue damage: Denture cleanser residue remaining on dentures may burn oral tissues.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that OTC denture cleansers be classified into class II (performance standards). Residues of the cleansers that may remain on the dentures have the potential for burning oral tissues. Porous dental plaque frequently accumulates on dentures, preventing the complete removal, by rinsing, of denture cleansers from denture surfaces. Performance standards for denture cleansers would control the cleanser formulations to assure that expected low levels of cleanser residues would not harm users. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risk to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that OTC denture cleansers should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and a list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3520, to read as follows:

§ 872.3520 OTC denture cleanser.

(a) *Identification.* An OTC denture cleanser is a device that consists of material in the form of a powder, tablet, or paste that is used to remove debris from removable prosthetic dental appliances, such as bridges or dentures. The dental appliance is removed from the patient's mouth when the applicance is cleaned.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39861 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2879]

Medical Devices; Classification of Mechanical Denture Cleaners

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mechanical denture cleaners into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305),

Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mechanical denture cleaners:

1. Identification: A mechanical denture cleaner is an AC-powered denture cleaning device that mechanically agitates the denture cleansing solution.

2. Recommended classification: Class I (general controls). The Panel recommends that mechanical denture cleaners be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that mechanical denture cleaners be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purposes recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, mechanical denture cleaners in the practice of dentistry.

5. Risks to health: Pacemaker interference: Operation of mechanical denture cleaners may cause interference with the proper function of a heart pacemaker.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that mechanical denture cleaners be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. This AC-powered device may interfere with the proper function of a heart pacemaker. In addition, leakage current or a malfunction of the device could result in an electrical shock. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that mechanical denture cleaners should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3530, to read as follows:

§ 872.3530 Mechanical denture cleaner.

(a) *Identification.* A mechanical denture cleaner is an AC-powered denture cleaning device that mechanically agitates the denture cleansing solution.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39862 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2880]

Medical Devices; Classification of Over-the-Counter (OTC) Denture Cushions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying over-the-counter (OTC) denture cushions into class III (premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of over-the-counter (OTC) denture cushions.

1. Identification: An over-the-counter (OTC) denture cushion is a prefabricated or noncustom made device consisting of a material, such as wax or cotton fibers, that is intended to be applied to the entire base or inner surface of a denture before the denture is inserted in a patient's mouth. The device is used to improve temporarily the fit of a loose or uncomfortable denture and can be purchased over-the-counter.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that over-the-counter (OTC) denture cushions be classified into class III because the device presents a potential unreasonable risk of illness or injury. Use of the device may cause an improper vertical dimension of a denture which may result in increased occlusal (biting) forces and lead to bone loss through resorption (degeneration of the bone through gradual dissolution). The Panel also believes that long-term irritation of oral tissue caused by incorrect vertical dimension could cause the formation of carcinomas. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel also believes that sufficient data do not exist to establish an adequate performance standard to assure the safety and effectiveness of this device because satisfactory performance has never been demonstrated. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device. The Panel also based its recommendation on statements by representatives of the Bureau of Drugs that further studies are necessary to determine the safety and effectiveness of this device (Ref. *1*).

5. Risks to health: (a) Bone degeneration: Use of the device may cause alteration in the vertical dimension of a denture, resulting in bone degeneration in the upper and lower jaw. (b) Carcinomas: Long-term irritation of oral tissues caused by incorrect vertical dimension may cause formation of carcinomas.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that over-the-counter (OTC) denture cushions be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonble risk of illness or injury because the device may cause a change in the vertical dimension of the denture resulting in bone loss. In addition long term irritation of oral tissue caused by incorrect vertical dimension may cause the formation of carcinomas. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Summary Report on Denture Aids and Plaque Disclosants Transferred to the Bureau of Medical Devices," by the OTC Panel on Dentifrices and Dental Care Agents, May 22, 1978.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3540, to read as follows:

§ 872.3540 Over-the-counter (OTC) denture cushion.

(a) *Identification.* An over-the-counter (OTC) denture cushion is a prefabricated or noncustom made device consisting of a material, such as wax or cotton fibers, that is intended to be applied to the entire base or inner surface of a denture before the denture is inserted in the patient's mouth. The device is used to improve temporarily the fit of a loose or uncomfortable denture and can be purchased over-the-counter.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39863 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N–2881]

Medical Devices; Classification of Over-the-Counter (OTC) Denture Pads

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying over-the-counter (OTC) denture pads into class III (premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of over-the-counter (OTC) denture pads:

1. Identification: An over-the-counter (OTC) denture pad is a prefabricated or noncustom-made device consisting of a material, such as wax or cotton fibers, that is intended to be applied to a portion of the base or inner surface of a denture before the denture is inserted in a patient's mouth. The device is used to soothe temporarily sore areas of the gums caused by an improperly fitting denture and can be purchased over-the-counter.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that over-the-counter (OTC) denture pads be classified into class III because the device presents a potential unreasonable risk of illness or injury. Use of the device may cause an improper vertical dimension of the denture which may result in increased occlusal (biting) forces and lead to bone loss through resorption (degeneration of the bone through gradual dissolution). The Panel also believes that long-term irritation of oral tissue caused by incorrect vertical dimension could cause formation of carcinomas. The Panel believes that general controls would not provide sufficient control over this characteristic. The Panel believes that sufficient data do not exist to establish an adequate performance standard to assure the safety and effectiveness of this device because satisfactory performance has never been demonstrated. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The Panel also based its recommendation on statements by representatives of the Bureau of Drugs that further studies are necessary to determine the safety and effectiveness of this device (Ref. 1).

5. Risks to Health: (a) Bone degeneration: Use of the device may cause alteration in the vertical dimension of a denture and result in bone degeneration in the upper and lower jaw. (b) Carcinomas: Long-term irritation of oral tissues caused by incorrect vertical dimension may cause formation of carcinomas.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that over-the-counter (OTC) denture pads be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness or injury because the device may cause a change in the vertical dimension of the jaw, resulting in bone loss. In addition, long-term irritation of oral tissue caused by incorrect vertical dimension may cause the formation of carcinomas. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Summary Report on Denture Aids and Plaque Disclosants Transferred to the Bureau of Medical Devices," by the OTC Panel on Dentifrices and Dental Care Agents, 1978.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3550, to read as follows:

§ 872.3550 Over-the-counter (OTC) denture pad.

(a) *Identification.* An over-the-counter (OTC) denture pad is a prefabricated or noncustom-made device consisting of a material, such as wax or cotton fibers, that is intended to be applied to a portion of the base or inner surface of a denture before the denture is inserted in a patient's mouth. The device is used to soothe temporarily sore areas of the gums caused by an improperly fitting denture and can be purchased over-the-counter.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39864 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2882]

Medical Devices; Classification of Over-the-Counter (OTC) Denture Reliners

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying over-the-counter (OTC)

denture reliners into class III (premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacuter of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of over-the-counter (OTC) denture reliners:

1. Identification: An over-the-counter (OTC) denture reliner is a device consisting of a material, such as plastic resin, that is intended to be applied as a permanent coating or lining on the base or tissue-contacting surface of a denture. The device is used to replace a worn denture lining and can be purchased over-the-counter.

2. Recommended classification: Class III (premarket approval). The Panel recommends that the premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that over-the-counter (OTC) denture reliners be classified into class III because the device presents a potential unreasonable risk of illness or injury. Use of the device may cause an improper vertical dimension of the denture which may result in increased occlusal (biting) forces and lead to bone loss through resorption (degeneration of the bone through gradual dissolution). The Panel also believes that long-term irritation of oral tissue caused by incorrect vertical dimension could cause formation of carcinomas. The Panel believes that general controls would not pvovide sufficient control over this characteristic.The Panel believes that sufficient data do not exist to establish an adequate performance standard to assure the safety and effectiveness of this device because satisfactory performance has never been demonstrated. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry. The Panel also based its recommendation on statements by representatives of the Bureau of Drugs that further studies are necessary to determine the safety and effectiveness of this device (Ref. *1*).

5. Risks to health: (a) Bone degeneration: Use of the device may cause an alteration in the vertical dimension of the denture and result in bone degeneration in the upper and lower jaw. (b) Carcinomas: Longterm irritation of oral tissues caused by incorrect vertical dimension may cause formation of carcinomas.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that over-the-counter (OTC) denture reliners be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness or injury because the device may cause a change in the vertical dimension of the jaw, resulting in bone loss. In addition, long-term irritation of oral tissues caused by incorrect vertical dimension may cause formation of carcinomas. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Summary Report on Denture Aids and Plaque Disclosants Transferred to the Bureau of Medical Devices," by the OTC Panel on Dentifrices and Dental Care Agents, 1978.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3560, to read as follows:

§ 872.3560 Over-the-counter (OTC) denture reliner.

(a) *Identification.* An over-the-counter (OTC) denture reliner is a device consisting of a material such as plastic resin, that is intended to be applied as a permanent coating or lining on the base or tissue-contacting surface of a denture. The device is used to replace a worn denture lining and can be purchased over-the-counter.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39865 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 872

[Docket No. 78N-2883]

Medical Devices; Classification of Over-the-Counter (OTC) Denture Repair Kits

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying over-the-counter (OTC) denture repair kits into class III (premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Aministration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of over-the-counter (OTC) denture repair kits:

1. Identification: An over-the-counter (OTC) denture repair kit is a device consisting of material, such as a resin monomer system of powder and liquid glues, that is intended to be applied permanently to a denture to mend cracks or breaks. The device can be purchased over-the-counter.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that over-the-counter (OTC) denture repair kits be classified into class III because the device presents a potential unreasonable risk of illness or injury. If the repaired denture does not have the same characteristics and fit as the original denture, the repaired denture may cause a change in the vertical dimension of the denture which may result in increased occlusal (biting) forces and lead to bone loss through resorption (degeneration of the bone through gradual dissolution). The Panel also believes that long-term irritation of oral tissue caused by incorrect vertical dimension could cause formation of carcinomas. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that sufficient data do not exist to establish an adequate performance standard to assure the safety and effectiveness of this device because satisfactory performance has never been demonstrated. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with the inherent properties of this device and on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry. The Panel also based its recommendation on statements by representatives of the Bureau of Drugs that further studies are necessary to determine the safety and effectiveness of this device (Ref. *1*).

5. Risks to health: Bone degeneration: If the repaired denture does not have the same characteristics and fit as the original denture, the repaired denture may cause alteration of the vertical dimension of the patient's jaw and lead to bone degeneration in the jaws. (b) Carcinomas: Long term irritation of oral tissue caused by incorrect vertical dimension may cause formation of carcinomas.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that over-the-counter (OTC) denture repair kits be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness or injury because the device may cause a change in the vertical dimension of the jaw, resulting in bone loss. In addition, long term irritation of oral tissue caused by incorrect vertical dimension may cause the formation of carcinomas. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Summary Report on Denture Aids and Plaque Disclosants Transferred to the Bureau of Medical Devices," by the OTC Panel on Dentifrices and Dental Care Agents, 1978.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3570, to read as follows:

§ 872.3570 Over-the-counter (OTC) denture repair kit.

(a) *Identification.* An over-the-counter (OTC) denture repair kit is a device consisting of a material, such as a resin monomer system of powder and liquid glues, that is intended to be applied permenently to a denture to mend cracks or breaks. The device can be purchased over-the-counter.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers

Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 39866 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2884]

Medical Devices; Classification of Preformed Gold Denture Teeth

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed gold denture teeth into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of preformed gold denture teeth:

1. Identification: A preformed gold denture tooth is a device composed principally of gold metal and containing other metals, that is used as a tooth or a portion of a tooth in a fixed or removable partial denture.

2. Recommended classification: Class I (general controls). The Panel recommends that preformed gold denture teeth be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that prefabricated gold denture teeth be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, preformed gold denture teeth in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that preformed gold denture teeth be classified into class II (performance standards). The properties of the materials used to form preformed gold denture teeth depend upon the correct composition of these materials. Moreover, preformed gold denture teeth directly contact oral tissues. Altering the composition of the materials used in the device or contaminaton of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that preformed gold denture teeth should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3580, to read as follows:

§ 872.3580 Preformed gold denture tooth.

(a) *Identification.* A preformed gold denture tooth is a device composed principally of gold metal and containing other metals, that is used as a tooth or a portion of a tooth in a fixed or removable partial denture.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written

comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39867 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2885]

Medical Devices; Classification of Preformed Plastic Denture Teeth

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed plastic denture teeth into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed plastic denture teeth:

1. Identification: A preformed plastic denture tooth is a prefabricated device composed of materials, such as methyl methacrylate, that is used as a tooth in a denture.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that plastic denture teeth be classified into class II because the materials used in the device that contact the body should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that preformed plastic denture teeth be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 abd 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3590, to read as follows:

§ 872.3590 Preformed plastic denture teeth.

(a) *Identification.* A preformed plastic denture tooth is a prefabricated device composed of materials, such as methyl methacrylate, that is used as a tooth in a denture.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39868 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2886]

Medical Devices; Classification of Partially Fabricated Denture Kits

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying partially fabricated denture kits into class III (premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future

regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of partially fabricated denture kits:

1. Identification: A partially fabricated denture kit is a device, composed of connected preformed teeth, that is used in the construction of dentures. A denture base is constructed, using the patient's mouth as the mold, by partially polymerizing the resin denture base materials while the materials are in contact with the oral tissues. After the denture base is constructed, the connected preformed teeth are inserted into the base.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that partially fabricated denture kits be classified into class III because the device presents a potential unreasonable risk of illness or injury. Failure of the device to reproduce accurately the physiological dimensions of the mouth may cause dysfunction of the jaw.

In addition, the necessity of partial polymerization of the materials used in the device while these materials are in contact with oral tissue may cause unnecessary tissue irritation and damage. The Panel believes that use of this device involves a questionable technique that omits a number of generally accepted steps in the fabrication of denture prostheses. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel also believes that sufficient data does not exist to establish an adequate performance standard to assure the safety and effectiveness of this device because satisfactory performance has never been demonstrated. Therefore, premarket approval is necessary for this device. The Panel further recommends that use of this device be reserved for emergency situations until a conventional denture can be made.

4. Summary of data on which the recommendation is based: The Panel based its recommendation of the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry. The Panel members believe that the absence of a generally accepted denture construction procedure using this device produces a denture that is not as safe and effective as a prosthesis constructed in a conventional manner.

5. Risks to health: (a) Jaw joint dysfunction: Jaw joint dysfunction may result from inaccurate reproduction of the physiologic dimensions of the mouth. (b) Adverse tissue reaction: Irritation of oral tissues may result from the polymerization of the lining materials while in contact with the tissues of the mouth.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that partially fabricated denture kits be classified into class III (premarket approval). The agency believes that premarket approval is necessary for this device because the device presents a potential unreasonable risk of illness or injury. Failure of the device to reproduce accurately the physiologic dimensions of the mouth may cause jaw joint dysfunction. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of this device, and that insufficient information exists to establish a performance standard to provide this assurance.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3600 to read as follows:

§ 872.3600 Partially fabricated denture kit.

(a) *Identification.* A partially fabricated denture kit is a device, composed of connected preformed teeth, that is used in the construction of dentures. A denture base is constructed using the patient's mouth as the mold, by partially polymerizing the resin denture base materials while the materials are in contact with the oral tissues. After the denture base is constructed, the connected preformed teeth are inserted into the base.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39869 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2887]

Medical Devices; Classification of Endosseous Implants

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endosseous implants into class III (premarket approval). FDA is

also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–437–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of endosseous implants:

1. Identification: An endosseous implant is a device of a material, such as titanium, that is surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that endosseous implants be classified into class III because the device is implanted into the human body and because the device presents a potential unreasonable risk of illness or injury. Use of this device involves a risk of abnormal spontaneous pain due to nerve impingement by the implant and a risk of perforation of the lingual and labial bony plates of the upper or lower jaws. The Panel also believes that sufficient data do not exist to establish an adequate performance standard to provide reasonable assurance of the safety and effectiveness of the device. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

(4) Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, endosseous implants in the practice of dentistry and on a presentation by the Oral Implant Subcommittee (Ref. *1*). The Subcommittee presented information regarding adverse conditions and injuries caused by the device, and stated that there is an absence of criteria for determining a successful implant. The Panel believes that further research will be required to obtain this information.

5. Risks to health: (a) Tissue degeneration: Localized tissue degeneration may be caused by endosseous implants due to excessive mobility. (b) Pain: Nerve impingement by the device may cause pain. (c) Bone perforation: Improper design of the device may cause excess mobility of the implant following surgical placement and subsequent perforation of the bony plates of the upper or lower jaws. (d) Infection: Micro-organisms may be harbored between the implant and the gums and cause localized infection.

Proposed Classification

FDA has sought additional information and data concerning the use of endosseous implants in dentistry. According to some of the literature, these implants may be engulfed by a fibrous tissue layer when they are not exposed to the oral cavity and show only low-grade chronic inflammation, if any (Ref. *2*). However, Natiella, et al. (Ref. *3*) assert that there are not adequate data to determine the indications for use of the implants and the response of oral tissues to these devices. Furthermore, the agency is aware, through informal discussions of the Panel, that opinions of investigators differ as to epithelial proliferation, inflammatory infiltration, and response of subperiosteal tissues.

FDA agrees with the Panel recommendation and is proposing that Endosseous Implants be classified into class III (premarket approval). FDA believes that the device presents a potential risk of illness or injury to the patient if there are not adequate data to assure the safe and effective use of the device. In addition, the device is purported or represented to be for a use (support of prosthetic dental devices) that is of substantial importance in preventing impairment of human health. Furthermore, the device is an implant, which the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(d)) requires to be classified into class III unless the agency determines that premarket approval is not necessary to provide reasonable assurance of a device's safety and effectiveness. In this case, the agency has determined that premarket approval is necessary for the device because general controls and performance standards are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Minutes to the Oral Implant Subcommittee, FDA, Bureau of Medical Devices, July 19, 1976.

2. Langeland, K., and L. Spangberg, "Methodology and Criteria in Evaluation of Dental Endosseous Implants," *Journal of Dental Research*, 54:B158–B165, June 1975.

3. Natiella, J. R., et al., "Current Evalution of Dental Implants," *Journal of the American Dental Association*, 84:1358, June 1972.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3640, to read as follows:

§ 872.3640 Endosseous implant.

(a) *Identification.* An endosseous implant is a device made of a material, such as titanium, that is surgically placed in the bone of the upper or lower

jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39670 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2888]

Medical Devices; Classification of Titanium Subperiosteal Implant Materials

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying titanium subperiosteal implant materials into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8657 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of titanium subperiosteal implant materials:

1. Identification: Titanium subperiosteal implant material is a device composed of titanium that is used to construct custom prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device provides support for prostheses, such as dentures.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that titanium subperiosteal implant materials be classified into class II. Although this device is implanted into the human body, the Panel believes that premarket approval is not necessary to assure its safety and effectiveness because it has been used successfully for years as a subperiosteal implant material and sufficient data exist to establish performance standards.

Materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommandation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry, on the past use of this device in the fabrication of subperiosteal implants, and on the studies of laboratory animals which demonstrate the device's biocompatibility (Ref. *1*).

5. Risks to health: (a) Bone loss: Bone loss may result from impingement by the device on the bony ridge of the jaws. (b) Localized tissue degeneration and infection: Localized tissue degeneration may result from exposure of the tissues to micro-organisms entering the body at the site of the implant, causing infection. (c) Pain: Nerve impingement by the device, as a result of chewing force, may cause pain.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that titanium subperiosteal implant materials be classified into class II (performance standards). FDA has reviewed the literature regarding the use of titanium materials in the fabrication of subperiosteal implants and the research conducted with these materials. Research on the biocompatibility of materials used in the construction of implanted devices has established the properties necessary for acceptable implant materials. Muratori (Ref. *2*) specifies that tissue compatibility, hardness, and resistance to fatigue (mechanical failure due to stress over time) are the most important considerations. These findings are supported by Bodine (Ref. *3*) who evaluated the success rate of subperiosteal implants. Bodine concludes that a major cause of subperiosteal implant failure is inflammation due to deterioration of the implant material, a deterioration caused by impurities in that material. FDA believes that a performance standard for titanium materials used in subperiosteal implants can be established to detail the properties necessary for a safe and effective implant. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficent information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Harris, R., "Implantation of Chrome Cobalt Alloy Forms in the Rabbit's Mandible," *Australian Dental Journal*, 14:396, 1969.

2. Muratori, Giordano, "Multi-Type Oral Implantology," The Marino Cantellic Publishing Co., 64:156, June 1973.

3. Bodine, R., "Implant Dentures," *Journal of Prosthetic Dentistry*, 32(2):188–197, August 1974.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3645, to read as follows:

§ 872.3645 Titanium subperiosteal implant material.

(a) *Identification.* Titanium subperiosteal implant material is a device composed of titanium that is used to construct custom prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device provides support for prostheses, such as dentures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39871 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 872

[Docket No. 78N–2869]

Medical Devices, Classification of Cobalt Chrome Molybdenum Subperiosteal Implant Materials

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cobalt chrome molybdenum subperiosteal implant material into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cobalt chrome molybdenum subperiosteal implant material:

1. Identification: Cobalt chrome molybdenum subperiosteal implant material is a device composed of cobalt chrome molybdenum that is used to construct custom prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device provides support for prostheses, such as dentures.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cobalt chrome molybdenum subperiosteal implant materials be classified into class II. Although this device is implanted into the human body, the Panel believes that premarket approval is not necessary to assure its safety and effectiveness because it has been used successfully for years as a subperiosteal implant material and sufficient data exist to establish performance standards. Materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry, on the past use of this device in the fabrication of subperiosteal implants, and on the studies of laboratory animals which demonstrate the device's biocompatibility (Ref. *1*).

5. Risks to health: (a) Bone loss: Bone loss may result from impingement by the device on the bony ridge of the jaws. (b) Localized tissue degeneration and infection: Localized tissue degeneration may result from exposure of tissues to oral microorganisms which may enter the body at the site of the implant causing infection. (c) Pain: Nerve impingement by the device, as a result of chewing force, may cause pain.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cobalt chrome molybdenum subperiosteal implant materials be classified into class II (performance standards).

FDA has reviewed the literature regarding the use of cobalt chrome molybdenum materials in the fabrication of subperiosteal implants and the research conducted with these materials. Research on the biocompatibility of materials used in the construction of implanted devices has established the properties necessary for acceptable implant materials. Muratori (Ref. *2*) specifies that tissue

compatibility, hardness, and resistance to fatigue (mechnical failure due to stress over time) are the most important considerations. These findings are supported by Bodine (Ref. *3*) who evaluated the success rate of subperiosteal implants. Bodine concludes that a major cause of subperiosteal implant failure is inflammation due to deterioration of the implant material, a deterioration caused by impurities in that materials. FDA believes that a performance standard for cobalt chrome molybdenum materials used in subperiosteal implants can be established to detail the properties necessary for a safe and effective implant. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Harris, R., "Implantation of Chrome Cobalt Alloy Forms in the Rabbit's Mandible," *Australian Dental Journal*, 14:396, 1969.

2. Muratori, G., "Multi-Type Oral Implantology," The Marino Cantellic Publishing Co., 64:156, June 1973.

3. Bodine, R., "Implant Dentures," *Journal of Prosthestic Dentistry*, 32(2):188–197, August 1974.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3650, to read as follows:

§ 872.3650 Cobalt chrome molybdenum subperiosteal implant material.

(a) *Identification.* Cobalt chrome molybdenum subperiosteal implant material is a device composed of cobalt chrome molybdenum that is used to construct custom prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device provides support for prostheses, such as dentures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981,submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. to 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39872 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2890]

Medical Devices; Classification of Impression Materials

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying impression materials into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of impression materials:

1. Identification: Impression material is a device composed of materials, such as alginate or polysulfide, that are placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums. The device provides models for study and for production of restorative and prosthetic devices, such as gold inlays and dentures.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that impression materials be classified into class II because the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The quality of the materials must also be controlled to prevent trauma to surrounding tissues or an allergic response in the patient. The Panel believes that general controls alone would not provide sufficient control over the characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry, and on references in the literature that state that impression materials may cause an allergic reaction or trauma to surrounding tissue (Refs. *1* and *2*).

5. Risks to health: (a) Adverse tissue reaction: If the materials of the device are not biocompatible, the patient may have an adverse tissue reaction. (b) Tissure trauma: If the material is not of adequate quality, trauma to the patient's oral tissue may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that impression materials be classified into class II (performance standards). The agency bellieves that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Kaloyannides, T. M. and D. J. Kapari, "Mixtures of Elastomer Impression Materials: II, " *Journal of Dental Research*, 54:493, 1975.

2. Glenwright, H. D., "Bone Regeneration Following Damage by Polysulfide Impression Material," *Journal of Clinical Periodontology*, 2:250–252, 1975.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs, 513, 701(a), 52 Stat. 1055, 90 Stat. 540–564 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.3660, to read as follows:

§ 872.3660 Impression material.

(a) *Identification.* Impression material is a device composed of materials, such as alginate or polysulfide, that are placed on a preformed impression tray and used to reproduce the structure of a patient's teeth and gums. The device provides models for study and for production of restorative and prosthetic devices, such as gold inlays and dentures.

(b) *Classification.* Class II (performance standard).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in bracket in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Date: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39873 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR PART 872

[Docket No. 78N-2891]

Medical Devices; Classification of Resin Impression Tray Material

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying resin impression tray material into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of resin impression tray material:

1. Identification: Resin impression tray material is a device used in a two-step dental mold fabricating process. The device consists of a resin material, such as methyl methacrylate, and is used to form a custom impression tray is not suitable, such as in the fabrication of crowns, bridges, or full dentures. A preliminary plaster or stone model of the patient's teeth and gums is made. The resin impression tray material is applied to this preliminary study model to form a custom tray. This tray is then filled with impression material and inserted into the patient's mouth to make an impression, from which a final, more precise, model of the patient's mouth is cast.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that resin impression tray material be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and

clinical experience with, resin impression tray material in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the panel recommendation and is proposing that resin impression tray material be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

FDA disagrees with the Panel's recommendation that manufacturers of resin impression tray material be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of resin impression tray material be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198)), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of resin impression tray material must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of resin impression tray material must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective from oher sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3670, to read as follows:

§ 870.3670 Resin impression tray material.

(a) *Identification.* Resin impression tray, material is a device used in a two-step dental mold fabricating process. The device consists of a resin material, such as methyl methacrylate, and is used to form a custom impression tray for use in cases in which a preformed impression tray is not suitable, such as in the fabrication of crowns, bridges, or full dentures. A preliminary plaster or stone model of the patient's teeth and gums is made. The resin impression tray material is applied to this preliminary study model to form a custom tray. This tray is then filled with impression material and inserted into the patient's mouth to make an impression, from which a final, more precise, model of the patient's mouth is cast.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in bracket in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39874 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2892]

Medical Devices; Classification of Polytetranluoroethylene (PTFE) Vitreous Carbon Materials

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying polytetraluoroethylene (PTFE) vitreous carbon materials into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of polytetrafluoroethylene (PTFE) vitreous carbon materials:

1. Identification: Polytetrafluoroethylene (PTFE) vitreous carbon material is a device composed of polytetrafluoroethylene (PTFE) vitreous carbon that is used in maxillofacial alveolar ridge augmentation (building up the upper jaw area that contains the sockets in which teeth are rooted) and to coat metal surgical implants in the alveoli (sockets in which the teeth are rooted) and the temporomandibular joints (the joint between the upper and lower jaws).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of the reasons for recommendation: The Panel recommends that polytetrafluoroethylene (PTFE) vitreous carbon materials be classified into class II. Although this device is implanted into the human body, the Panel believes that premarket approval is not necessary to assure its safety and effectiveness. Adverse reactions to this device are minimal and generally, are the result of poor surgical technique rather than material failure. However, Materials used in the device should meet a generally acceptable satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry and on presentation by a developer, a manufacturer, and a user of the material which discussed the use and success of polytetrafluoroethylene polymer material in oral surgery (Ref. *1*)

5. Risks to health: (a) Infection: If the device cannot be sterilized adequately, postsurgical infection may result. (b) Adverse tissue reaction: If the materials of the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that polytetrafluoroethylene vitreous carbon materials be classified into class II (performance standards). Although this device is implanted into the human body, the agency believes that premarket approval is not necessary to assure its safety and effectiveness. The agency believes that a performance standard is necessary for this device because general controls alone are sufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Kent, J. N., C. A. Homsy, and A. Abbott, Presentation, Dental Device Classification Panel, "Proplast Implant Devices," December 5, 1977.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs., 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3680, to read as follows:

§ 872.3680 polytetrafluoroethylene (PTFE) vitreous carbon materials.

(a) *Identification.* polytetrafluoroethylene (PTFE) vitreous carbon material is a device composed of polytetrafluoroethylene (PTFE) vitreous carbon that is used in maxillofacial alveolar ridge augmentation (building up the upper jaw area that contains the sockets in which teeth are rooted) and to coat metal surgicial implants in the alveoli (sockets in which the teeth are rooted) and the temporomandibular joints (the joint between the upper and lower jaws).

(b) *Classification.* Class II (performance standards).

Interested persons may, on on before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39875 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 872]

[Docket No. 78N–2893]

Medical Devices; Classification of Tooth Shade Resin Materials

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tooth shade resin materials into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final

regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of tooth shade resin materials:

1. Identification: Tooth shade resin material is a device composed of materials such as bisphenol-A and glycidyl methacrylate (Bis-GMA) that is used to restore carious lesions or structural defects in teeth.

2. Recommended clasification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that tooth shade resin materials be classified into class II because improper chemical composition of the resin may cause roughening of the restorative surface, which results in discoloration of tooth enamel and plaque accumulation on the tooth. The materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of denistry, and on an article by G. L. Lee, M.D., et a., (ref. *1*). The article states that before a composite resin is used for restoration, the tooth enamel is etched with 50 percent phosphoric acid, which may irritate the tooth pulp.

5. Risks to health: (a) Periodontal disease: Discoloration and roughening of a restoration made with this device may cause plaque accumulation and lead to periodontal disease. (b) Pulp damage: Etching with 50 percent phosphoric acid before the restoration is completed may cause tooth pulp damage, unless the pulp is properly protected.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that tooth shade resin materials be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Lee, G. L., J. A. Orlowshi, G. C. Schidt, and R. L. Ihsen, "Histological Studies of an Adhesive Paint-on Restorative for Cervical Abrasions," *Australian Dental Journal*, 20:304–308, 1975.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3690, to read as follows:

§ 872.3690 Tooth shade resin material.

(a) *Identification.* Tooth shade resin material is a device composed of materials such as bisphenol-A glycidyl methacrylate (Bis-GMA) that is used to restore carious lesions or structural defects in teeth.

(b) *Classification.* Class II (performance standards).

Interested persons May, on or before March 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39876 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2894]

Medical Devices; Classification of Dental Mercury

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental mercury into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305).

Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental mercury:

1. Identification: Dental mercury is a device composed of mercury that is used as a component of amalgam alloy in the restoration of dental cavities or broken teeth.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that dental mercury be classified into class II because the material in the device should meet a generally accepted satisfactory level of tissue compatibility. Dental mercury is a toxic substance and must be handled properly to control the hazards it presents. The Panel believes that general controls alone would not provide sufficient control over this characteristic.

The Panel believes that a performace standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry, and on an article published in the *Journal of the American Dental Association* "An Environmental Study of Mercury Contamination in Dental Offices" (Ref. *1*). The article discusses the hazards associated with use of mercury in dentistry and concludes that there is no danger of systemic poisoning for patients whose teeth have been restored with amalgam containing mercury. However, if proper procedures are not followed, there are potential hazards to those who handle mercury.

5. Risks to health: (a) Mercury poisoning: If the device is not handled properly, the user may suffer mercury poisoning from inhalation of mercury vapors. (b) Adverse tissue reaction: If the material in the device is not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental mercury be classified into class II (performance standards).

FDA has reviewed the medical literature on use of dental mercury in dentistry and has found evidence to support the Panel recommendation. Kawahara et al. concluded that the cytotoxicity of the amalgam is related to free mercury available after mixing the alloy and the mercury, but that cytotoxicity was nearly nonexistent after complete setting of the amalgam (Ref. *2*). Cataldo and Santis studied the results of implantation of amalgam into the oral tissues (Ref. *3*). Encapsulation in connective tissue occurred with the smallest pieces of amalgam without inflammatory response, and larger pieces had connective tissue encapsulation with some macrophage (microorganism) response. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "An Environmental Study of Mercury Contamination in Dental Offices," *Journal of the American Dental Association*, Vol. 89, Nov. 1974.

2. Kawahara, H., et al., "Cellular Responses to Dental Amalgam in-Vitro," *Journal of Dentistry Research*, 54(2):394–401, March–April 1975.

3. Cataldo, E., and H. Santis, "Response of the Oral Tissue to Exogenous Foreign Materials," *Journal of Periodontics*, 45(2):93–106, February 1974.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3700, to read as follows:

§ 872.3700 Dental mercury.

(a) *Identification.* Dental mercury is a device composed of mercury that is used as a component of amalgam alloy in the restoration of dental cavities or broken teeth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39877 Filed 12–29–80; 8:45 am]
BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2895]

Medical Devices; Classification of Base Metal Alloys

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying base metal alloys into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II

is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of base metal alloys:

1. Identification: A base metal alloy is a device composed of a material, such as a mixture of nickel and chromium, that is used in the fabrication of a custom-made dental device, such as porcelain veneer for a tooth.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that base metal alloys be classified into class II because the materials used in the device contact the body and should meet a generally accepted satisfactory level of tissue compatibility. The composition of the materials should also be controlled to prevent toxic reactions to the alloys. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction. (b) Toxic reaction: Alloys containing nickel and beryllium may cause a toxic reaction in the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that base metal alloys be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3710, to read as follows:

§ 872.3710 Base metal alloy.

(a) *Identification.* A base metal alloy is a device composed of a material, such as a mixture of nickel and chromium, that is used in the fabrication of a custom-made dental device, such as porcelain veneer for a tooth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39678 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2897]

Medical Devices; Classification of Pantographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pantographs into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–406), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pantographs:

1. Identification: A pantograph is a device that is attached to a patient's head and is used to duplicate lower jaw movements to aid in the construction of restorative and prosthetic dental devices. A marking pen is attached to the lower jaw component of the device and, as the patient's mouth opens, the pen records on graph paper the angle between the upper and lower jaw.

2. Recommended classification: Class I (performance controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that pantographs be classified into class I because the Panel believes that general controls are suffcient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, pantographs in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pantographs be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of pantographs be exempted from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510(a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of pantographs, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning pantographs. The agency does not at this time anticipate the premarket approval will be required for this device. The agency believes that the semiananual updating of device listing under section 510(j)(2) will provide FDA will adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of pantographs be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experiences with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirments concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of pantographs be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other then §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of pantographs must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems from complaint investigation and followup. The agency also believes that manufacturers of pantographs must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3730, to read as follows:

§ 872.3730 Pantograph.

(a) *Identification.* A pantograph is a device that is attached to a patient's head and is used to duplicate lower jaw

movements to aid in the construction of restorative and prosthetic dental devices. A marking pen is attached to the lower jaw component of the device and, as the patient's mouth opens, the pen records on graph paper the angle between the upper and lower jaw.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39879 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2898]

Medical Devices; Classification of Retentive and Splinting Pins

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying retentive and splinting pins into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of retentive and splinting pins:

1. Identification: A retentive and splinting pin is a device made of a material, such as titanium, that is placed permanently in a tooth to provide retention and stabilization for a restoration, such as a crown, or to join two or more teeth together.

2. Recommended classification: Class I (general controls). The Panel recommends that retentive and splinting pins be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that retentive and splinting pins be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, retentive and splinting pins in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that retentive and splinting pins be classified into class II (performance standards). The properties of the materials used to form retentive and splinting pins depend upon the correct composition of these materials. Moreover, retentive and splinting pins directly contact oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that retentive and splinting pins should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513,

701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3740, to read as follows:

§ 872.3740 Retentive and splinting pin.

(a) *Identification.* A retentive and splinting pin is a device made of a material, such as titanium, that is placed permanently in a tooth to provide retention and stabilization for a restoration, such as a crown, or to join two of more teeth together.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39880 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2899]

Medical Devices; Classification of Bracket Adhesive Resin and Tooth Conditioners

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying bracket adhesive resin and tooth conditioners into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of bracket adhesive resin and tooth conditioners:

1. Identification: A bracket adhesive resin and tooth conditioner is a device composed of an adhesive compound of polymethyl methacrylate that is used to cement an orthodontic bracket to a tooth surface.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that bracket adhesive resin and tooth conditioners be classified into class II because the device contains an acid that may cause decalcification of the tooth and the development of dental caries if it contacts tooth enamel. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry, and on the Guide to Dental Materials (Ref. *1*), which states that little or no tissue reaction has been reported with the use of this device.

5. Risks to health: Decalcification: The conditioner in the resin may cause decalcification of a tooth and the development of dental caries.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that bracket adhesive resin and tooth conditioners be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Guide to Dental Materials and Devices," *American Dental Association*, pp. 143–144, Chicago, Illinois, 1976.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3750, to read as follows:

§ 872.3750 Bracket adhesive resin and tooth conditioner.

(a) *Identification.* A bracket adhesive resin and tooth conditioner is a device composed of an adhesive compound of polymethyl methacrylate that is used to cement an orthodontic bracket to a tooth surface.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug

Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39881 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2900]

Medical Devices; Classification of Denture Relining, Repairing, or Rebasing Resin

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying denture relining, repairing, or rebasing resin bases into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of denture relining, repairing, or rebasing resin bases:

1. Identification: A denture relining, repairing, or rebasing resin is a device composed of materials, such as methyl methacrylate, that is used to reline a denture surface that contacts tissue, to repair a fractured denture, or to form a new denture base. This device is not available for over-the-counter (OTC) use.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that denture relining, repairing, or rebasing resin be classified into class II because the chemical properties of this device may cause oral tissue irritation. Materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Tissue irritation: The materials used in the device may cause oral tissue irritation.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that denture relining, repairing, or rebasing resins be classified into class II (performance standards). FDA believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3760, to read as follows:

§ 872.3760 Denture relining, repairing, or rebasing resin.

(a) *Identification.* A denture relining, repairing, or rebasing resin is a device composed of materials, such as a methyl methacrylate, that is used to reline a denture surface that contacts tissue, to repair a fractured denture, or to form a new denture base. This device is not available for over-the-counter (OTC) use.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39882 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2901]

Medical Devices; Classification of Pit and Fissure Sealants and Conditioners

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pit and fissure sealants and conditioners into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pit and fissure sealants and conditioners:

1. Identification: A pit and fissure sealant and conditioner is a device composed of resin, such as polymethyl methacrylate, that is used primarily in young children to seal pit and fissure depressions (faults in tooth enamel) in the biting surfaces of teeth in order to prevent cavities.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pit and fissure sealants and conditioners be classified into class II because tooth decay may result if the sealant fails to remain in the tooth. Materials used in the device should also meet a generally accepted satisfactory level of tissue compatiblilty. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device in the practice of dentistry, and on review of the literature (Refs. *1, 2,* and *3).* The literature review reveals that pit and fissure sealants and conditioners, if applied to areas without caries, are safe and effective.

5. Risks to health: (a) Tooth decay: Acid etchant (removal of tooth enamel coating to enhance resin bonding) may cause decalcification of tooth enamel and lead to tooth decay.

(b) Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pit and fissure sealants and conditioners be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Pit and Fissure Sealants," Council on Dental Materials and Devices, *Journal of the American Dental Association,* 88:390, 1974.

2. Rock, W. P., A. R. Bailey, and R. M. Brown, "Tissue Reaction to Two Fissure Sealant Reactants," *Journal of Oral Pathology,* 3:224–231, 1974.

3. Handelman, S. L., M. G. Buonocore, P. C. Schoute, "Progress Report on the Effect of a Fissure Sealant on Bacteria in Dental Caries," *Journal of the American Dental Association,* 87:1189–1191, 1973.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3765, to read as follows:

§ 872.3765 Pit and fissure sealant and conditioner.

(a) *Identification.* A base pit and fissure sealant and conditioner is a device composed of resin, such as polymethylmethacrylate, that is used primarily in young children to seal pit and fissures depressions (faults in tooth enamel) in the biting surfaces of teeth in order to prevent cavities.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39883 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2902]

Medical Devices; Classification of Temporary Crown and Bridge Resins

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation

classifying temporary crown and bridge resins into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Devices Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fisher Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA adivisory committee, made the following recommendation regarding the classification of temporary crown and bridge resins:

1. Identification: A temporary and bridge resin is a device composed of a material, such as polmethylmethacrylate, that is used to make a temporary prothesis, such as a crown or bridge. The temporary prothesis is used until a permanent restoration is fabricated.

2. Recommended classification: Class I (general controls). The Panel recommends that temporary crown and bridge resins be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j (f)).

3. Summary of reasons for recommendation: The Panel recommends that temporary crown and bridge resins be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, temporary crown and bridge resins in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that temporary crown and bridge resins be classified into class II (performance standards). The properties of the materials used to form temporary crown and bridge resins depend upon the proper composition of these materials. Moreover, temporary crown and bridge resins directly contact oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is neccessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that temporary crown and bridge resins should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3770, to read as follows:

§ 872.3770 Temporary crown and bridge resin.

(a) *Identification.* A temporary crown and bridge resin is a device composed of a material, such as polymethyl-methacrylate, that is used to make a temporary prothesis, such as a crown or bridge. The temporary prothesis is used until a permanent restoration is fabricated.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39684 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2904]

Medical Devices; Classification of Root Canal Posts

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying root canal posts into class II

(performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of root canal posts:

1. Identification: A root canal post is a metal device that is cemented into the root canal of a tooth to stabilize and support a restoration.

2. Recommended classification: Class I (general controls). The Panel recommends that root canal posts be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that root canal posts be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, root canal posts in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that root canal posts be classified into class II (performance standards). The properties of the materials used to form root canal posts depend upon the correct composition of these materials. Moreover, root canal posts directly contact oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that root canal posts should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 2168) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elswhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3810, to read as follows:

§ 872.3810 Root canal post.

(a) *Identification.* A root canal post is a metal device that is cemented into the root canal of a tooth to stabilize and support a restoration.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39885 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2905]

Medical Devices; Classification of Root Canal Filling Resins

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying root canal filling resins into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of

the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of root canal filling resins:

1. Identification: A root canal filling resin is a device composed of a material, such as methyl methacrylate, that is used during endodontic therapy to fill the root canal of a tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that root canal filling resins be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that root canal filling resins be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents to undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, root canal filling resins in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that root canal filling resins be classified into class II (performance standards). The properties of the materials used to form root canal filling resins depend upon the correct composition of these materials. Moreover, root canal filling resins directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that root canal filling resins should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3820, to read as follows:

§ 872.3820 Root canal filling resin.

(a) *Identification.* A root canal filling resin is a device composed of material, such as methylmethacrylate, that is used during endodontic therapy to fill the root canal of a tooth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39886 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2906]

Medical Devices; Classification of Endodontic Paper Points

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endodontic paper points into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the

device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classfication of endodontic paper points:

1. Identification: A endodontic paper point is a device made of paper that is used during endodontic thereapy to dry, or apply medication to, the root canal of a tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the Act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that endodontic paper points be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, endodontic paper points in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel's recommendation and is proposing that endodontic paper points be classified into class II (performance standards). The properties of the materials used to form endodontic paper points depend upon the proper composition of these materials. Moreover, endodontic paper points directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that endodontic paper points should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3830, to read as follows:

§ 872.3830 Endodontic paper point.

(a) *Identification.* An endodontic paper point is a device made of paper that is used during endontic therapy to dry, or apply medication to, the root canal of a tooth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39887 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2907]

Medical Devices; Classification of Endodontic Silver Points

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endodontic silver points into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device to be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation

based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the porposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of endodontic silver points:

1. Identification: An endodontic silver point is a device made of silver that is used during endodontic therapy to fill permanently the root canal of a tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that endodontic silver points be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, endodontic silver points in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel's recommendation and is proposing that endodontic silver points be classified into class II (performance standards). The properties of the materials used to form endodontic silver points depend upon the proper composition of these materials. Moreover, endodontic silver points directly contact oral tissue. Alterting the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that endodontic silver points should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3840, to read as follows:

§ 872.3840 Endodontic silver point.

(a) *Identification.* An endodontic silver point is a device made of silver that is used during endodontic therapy to fill permanently the root canal of a tooth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39888 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2908]

Medical Devices; Classification of Gutta Percha

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gutta percha into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gutta percha:

1. Identification: Gutta percha is a device made from coagulated sap of certain tropical trees that is used during endodontic therapy to fill the root canal of a tooth. The gutta percha is softened by heat and inserted into the root canal, where it hardens as it cools.

2. Recommended classification: Class I (general controls). The Panel recommends that gutta percha be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that gutta percha be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, gutta percha in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that gutta percha be classified into class II (performance standards). The properties of the materials used to form gutta percha depend upon the correct composition of these materials. Moreover, gutta percha directly contacts oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that gutta percha should be classified into class II rather then class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3850, to read as follows:

§ 872.3850 Gutta percha.

(a) *Identification.* Gutta percha is a device made from coagulated sap of certain tropical trees that is used to fill the root canal of a tooth. The gutta percha is softened by heat and inserted into the root canal, where it hardens as it cools.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39689 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2909]

Medical Devices; Classification of Endodontic Stabilizing Splints

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endodontic stabilizing splints into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of the classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of endodontic stabilizing splints.

1. Identification: An endodontic stabilizing splint is a device made of a material such as titanium that is used to stabilize a tooth by inserting the device through the root canal and into the upper or lower jaw bone.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that endodontic stabilizing splints be classified into class II because improperly constructed devices may cause infection or adverse tissue reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Infection: If the device cannot be properly sterilized, postsurgical infection may occur. (b) Fracture of the root: If faulty materials are used to construct the device, the stabilizing splint could break within the root canal, causing fracture of the tooth's root and possible infection. (c) Adverse tissue reaction: If the materials used in construction of the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that endodontic stabilizing splints be classified into class II (performance standards). The agency believes that endodontic stabilizing splints should be considered implants, because they are designed to be placed within the tissues of the human body and remain for an indefinite period of time. The agency believes that, although the device is an implant, premarket approval is not necessary to assure the safety and effectiveness of the device. Strock and Strock (Ref. *1*) report a method for increasing the stability of anterior teeth, the roots of which were shortened or amputated by disease. After the pulp and granulation tissue have been removed from a tooth, a vitallium or tantalum rod is inserted through the crown and into the root. Regeneration of bone occurs around the end of the rod, increasing the stability of the tooth. Linkow, et al. (Ref. *2*) state that there is substantial radiographic evidence that endodontic implants are well tolerated by tissue and that bone regeneration occurs around the implant. According to Linkow, because endodontic implants are completely imbedded in tissue and do not protrude into the oral cavity, there is no danger of infection or irritation from chemical reactions caused by substances in the mouth. FDA believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Strock, A., and M. Strock, method of Reinforcement for Pulpless Anterior Teeth, *Journal of Oral Surgery*, 1:252–255, 1943.

2. Linkow, L. I., and R. Cherecheve, "Theories and Techniques of Oral Implantology," Chapter 13, pp. 586–593, 1974.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3890, to read as follows:

§ 872.3890 Endodontic stabilizing splint.

(a) *Identification.* An endodontic stabilizing splint is a device made of a material such as titanium that is used to stabilize a tooth by inserting the device through the root canal and into the upper or lower jaw bone.

(b) *Classification.* Class III (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39890 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2910]

Medical Devices; Classification of Posterior Artificial Teeth With Metal Inserts

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying posterior artificial teeth with metal inserts into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the

safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA Proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classfication of posterior artificial teeth with metal inserts:

1. Identification: A posterior artificial tooth with metal insert is a porcelain device with a metal insert that is used to replace a natural tooth. The device is attached to surrounding teeth by a bridge and provides both an improvement in appearance and a functional occlusion (bite) which improves chewing ability.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that posterior artificial teeth with metal inserts be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, posterior artificial teeth with metal inserts in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that posterior artificial teeth with metal inserts be classified into class II (performance standards). The properties of the materials used to form posterior artificial teeth with metal inserts depend upon the correct composition of these materials. Moreover, posterior artificial teeth with metal inserts directly contact oral tissues. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that posterior artificial teeth with metal inserts should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsehwere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3900, to read as follows:

§ 872.3900 Posterior artificial tooth with metal insert.

(a) *Identification.* A posterior artificial tooth with a metal insert is a porcelain device with metal insert that is used to replace a natural tooth. The device is attached to surrounding teeth by a bridge and provides both an improvement in appearance and a functional occlusion (bite) which improves chewing ability.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39891 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2911]

Medical Devices; Classification of Backing and Facing for Artificial Teeth

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying backing and facing for artificial teeth into class II (performance standards). FDA is also publishing the recommendation of the Dental Device

Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA Proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classfication of backing and facing for artificial teeth:

1. Identification: A backing and facing for an artificial tooth is a device used in the fabrication of a fixed or removable dental appliance, such as a crown or bridge. The backing, which is made of gold, is attached to the dental appliance and supports the tooth-colored facing, which is made of porcelain or plastic.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that backing and facing for artificial teeth be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, backing and facing for artificial teeth in the practice of dentistry.

5. Risk to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that backing and facing for artificial teeth be classified into class II (performance standards). The properties of the materials used to form backing and facing for artificial teeth depend upon the proper composition of these materials. Moreover, backing and facing for artificial teeth directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that backing and facing for artificial teeth should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart C by adding new § 872.3910, to read as follows:

§ 872.3910 Backing and facing for artificial teeth.

(a) *Identification.* A backing and facing for an artificial tooth is a device used in the fabrication of a fixed or removable dental appliance, such as a crown or bridge. The backing, which is made of gold, is attached to the dental appliance and supports the tooth-colored facing, which is made of porcelain or plastic.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39892 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2912]

Medical Devices; Classification of Porcelain Teeth

AGENCY: Food and Drug. Administration.

ACTION Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation

classifying porcelain teeth into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of porcelain teeth:

1. Identification: A porcelain tooth is a device made of porcelain powder for clinical use that is used in the construction of both fixed and removable prostheses, such as crowns and partial dentures.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that porcelain teeth be classified into class II because the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. In addition, the fluorescing agents in the porcelain powder for clinical use that is used to make the porcelain teeth may contain radioactive components which decay, resulting in the production of prosthetic devices that emit readiation. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Exposure to radiation: The patient may be exposed to radiation emitted by fluorescent agents in the porcelain by protheses made from porcelain powder for clinical use that contains radioactive ingredients. (b) Adverse tissue reaction: If the materials used in the construction of the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that porcelain teeth be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. Exposure of surrounding tissue to the ionizing radiation emitted by radioactive material that may be present in dental products fabricated from porcelain powder for clinical use may result in acute tissue damage, if the radiation is sufficiently intense, or in neoplastic (abnormal) changes, if radiation is chronically received at lower levels. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3920, to read as follows:

§ 872.3920 Porcelain teeth.

(a) *Identification.* A porcelain tooth is a prefabricated device made of porcelain powder for clinical use that is used in the construction of both fixed and removable prostheses, such as crowns and partial dentures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39893 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2913]

Medical Devices; Classification of Zinc Oxide Eugenol

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying zinc oxide eugenol into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of the classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of zinc oxide eugenol:

1. Identification: Zinc oxide eugenol is a device material that is used as a base cement for temporary fillings and as a cementing agent.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that zinc oxide eugenol be classified into class II because the device may cause irritation to tooth pulp. Materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Adverse tissue reaction: If the materials used in the device are biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that zinc oxide eugenol be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard woule provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.3980, to read as follows:

§ 872.3980 Zince oxide eugenol.

(a) *Identification.* Zinc oxide eugenol is a device material that is used as a base cement for temporary fillings and as a cementing agent.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that indivuduals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 39894 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M §

21 CFR Part 872

[Docket No. 78N–3027]

Medical Devices; Classification of Endodontic Broaches

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endodontic broaches into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA Proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classfication of endodontic broaches:

1. Identification: An endodontic broach is a hand-held device used to remove the pulp from a tooth during endodontic (root canal) procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and the good manufacturing

practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that endodontic broaches be classified into class I because the Panel believes that general controls are sufficient to ensure the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purposes recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, endodontic broaches in the practice of dentistry.

5. Risk to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that endodontic broaches be classified into class II (performance standards). The properties of the materials used to form endodontic broaches depend upon the proper composition of these materials. Moreover, endodontic broaches directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that endodontic broaches should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.4040, to read as follows:

§ 872.4040 Endodontic broach.

(a) *Identification.* An endodontic broach is a hand-held device used to remove the pulp from a tooth during endodontic (root canal) procedures.

(b) *Classification.* Class II (Performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39895 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2914]

Medical Devices; Classification of Dental Wax Carvers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental wax carvers into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA Proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classfication of dental wax carvers:

1. Identification: A dental wax carver is a device used to shape wax into a mold cavity for casting removable and fixed restorative dental appliances. The device is a hand instrument with a smoothing tip at one end and a carving tip at the opposite end.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental wax carvers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The Panel believes that

manufacturers of this device not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because a dental wax carver is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental wax carvers in the practice of dentistry.

5. Risk to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental wax carvers be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendations that manufacturers of dental wax carvers be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510(a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of dental wax carvers, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning dental wax carvers. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of dental wax carvers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements is found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of dental wax carvers be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of dental wax carvers must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of dental wax carvers must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4075, to read as follows:

§ 872.4075 Dental wax carver.

(a) *Identification.* A dental wax carver is a device used to shape wax into a mold cavity for casting removable and fixed restorative dental appliances. The device is a hand instrument with a smoothing tip at one end and a carving tip at the opposite end.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39896 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2915

Medical Devices; Classification of Manual Bone Drill and Wire Drivers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual bone drill and wire drivers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FUR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of manual bone drill and wire drivers:

1. Identification: A manual bone drill and wire driver is a metal rotary device that is used in reconstructive oral surgery to drill a hole into the upper or lower jaw in preparation for insertion of a wire, pin, or screw.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for manual bone drill and wire drivers be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that manual bone drill and wire drivers be classified into class II because improper design of the device may cause bone damage from unnecessary heat buildup. In addition, the materials used in the device that contact the body should meet a generally accepted satisfactory level of tissue compatibility. The panel believes that general controls alone would not provide sufficient control over these characteristics. The panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Infection: If the device cannot be cleaned properly, use of the device could cause an infection. (b) Bone damage: Improper design of the device may cause bone damage from unnecessary heat buildup. (c) Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that manual bone drill and wire drivers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673. This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4120, to read as follows:

§ 872.4120 Manual bone drill and wire driver.

(a) *Identification.* A manual bone drill and wire driver is a metal rotary device that is used in reconstructive oral surgery to drill a hole into the upper or lower jaw in preparation for insertion of a wire, pin, or screw.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39897 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2916]

Medical Devices; Classification of Intraoral Dental Drills

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intraoral dental drills into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to

assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of intraoral dental drills:

1. Identification: An intraoral dental drill is a rotary device that is attached to a dental handpiece and is used to drill holes in teeth in order to secure cast or preformed pins used to retain operative dental appliances.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21, U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that intraoral dental drills be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, intraoral dental drills in the practice of dentistry.

5. Risks to health: Tissue damage: If the device does not have adequate strength and hardness, teeth and underlying tissue may be damaged.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that intraoral dental drills be classified into class II (performance standards). Dental drills are used to cut human tooth structure, and must meet standards of minimum hardness and strength to be able to accomplish this cutting function. The agency also believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a standard for this device.

Because the agency has determined that intraoral dental drills should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4130, to read as follows:

§ 872.4130 Intraoral dental drill.

(a) *Identification.* An intraoral dental drill is a rotary device that is attached to a dental handpiece and is used to drill holes in teeth in order to secure cast or preformed pins used to retain operative dental appliances.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39898 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2917]

Medical Devices; Classification of Powered Bone Drills

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered bone drills into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation

based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered bone drills:

1. Identification: A powered bone drill is an AC-powered rotary device that is used in reconstructive oral surgery to drill a hole into the upper or lower jaw in preparation for insertion of a wire, pin, or screw.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that powered bone drills be classified into class II because improper design of the device may cause bone degeneration from unnecessary heat buildup. The electrical design of the device also must be controlled to ensure electrical safety. Moreover, the materials used in the device that contact the body should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Infection: If the device cannot be cleaned properly, use of the device could cause an infection. (b) Bone damage: Improper design of the device may cause bone damage from unnecessary heat buildup. (c) Adverse tissue reaction: If the materials used in the device are not biocompatible, the patient may have an adverse tissue reaction. (d) Electrical shock: Faulty electrical design or malfunction of the device may cause an electrical shock to the patient or the user.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that powered bone drills be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and efffectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4140, to read as follows:

§ 872.4140 Powered bone drill.

(a) *Identification.* A powered bone drill is an AC-powered rotary device that is used in reconstructive oral surgery to drill a hole into the upper or lower jaw in preparation for insertion of a wire, pin, or screw.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39899 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–3026]

Medical Devices; Classification of Endodontic Pulp Canal Files

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endodontic pulp canal files into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, RM. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel,

an FDA advisory committee, made the following recommendation regarding the classification of endodontic pulp canal files:

1. Identification: An endodontic pulp canal file is a hand-held device with a finely serrated surface that is used to smooth, enlarge, and clean the pulp canal during endodontic (root canal) procedures.

2. Recommended classification: Class I (general controls). The Panel recomments that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because it is a simple device that presents no undue risks to health when used in a normal manner and for the purposes recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that endodontic pulp canal files be classified into class II (performance standards). The properties of the materials used to form endodontic pulp canal files depend upon the correct composition of these materials. Moveover, endodontic pulp canal files directly contact oral tissue. Alteration of the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. FDA believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that endodontic pulp canal files should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 701(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4150, to read as follows:

§ 872.4150 Endodontic pulp canal file.

(a) *Identification.* An endodontic pulp canal file is a hand-held device with a finely serrated surface that is used to smooth, enlarge and clean the pulp canal during endodontic (root canal) procedures.

(b) *Classification.* Class I (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39900 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2918]

Medical Devices; Classification of Air-Powered Dental Handpieces

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying air-powered dental handpieces into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of air-powered dental handpieces:

1. Identification: An air-powered dental handpiece is a device powered by compressed air that is used to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. A burr or cleaning tip is inserted into the handpiece, which is rotated by the pressure of the compressed air.

2. Recommended classification: Class I (general controls). The Panel recommends that air-powered dental handpieces be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that air-powered dental handpieces be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practices regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members; personal knowledge of, and clinical experience with, air-powered dental handpieces in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that air-powered dental handpieces be classified into class II (performance standards). The device must be capable of sterilization to avoid contamination and transmission of infection between patients. A performance standard also is needed to assure that the device stops immediately upon release of the foot control in order to prevent injury to the patient. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that air-powered dental handpieces should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4200, to read as follows:

§ 872.4200 Air-powered dental handpiece.

(a) *Identification.* An air-powered dental handpiece is a device powered by compressed air that is used to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. A bur or cleaning tip is inserted into the handpiece, which is rotated by the pressure of the compressed air.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39901 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2919]

Medical Devices; Classification of Belt-Driven Dental Handpieces

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying belt-driven dental handpieces into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of belt-driven dental handpieces:

1. Identification: A belt-driven dental handpiece is a device that is used to prepare dental cavities for restorations,

such as fillings, and for cleaning teeth. A bur or cleaning tip is inserted into the handpiece, which is rotated by a belt running over a series of pulleys.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that belt-driven dental handpieces be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and efffectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, belt-driven dental handpieces in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that belt-driven dental handpieces be classified into class II (performance standards). The device must be capable of sterilization to avoid contamination and transmission of infection between patients. A performance standard is also needed to control the electrical design of the device in order to prevent electrical shock to the patient or user. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that belt-driven dental handpieces should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4220, to read as follows:

§ 872.4220 Belt-driven dental handpiece.

(a) *Identification.* A belt-driven dental handpiece is a device that is used to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. A bur or cleaning tip is inserted into the handpiece, which is rotated by a belt running over a series of pulleys.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39902 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2920]

Medical Devices; Classification Of Rotary Bone-Cutting Handpieces

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rotary bone-cutting handpieces into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of rotary bone-cutting handpieces:

1. Identification: A rotary bone-cutting handpiece is an AC-powered dental device used to cut and shape bone in the oral cavity.

2. Recommended classification: Class II (performance standards). The Panel

recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that rotary bone-cutting handpieces be classified into class II because the electrical properties of the device need to be controlled in order to prevent electrical shock to the patient or user. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Bone damage: Improper design of the blade could cause bone damage.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rotary bone-cutting handpieces be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4240, to read as follows:

§ 872.4240 Rotary bone-cutting handpiece.

(a) *Identification.* A rotary bone-cutting handpiece is an AC-powered dental device used to cut and shape bone in the oral cavity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39903 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2921]

Medical Devices; Classification of Contra Angle Handpiece Attachments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying contra angle handpiece attachments into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of contra angle handpiece attachments:

1. Identification: A contra angle handpiece attachment is an accessory device that is attached to the end of a dental handpiece. The device is bent at an angle to allow easy access to, and movement within, the mouth. It is used to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that contra angle handpiece attachments be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers ofthis device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel

members' personal knowledge of, and clinical experience with, contra angle handpiece attachments in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that contra angle handpiece attachments be classified into class II (performance standards). The device must be capable of sterilization to avoid contamination and transmission of infection between patients. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that contra angle handpiece attachments should be classified into class II rather than Class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4260, to read as follows:

§ 872.4260 Contra angle handpiece attachment.

(a) *Identification.* A contra angle handpiece attachment is an accessory device that is attached to the end of a dental handpiece. The device is bent at an angle to allow easy access to, and movement within, the mouth. It is used to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39904 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N.2922]

Medical Devices; Classification of Direct Drive Handpieces

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying direct drive handpieces into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of direct drive handpieces:

1. Identification: A direct-drive handpiece is an AC-powered rotary device used to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. The handpiece is powered by a motor without a pulley.

2. Recommended classification: Class I (general controls). The Panel recommends that direct drive handpieces be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that direct drive handpieces be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with permarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, direct drive handpieces in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that direct drive handpieces be classified into class II (performance standards). The device must be capable of sterilization to avoid contamination and transmission of infection between patients. A performance standard is also needed to control the electrical properties of the device in order to prevent electrical shock to the patient or user. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that direct drive handpieces should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4280, to read as follows:

§ 872.4280 Direct drive handpiece.

(a) *Identification.* A direct-drive handpiece is an AC-powered rotary device used to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. The handpiece is powered by a motor without a pulley.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39905 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2923]

Medical Devices; Classification of Foot Controllers for Handpieces

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying foot controllers for handpieces into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Aministration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of foot controllers for handpieces:

1. Identification: A foot controller for handpieces is a device operated by the user's foot that is used to control the speed and direction of rotation of dental handpieces, such as a dental drill.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that foot controllers for handpieces be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because the Panel believes that the quality of the device is easily discernible and defects are readily apparent to the user.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, foot controllers for handpieces in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that foot controllers for handpieces be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of foot controllers for handpieces be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that

these manufacturers be subject to registration, device listing and premarket notification under section 510(a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of foot controllers for handpieces, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections, and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of foot controllers for handpieces be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of foot controllers for handpieces be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of foot controllers for handpieces must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of foot controllers for handpieces must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.4300, to read as follows:

§ 872.4300 Foot controller for handpieces.

(a) *Identification.* A foot controller for handpieces is a device operated by the user's foot that is used to control the speed and direction of rotation of dental handpieces, such as a dental drill.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180 regarding general requirements concerning records, and § 820.198 regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Room 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39906 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2924]

Medical Devices; Classification of Water-Powered Handpieces

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying water-powered handpieces into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by (March 2, 1981. FDA proposes that the final regulation based on this proposal become effective

30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of water-powered handpieces:

1. Identification: A water-powered handpiece is a rotary device used to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. An AC-powered water pump provides water under pressure to the device . hand-piece through coaxial (a tube inside a tube) plastic tubing; the pressurized water powers the device.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that water-powered handpieces be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, water-powered handpieces in the practice of dentistry.

5. Risks to health: None identified.

FDA disagrees with the Panel's recommendation and is proposing that water-powered handpieces be classified into class II (performance standards). The device must be capable of sterilization to avoid contamination and transmission of infection between patients. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that water-powered handpieces should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under secton 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4320, to read as follows:

§ 872.4320 Water-powered handpiece.

(a) *Identification.* A water-powered handpiece is a rotary device used to prepare dental cavities for restorations, such as fillings, and for cleaning teeth. An AC-powered water pump provides water under pressure to the device handpiece through coaxial (a tube inside a tube) plastic tubing; the pressurized water powers the device.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39907 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2925]

Medical Devices; Classification of Gas-Powered Jet Injectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas-powered jet injectors into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug

Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas-powered jet injectors:

1. Identification: A gas-powered jet injector is a syringe device used to administer a local anesthetic. The syringe is powered by a cartridge containing pressurized carbon dioxide which provides the pressure to force the anesthetic out of the syringe.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas-powered jet injectors be classified into class II because the Panel believes that a performance standard is necessary to assure that the device is properly designed so as to allow aspiration. By syringe aspiration, the user determines whether a blood vessel has been penetrated during the injuction procedure. Penetration of a blood vessel during an injection may cause an adverse reaction in the patient. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Adverse reaction: If the aspiration mechanism of the device is not adequate, the user may not be able to determine whether the anesthetic has been injected directly into a blood vessel; injection into a blood vessel may cause the patient to have an adverse reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas-powered jet injectors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4465, to read as follows:

§ 872.4465 Gas-powered jet injector.

(a) *Identification.* A gas-powered jet injector is a syringe device used to administer a local anesthetic. The syringe is powered by a cartridge containing pressurized carbon dioxide which provides the pressure to force the anesthetic out of the syringe.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39808 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 872

[Docket No. 78N–2926]

Medical Devices; Classification of Spring-Powered Jet Injectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying spring-powered jet injectors into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of spring-powered jet injectors:

1. Identification: A spring-powered jet injector is a syringe device used to administer a local anasthetic. The syringe is powered by a srping mechanism which provides the pressure to force the anesthetic out of the syringe.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that spring-powered jet injectors be classified into class II because the Panel believes that a performance standard is necessary to assure that the device is properly designed as to follow aspiration. By syringe aspiration, the user determines whether a blood vessel has been penetrated during the injection procedure. Penetration of a blood vessel during an injection may cause an adverse reaction in the patient. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Adverse reaction: If the aspiration mechanism of the device is not adequate, the user may not be able to determine whether the anesthetic has been injected directly into a blood vessel; injection into a blood vessel may cause the patient to have an adverse reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that spring-powered jet injectors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4475, to read as follows:

§ 872.4475 Spring-powered jet injector.

(a) *Identification.* A spring-powered jet injector is a syringe device used to administer a local anesthetic. The syringe is powered by a spring mechanism which provides the pressure to force the anesthetic out of the syringe.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 39909 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2927]

Medical Devices; Classification of Hand Instruments for Calculus Removal

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hand instruments for calculus removal into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hand instruments for calculus removal:

1. Identification: A hand instrument for calculus removal is a hand-held, metal scraper device used to remove calculus deposits form tooth surfaces.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low a priority.

3. Summary of reasons for recommendation: The Panel recommends that hand instruments for calculus removal be classified into class II because the materials used in the device that contact the body should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Tissue trauma: Improper design of the device may cause unnecessary trauma to gum tissue. (b) Adverse tissue reaction: If the materials used in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hand instruments for calculus removal be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4500, to read as follows:

§ 872.4500 Hand instrument for calculus removal.

(a) *Identification.* A hand instrument for calculus removal is a hand-held metal scraper device used to remove calculus deposits from tooth surfaces.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39910 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2928]

Medical Devices; Classification of Dental Depth Gauge Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental depth gauge instruments into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental depth gauge instruments:

1. Identification: A dental depth gauge instrument is a slender metal device that is used in endodontic (root canal) treatment to prepare for placement of a retentive or splinting pin. The device is used to measure the depth of a small hole in a tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental depth gauge instruments be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental depth gauge instruments in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental depth gauge instruments be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of dental depth gauge instruments be exempt from section 510(k) of the act (21 U.S.C. 360), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510

only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of dental depth gauge instruments, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notifications from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of dental depth gauge instruments be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel's recommendation that manufacturers of dental depth gauge instruments be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of dental depth gauge instruments having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure, FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4520, to read as follows:

§ 872.4520 Dental depth gauge instruments.

(a) *Identification.* A dental depth gauge instrument is a slender metal device that is used in endodontic (root canal) treatment to prepare for placement of a retentive or splinting pin. The device is used to measure the depth of a small hole in a tooth.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39911 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 872]

[Docket No. 78N–2929]

Medical Devices; Classification of Dental Diamond Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental diamond instruments into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of dental diamond instruments:

1. Identification: A dental diamond instrument is an abrasive device used to smooth tooth surfaces during the fitting of crowns or bridges. The device consists of a shaft which is inserted into a handpiece and a head which has diamond chips imbedded into it. Rotation of the diamond instrument provides an abrasive action when it contacts the tooth.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a

performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that dental diamond instruments be classified into class II because if the abrasive properties of the device are inadequate the device may cause damage to the dental pulp. The Panel believes that general contros alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Tissue damage: Inadequate abrasive properties of the device may cause damage to the dental pulp.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental diamond instruments be classified into class II (performance standards). The agency believes that a performance standards is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4535, to read as follows:

§ 872.4535 Dental diamond instrument.

(a) *Identification.* A dental diamond instrument is an abrasive device used to smooth tooth surfaces during the fitting of crowns or bridges. The device consists of a shaft which is inserted into a handpiece and a head which has diamond chips imbedded into it. Rotation of the diamond instrument provides an abrasive action when it contacts the tooth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39912 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2930]

Medical Devices; Classification of Plastic Dental Filling Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying plastic dental filling instruments into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of plastic dental filling instruments:

1. Identification: A plastic dental filling instrument is a device made of plastic that is used to carry filling material to the site of a restoration in the oral cavity.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that plastic dental filling instruments be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The device materials that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, plastic dental filling instruments in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that plastic dental filling instruments be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of plastic dental filling instruments be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510(a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of plastic dental filling instruments, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning plastic dental filling instruments. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of plastic dental filling instruments be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive use of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experiences with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP requirements. The exemption wil not extend to two device GMP requirement, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of plastic dental filling instruments be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of plastic dental filling instruments must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of plastic dental filling instruments must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 361c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4555, to read as follows:

§ 872.4555 Plastic dental filling instrument.

(a) *Identification.* A plastic dental filling instrument is a device made of plastic that is used to carry filling material to the site of a restoration in the oral cavity.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is also exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39913 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2931]

Medical Devices; Classification of Dental Hand Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental hand instruments into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the devices be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental hand instruments:

1. Identification: A dental hand instrument is a hand-held device used to perform various tasks in general dentistry and oral surgery procedures. The following devices are included in this generic type device: operative burnisher, operative amalgam carrier, operative dental amalgam carver, surgical bone chisel, operative emalgam and foil condenser, endodontic curette, operative curette, periodontic curette, surgical curette, dental surgical elevator, operative dental excavator, operative explorer, surgical bone file, operative margin finishing file, periodontic file, periodontic probe, surgical rongeur forceps, surgical tooth extractor forceps, surgical hemostat, periodontic hoe, operative matrix contouring instrument, operative cutting instrument, operative margin-finishing knife, periodontic knife, periodontic marker, operative pliers, endodontic root canal plugger, endodontic root canal preparer, surgical biopsy punch, endodontic pulp canal reamer, crown remover, periodontic scaler, collar and crown scissors, endodontic pulp canal filling material spreader, and surgical osteotome chisel.

2. Recommended classification: Class I (general controls). The Panel recommends that these devices be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental hand instruments be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. These devices have been used in dentistry for many years. The materials used in the devices that contact the body have known and acceptable properties. The Panel believes that manufacturers of these devices should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because they are simple devices that present no undue risks to health when used in a normal manner and for the purposes recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental hand instruments in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental hand instruments be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by these devices.

In response to the Panel's recommendation that manufacturers of dental and hand instruments be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of dental hand instruments, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspection and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of dental hand instruments be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel's recommendation that manufacturers of dental hand instruments be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of dental hand instruments having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart D by adding new § 872.4565, to read as follows:

§ 872.4565 Dental hand instrument.

(a) *Identification.* A dental hand instrument is a hand-held device used to perform various tasks in general dentistry and oral surgery procedures. The following devices are included in this generic type device: operative burnisher, operative amalgam carrier, operative dental amalgam carver, surgical bone chisel, operative amalgam and foil condenser, endodontic curette, operative curette, periodontic curette, surgical curette, dental surgical elevator, operative dental excavator, operator explorer surgical bone file, operative margin finishing file, periodontic file, periodontic probe, surgical rongeur forceps, surgical tooth extractor forceps, surgical hemostat, periodontic hoe, operative matrix contouring instrument, operative cutting instrument, operative marginfinishing periodontic knife, periodontic marker, operative pliers, endodontic root canal plugger, endodontic root canal preparer, surgical biopsy punch, endodontic pulp canal reamer, crown remover, periodontic scaler, collar and crown scissors, endodontic pulp canal filling material spreader, and surgical osteotome chisel.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39914 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2932]

Medical Devices; Classification of Dental Instrument Handles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is isssuing for public comment a proposed regulation classifying dental instrument handles into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental instrument handles:

1. Identification: A dental instrument handle is a device made of metal or plastic that is used as a grip for working tips and mirrors used during dental procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: Panel recommends that dental instrument handles be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental instrument handles in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental instrument handles be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of dental instrument handles be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by

manufacturers of dental instrument handles, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning dental instrument handles. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of dental instrument handles be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of dental hand instrument be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of dental instrument handles must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of dental instrument handles must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act, (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drug proposes to amend Part 872 in Subpart E by adding new § 872.4575, to read as follows:

§ 872.4575 Dental instrument handle.

(a) *Identification.* A dental instrument handle is a device made of metal or plastic that is used as a grip for working tips and mirrors used during dental procedures.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39915 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2933]

Medical Devices; Classification of Intraoral Ligature and Wire Locks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intraoral ligature and wire locks into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–

62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTAL INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of intraoral ligature and wire locks:

1. Identification: An intraoral ligature and wire lock is a metal device used to constrict fractured bone segments in the oral cavity. The bone segments are stabilized by wrapping the ligature (wire) around the fractured bone segments and locking the ends together.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that intraoral ligature and wire locks be classified into class II because if the device is poorly constructed and the lock breaks, the bone fracture may reopen. Also, the materials used in the device that contact the body should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Infection: If the device connot be properly sterilized or is contaminated, an infection may result.

(b) Reopening of the fracture: If the ligature or wire lock breaks as a result of poor construction, the bone fracture may reopen which could lead to infection, requiring additional surgical procedures or administration of antibiotics.

(c) Adverse tissue reaction: If the materials used in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that intraoral ligature and wire locks be classified into class II (performance standards). FDA believes that intraoral ligature and wire locks should be considered implants. This device is designed to be placed within the tissues of the human body for an indefinite period of time. However, the agency believes that premarket approval is not necessary to assure the safety and effectiveness of the device. Intraoral ligature and wire locks are completely imbedded in tissues, and there is no possibility that microorganisms will enter and cause an infection. Moreover, because the device does not protrude into the oral cavity, there is no possibility of irritation caused by chemical reactions from substances in the mouth. The materials used in the construction of the device have been used in dentistry for many years and have demonstrated acceptable biocompatibility characteristics. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also belives that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4600, to read as follows:

§ 872.4600 Intraoral ligature and wire lock.

(a) *Identification.* An intraoral ligature and wire lock is a metal device used to constrict fractured bone segments in the oral cavity. The bone segments are stabilized by wrapping the ligature (wire) around the fractured bone segments and locking the ends together.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the hearding of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Date: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 39916 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2934]

Medical Devices; Classification of Fiber Optic Dental Lights

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fiber optic dental lights into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Greg Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fiber optic dental lights:

1. Identification: A fiber optic dental light is an AC-powered device, usually attached to a dental handpiece, that consists of glass or plastic fibers which have special optical properties. The device is used to illuminate oral structures.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that fiber optic dental lights be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, fiber optic dental lights in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that fiber optic dental lights be classified into class II (performance standards). The device must be capable of sterilization to avoid contamination and transmission of infection between patients. A performance standard is needed to control the electrical design of the device in order to prevent electrical shock to the patient or user. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

Becuase the agency has determined that fiber optic dental lights should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commisisoner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4620, to read as follows:

§ 872.4620 Fiber optic dental light.

(a) *Identification.* A fiber optic dental light is an AC-powered device, usually attached to a dental handpiece, that consists of glass or plastic fibers which have special optical properties. The device is used to illuminate oral structures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39917 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2935]

Medical Devices; Classification of Dental Operating Lights

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental operating lights into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposed become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug

Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental operating lights:

1. Identification: A dental operating light is an AC-powered device used to illuminate oral structures and operating areas.

2. Recommendation classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that dental operating lights be classified into class II because the design and performance of this device must be controlled in order to prevent photosensitization (abnormal reaction of the skin to light) and burns to the facial area of patients and to ensure electrical safety. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry, and on an article by Russell Paravecchio, M.D. (Ref. *1*). This article described a patient who developed facial lesions after exposure to light from a dental operating lamp.

5. Risks to health: (a) Photosensitization: If the device is improperly designed, various wavelengths of ultraviolet light may leak, causing photosensitization.

(b) Burns: If the temperature of the light housing exceeds tolerable levels, contact with the light could burn the patient or user.

(c) Electrical shock: If the electrical design of the device is faulty, the user may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental operating lights be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed on file in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Paravecchio, R. "Photosensitization of a Patient with Discoid Lupus Erythematosus by a Dental Operating Light, Report of Case," *Journal of the American Dental Association*, 94:907–909, 1977.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therfore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4630, to read as follows:

§ 872.4630 Dental operating light.

(a) *Identification:* A dental operating light is an AC-powered device used to illuminate oral structures and operating areas.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that the individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39918 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N–2936]

Medical Devices; Classification of Surgical Headlights

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying surgical headlights into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the

following recommendation regarding the classification of surgical headlights:

1. Identification: A surgical headlight is a device which is attached to the user's head that is used as a supplementary or auxiliary light source to illuminate the patient's oral cavity during surgical procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that surgical headlights be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The Panel believes that manufacturers of this device should not be required to comply with the premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, surgical headlights in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that surgical headlights be classified into class II (performance standards). The electrical design of this device must be controlled in order to prevent electrical shock to the user. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that surgical headlights should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes amend Part 872 in Subpart E by adding new § 872.4640, to read as follows:

§ 872.4640 Surgical headlight.

(a) *Identification.* A surgical headlight is a device which is attached to the user's head that is used as a supplementary or auxiliary light source to illuminate the patient's oral cavity during surgical procedures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39919 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 872

[Docket No. 78N-2937]

Medical Devices; Classification of Dental Injecting Needles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental injecting needles into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental injecting needles:

1. Identification: A dental injecting needle is a slender, hollow metal device with a sharp point that is attached to a syringe and is used to inject local anesthetics and other drugs.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that dental injecting needles be classified into class II because tissue damage may result if the

device is not sufficiently sharp or straight. The needle is used in conjunction with a syringe; the entire apparatus may be hazardous if it is not satisfactorily assembled, maintained, or used. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Tissue trauma: Poorly constructed needles with defective points or the use of inferior materials may cause tissue trauma and require an additional injection. (b) Adverse tissue reaction: If the materials used in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental injecting needles be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4730, to read as follows:

§ 872.4730 Dental injecting needle.

(a) *Identification.* A dental injecting needle is a slender, hollow metal device with a sharp point that is attached to a syringe and is used to inject local anesthetics and other drugs.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39920 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2938]

Medical Devices; Classification of Bone Plates

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administation (FDA) is issuing for public comment a proposed regulation classifying bone plates into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of bone plates:

1. *Identification:* A bone plate is a metal device used to stabilize fractured bone structures in the oral cavity. The bone segments are attached to the plate with screws to prevent movement of the segments.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that bone plates be classified into class II because faulty construction of the device could result in a reopening of the bone fracture. The materials used in the device that contact the body should meet a generally accepted level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to helath: (a) Infection: If the device cannot be properly sterilized or is contaminated, an infection may result. (b) Bone damage: If the device is improperly constructed, bone damage may occur. (c) Adverse tissue reaction: If the materials in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that bone plates be classified into class II

(performance standards). FDA believes that bone plates should be considered implants. This device is designed to be placed within the tissues of the human body for an indefinite period of time. However, the agency also believes that premarket approval is not necessary to assure the safety and effectiveness of the device. Bone plates are completely imbedded in tissues, and there is no possibility of entry of microorganisms causing infection. Moreover, because the device does not protrude into the oral cavity, there is no possibility of irritation for chemical reactions with substances placed in the mouth. The materials used in the construction of bone plates have been used in dentistry for many years and have demonstrated acceptable biocompatibility characteristics. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4760, to read as follows:

§ 872.4760 Bone plate.

(a) *Identification.* A bone plate is a metal device used to stabilize fractured bone structures in the oral cavity. The bone segments are attached to the plate with screws to prevent movement of the segments.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39921 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2941]

Medical Devices; Classification of AC-Powered Bone Saws

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying AC-powered bone saws into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of AC-powered bone saws:

1. Identification: An AC-powered bone saw is a device with a serrated edge that is used during oral surgery for cutting and contouring bone.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that AC-powered bone saws be classified into class II because the electrical design of the device should be controlled to prevent electrical shock to the patient or user. The general design of the device should be controlled to prevent bone and tissue trauma. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Bone and adverse tissue trauma: Improper design of the device may cause trauma to bone and underlying tissue. (b) Electrical shock: Improper electrical design of the device may cause electrical shock to the patient or user.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that AC-powered bone saws be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA

published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4820, to read as follows:

§ 872.4820 AC-powered bone saw.

(a) *Identification.* An AC-powered bone saw is a device with a serrated edge used during oral surgery for cutting and contouring bone.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39922 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2942]

Medical Devices; Classification of Rotary Scalers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rotary scalers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposed become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:.

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rotary scalers:

1. Identification: A rotary scaler is an abrasive devices that is attached to a powered handpiece and is used to remove calculus deposits from teeth during dental cleaning and periodontal (gum) therapy.

2. Recommendation clasification: Class II (performance standards). The Panel recommends that establishing a performance standard for rotary scalers to be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that rotary scalers be classified into class II because the abrasive qualities of the device must be controlled to reduce the surface damage to tooth enamel and dental pulp which may be caused by the scouring action and heat from the device during calculus removal. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is suffiicient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Damage to tooth structures: The scouring action of the device may generate heat. Both the abrasive action and heat may damage the teeth and gums.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rotary scalers be classified into class II (performance standards). FDA believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4840, to read as follows:

§ 872.4840 Rotary scaler.

(a) *Identification.* A rotary scaler is an abrasive device that is attached to a powered handpiece and is used to remove calculus deposits from teeth during dental cleaning and periodontal (gum) therapy.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be

identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39923 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2943]

Medical Devices; Classification of Ultrasonic Scalers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ultrasonic scalers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ultrasonic scalers:

1. Identification: An ultrasonic scaler is a device used during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonically vibrating scaler tip to the teeth.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that ultrasonic scalers be classified into Class II because standards are needed to control the pulsation strength and frequency and to provide proper cooling for the teeth during cleaning to avoid dental pulp damage. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Pulp destruction: Excessive amplitude of vibration or inadequate cooling may cause damage to dental pulp. (b) Pacemaker interference: Electronic interference may have an adverse effect on heart pacemaker function.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ultrasonic scalers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4850, to read as follows:

§ 872.4850 Ultrasonic scaler.

(a) *Identification.* An ultrasonic scaler is a device used during dental cleaning and periodontal (gum) therapy to remove calculus deposits from teeth by application of an ultrasonic vibrating scaler tip to the teeth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39924 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2945]

Medical Devices; Classification of Surgical Tissue Scissors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying surgical tissue scissors into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a

device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of surgical tissue scissors:

1. Identification: Surgical tissue scissors are a device used to cut soft tissue of the mouth, such as gums, during surgical procedures. The device has short, slightly curved stainless steel blades which allow easy access to the surgical site.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that surgical tissue scissors be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, surgical tissue scissors in the practice of dentistry.

5. Risks to health: None identified.

FDA disagrees with the Panel's recommendation and is proposing that surgical tissue scissors be classified into class II (performance standards). The properties of the materials used to form surgical tissue scissors depend upon the proper composition of these materials. Moreover, surgical tissue scissors directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that surgical tissue scissors should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend part 872 in Subpart E by adding new § 872.4875, to read as follows:

§ 872.4875 Surgical tissue scissors.

(a) *Identification.* Surgical tissue scissors are a device used to cut soft tissue of the mouth, such as gums, during surgical procedures. The device has short, slightly curved stainless steel blades which allow early access to the surgical site.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39925 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2946]

Medical Devices; Classification of Intraosseous Fixation Screws

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intraosseous fixation screws into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation

based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of intraosseous fixation screws:

1. Identification: An intraosseous fixation screw is a metal device that is used to stabilize fractured jaw bone segments by inserting it into both bone segments, thereby preventing their movement.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that intraosseous fixation screws be classified into class II because improper design or construction of the device may cause bone degeneration and failure of the bone segments to reunite. The materials used in the device that contact the body should meet a generally accepted level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Infection: If the device cannot be sterilized or is contaminated, infection may result.

(b) Bone damage: If the device is improperly designed or constructed, bone damage may occur due to mechanical trauma or failure of the bone segments to unite.

(c) Adverse tissue reaction: If the materials used in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that intraosseous fixation screws be classified into class II (performance standards).

FDA believes that intraosseous fixation screws should be considered implants. This device is designed to be placed within the tissues of the human body for an indefinite period of time. However, the agency also believes that premarket approval is not necessary to assure the safety and effectiveness of the device. Intraosseous fixation screws are completely imbedded in tissue, and there is no possibility of entry of microorganisms causing infection. Moreover, because the device does not protrude into the oral cavity, there is no possibility of irritation caused by chemical reactions from substances put into the mouth. The materials used to construct intraosseous fixation screws have been used in dentistry for many years and have demonstrated acceptable biocompatibility characteristics. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4880, to read as follows:

§ 872.4880 Intraosseous fixation screw.

(a) *Identification.* An intraosseous fixation screw is a metal device that is used to stabilize fractured jaw bone segments by inserting it into both bone segments, thereby preventing their movement.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39926 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 872]

[Docket No. 78N–2947]

Medical Devices; Classification of Dental Electrosurgical Units and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental electrosurgical units and accessories into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental electrosurgical units and accessories:

1. Identification: A dental electrosurgical unit and accessories is an AC-powered device consisting of a controlled power source and a set of cutting and coagulating electrodes. This device is used to cut or remove soft tissue or to control bleeding during surgical procedures in the oral cavity. An electrical current passes through the tip of the electrode into the tissue and, depending upon the operating mode selected, cuts through soft tissue or coagulates the tissue.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommmendation: The Panel recommends that dental electrosurgical units and accessories be classified into class II because the electrical properties of the device must be controlled to prevent electrical shock and burns to the patient or user. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Tissue damage: If, due to improper or inadequate performance of the device, the cutting process is prolonged, extensive heat-induced damage may occur in the tissue surrounding the surgical site.

(b) Electrical shock: Improper design of the device may cause electrical shock to the patient or user.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental electrosurgical units and accessories be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identified each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4920, to read as follows:

§ 872.4920 Dental electrosurgical unit and accessories.

(a) *Identification.* An electrosurgical unit and accessories is an AC-powered device consisting of a controlled power source and a set of cutting and coagulating electrodes. This device is used to cut or remove soft tissue or to control bleeding during surgical procedures in the oral cavity. An electrical current passes through the tip of the electrode into the tissue and, depending upon the operating mode selected, cuts through soft tissue or coagulates the tissue.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39927 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2948]

Medical Devices; Classification of Intraosseous Fixation Wires

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intraosseous fixation wires into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after of its publication in the **Federal Register**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation.

The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of intraosseous fixation wires:

1. Identification: An intraosseous fixation wire is a metal device that is used to stabilize and constrict fractured jaw bone segments by wrapping the wire around the ends of the bone segments.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that intraosseous fixation wires be classified into class II because improper design or construction of the device may cause bone degeneration and failure of the bone segments to reunite. The materials used in the device that contact the body should meet a generally accepted level of tissue compatibility. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Infection: If the device cannot be sterilized or is contaminated, infection may result.

(b) Bone damage: If the device is improperly designed, bone damage may occur.

(c) Adverse tissue reaction: If the materials used in the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that intraosseous fixation wires be classified into class II (performance standards). FDA believes that intraosseous fixation wires should be considered implants. This device is designed to be placed within the tissues of the human body for an indefinite period of time. However, the agency also believes that premarket approval is not necessary to assure the safety and effectiveness of the device. Intraosseous fixation wires are completely imbedded in tissue, and there is no possibility of entry of microorganisms causing infection. Moreover, because the device does not protrude into the oral cavity, there is no possibility of irritation caused by chemical reactions from substances put in the mouth. The materials used in the construction of intraosseous fixation wires have been used in dentistry for many years and have demonstrated acceptable biocompatibility characteristics. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.4950, to read as follows:

§ 872.4950 Intraosseous fixation wires.

(a) *Identification.* An intraosseous fixation wire is a metal device that is used to stabilize and constrict fractured jaw bone segments by wrapping the wire around the ends of the bone segments.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that the individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39028 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N–2950]

Medical Devices; Classification of Orthodontic Elastic Bands

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic elastic bands into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic elastic bands:

1. Identification: An orthodontic elastic band is a device made of rubber that is used with orthhodontic appliances to alter the position of teeth by applying pressure on them.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic elastic bands be classified into class I because the Panel believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic elastic bands in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that orthodontic elastic bands be classified into class II (performance standards). The properties of the materials used to form orthodontic elastic bands depend upon the correct composition of these materials. Moreover, orthodontic elastic bands directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that orthodontic elastic bands should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5400, to read as follows:

§ 872.5400 Orthodontic elastic band.

(a) *Identification.* An orthodontic elastic band is a device made of rubber that is used with orthodontic appliances to alter the position of teeth by applying pressure on them.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39929 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2951]

Medical Devices; Classification of Preformed Orthodontic Bands

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment and proposed regulation classifying preformed orthodontic bands into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed orthodontic bands:

1. Identification: A preformed orthodontic band is a prefabricated

device made of metal. In orthodontic treatment, the device is affixed to a tooth to provide a foundation for anchoring orthodontic appliances so that pressure can be exerted on the teeth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(fS) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that preformed orthodontic bands be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' pesrsonal knowledge of, and clinical experience with, preformed orthodontic bands in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that preformed orthodontic bands be classified into class II (performance standards). The properties of the materials used to form preformed orthodontic bands depend upon the proper composition of these materials. Moreover, preformed orthodontic bands directly contact oral tissue. Altering the composition of materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that preformed orthodontic bands should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5410, to read as follows:

§ 872.5410 Preformed orthodontic band.

(a) *Identification.* A preformed orthodontic band is a prefabricated device made of metal. In orthodontic treatment, the device is affixed to a tooth to provide a foundation for anchoring orthodontic appliances so that pressure can be exerted on the teeth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39930 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2952]

Medical Devices; Classification of Orthodontic Band Drivers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic band drivers into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic band drivers:

1. Identification: An orthodontic band driver is a spring-activated hand instrument that is used to place orthodontic bands on teeth. The device drives the band onto the tooth when the spring is released.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360 (k)), records and reports requirements under section 519 of the act (21 U.S.C 360), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic band drivers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic band drivers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that orthodontic band drivers be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the panel's recommendation that manufacturers of orthodontic band drivers be exempt from section 510(k) of the act (21 U.S.C. 360), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of orthodontic band drivers, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of orthodontic band drivers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of orthodontic band drivers be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of orthodontic band drivers, even when the device is not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of orthodontic band drivers must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notice of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5420, to read as follows:

§ 872.5420 Orthodontic band driver

(a) *Identification:* An orthodontic band driver is a spring-activated hand instrument that is used to place orthodontic bands on teeth. The device drives the band onto the tooth when the spring is released.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug

Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39931 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2953]

Medical Devices; Classification of Orthodontic Band Materials

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic band materials into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia, Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic band materials:

1. Identification: Orthodontic band material, such as stainless steel, is a device that is used to construct a custom orthodontic band. The band is placed around a tooth which, because of its size or location, cannot be fitted with a preformed orthodontic band. The band provides a foundation for anchoring orthodontic appliances, so that pressure can be exerted on the teeth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic band materials be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic band materials in the practice of dentistry,

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that orthodontic band materials be classified into class II (performance standards). The properties of the materials used to form orthodontic band materials depend upon the proper composition of these materials. Moreover, orthodontic band materials directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that orthodontic band materials should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5430, to read as follows:

§ 872.5430 Orthodontic band material.

(a) *Identification.* Orthodontic band material, such as stainless steel, is a device that is used to construct a custom orthodontic band. The band is placed around a tooth which, because of its size or location, cannot be fitted with a preformed orthodontic band. The band provides a foundation for anchoring

orthodontic appliances, so that pressure can be exerted on the teeth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39932 Filed 12–29–80; 8:45 am]

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21 CFR Part 872

[Docket No. 78N–2954]

Medical Devices; Classification of Orthodontic Band Pushers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic band pushers into class I (general controls). FDA is also publishing the recommendation of the Dentral Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, Md 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic band pushers:

1. Identification: An orthodontic band pusher is a barlike stainless steel device used is orthodontic treatment to apply pressure on orthodontic bands in order to place the bands on teeth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommedation: The Panel recommends that orthodontic band pushers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic band pushers in the practice of dentistry.

5. Risks to health: None identified.

Proposed classification

FDA agrees with the Panel recommendation and is proposing that orthodontic band pushers be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of orthodontic band pushers be exempt from section 510(k) of the act (21 U.S.C. 360), FDA is proposing that these manufacturers be subject to registration and device listing under section 510(a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of orthodontic band pushers, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning orthodontic band pushers. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of orthodontic band pushers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experiences with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption

will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of orthodontic band pushers be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 350j(f)), FDA is proposing that a manufacturer of this device be except, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of orthodontic band pushers must still be required to comply with the complaint file requirements of § 820.298 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of orthodontic band pushers must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5440, to read as follows:

§ 872.5440 Orthodontic band pusher.

(a) *Identification.* An orthodontic band pusher is a bar-like stainless steel device used in orthodontic treatment to apply pressure on orthodontic bands in order to place the bands on teeth.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockvile, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identifed with the Hearing Clerk docket number found in brackets, in the heading of this document. Received comments may be seen in the above office betwen the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39933 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2955]

Medical Devices; Classification of Orthodontic Bank Setters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic band setters into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administraton, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of orthodontic band setters:

1. Identification: An orthodontic band setter is a bar-like device used in orthodontic treatment to position orthodontic bands on teeth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic band setters be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements and the good manufacturing practice regulation, because this is a simple device that presents no undue risk to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel

based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic band setters in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that orthodontic band setters be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of orthodontic band setters be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510(a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of orthodontic band setters, the agency cannot make the required findings. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning orthodontic band setters. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of orthodontic band setters be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of orthodontic band setters be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of orthodontic band setters must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of orthodontic band setters must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5450, to read as follows:

§ 872.5450 Orthodontic band setter.

(a) *Identification.* an orthodontic band setter is a bar-like device used in orthodontic treatment to position orthodontic bands on teeth.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39934 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2956]

Medical Devices; Classification of Orthodontic Metal Brackets

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic metal brackets into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic metal brackets:

1. Identification: An orthodontic metal bracket is a metal device that is welded to an orthodontic band or bonded to a tooth and that applies pressure from flexible orthodontic wire to the tooth in order to alter the position of the tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic metal brackets be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic metal brackets in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that orthodontic metal brackets be classified into class II (performance standards). The properties of the materials used to form orthodontic metal brackets depend upon the proper composition of these materials. Moreover, orthodontic metal brackets directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that orthodontic metal brackets should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21678) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5460, to read as follows:

§ 872.5460 Orhrodontic metal bracket.

(a) *Identification.* An orthodontic metal bracket is a metal device that is welded to an orthodontic band or bonded to a tooth and that applies pressure from a flexible orthodontic wire to the tooth in order to alter the position of the tooth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m. Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39935 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2957]

Medical Devices; Classification of Orthodontic Plastic Brackets

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administation (FDA) is issuing for public comment a proposed regulation classifying orthodontic plastic brackets into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic plastic brackets:

1. Identification: An orthodontic plastic bracket is a plastic device that is bonded to a tooth and that applies pressure from a flexible orthodontic wire to the tooth in order to alter the position of the tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic plastic brackets be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic plastic brackets in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that orthodontic plastic brackets be classified into class II (perfomance standards). The properties of the materials used to form orthodontic plastic brackets depend upon the proper composition of these materials. Moreover, orthodontic plastic brackets directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that orthodontic plastic brackets should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5470, to read as follows:

§ 872.5470 Orthodontic plastic bracket.

(a) *Identification.* An orthodontic plastic bracket is a plastic device that is bonded to a tooth and that applies pressure from a flexible orthodontic wire to the tooth in order to alter the position of the tooth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39936 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N–2958]

Medical Devices; Classification of Orthodontic Bracket Aligners

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic bracket aligners into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic bracket aligners:

1. Identification: An orthodontic bracket aligner is a plier-like device used to align brackets on orthodontic bands that are affixed to the teeth. To align the brackets, the gauge on the device is set to the desired height and the stop of the device is placed against the bottom edge of the tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic bracket aligners be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, record and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic bracket aligners in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that orthodontic bracket aligners be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of orthodontic bracket aligners be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of orthodontic bracket aligners, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning orthodontic bracket aligners. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of orthodontic bracket aligners be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposed device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of orthodontic bracket aligners be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of orthodontic bracket aligners must still be required to comply with the

complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of orthodontic bracket aligners must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective action are adequte, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elswhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5480, to read as follows:

§ 872.5480 Orthodontic Bracket Aligner.

(a) *Identification.* An orthodontic bracket aligner is a plier-like device used to align brackets on orthodontic bands that are affixed to the teeth. To align the brackets, the guage on the device is set to the desired height and the stop of the device is placed against the bottom edge of the tooth.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39937 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2959]

Medical Devices; Classification of Orthodontic Wire Clamps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic wire clamps into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic wire clamps:

1. Identification: An orthodontic wire clamp is a device that is attached to the arch wire to prevent movement of the arch wire.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic wire clamps be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic wire clamps in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that orthodontic wire clamps be classified into class II (performance standards). The properties of the materials used to form orthodontic wire clamps depend upon the proper composition of these materials. Moreover, orthodontic wire clamps directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with

other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that orthodotic wire clamps should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation idntifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5490, to read as follows:

§ 872.5490 Orthodontic wire clamp.

(a) *Identification.* An orthodontic wire clamp is a device that is attached to the arch wire to prevent movement of the arch wire when placed in a tube on an orthodontic band.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39938 filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2960]

Medical Devices; Classification of Extraoral Orthodontic Headgear

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying extraoral orthodontic headgear into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that, the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of extraoral orthodontic headgear:

1. Identification: An extraoral orthodontic headgear is a device that is used, in conjunction with an orthodontic appliance, to exert pressure on the teeth from outside the mouth. The headgear has a strap that wraps around the patient's neck or head and an inner bow portion that is fastened to the orthodontic appliance in the patient's mouth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that extraoral orthodontic headgears be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for may years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, extraoral orthodontic headgear in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that extraoral orthodontic headgear be classified into class II (performance standards). The properties of the materials used to form extraoral orthodontic headgear depend upon the proper composition of these materials. Moreover, extraoral orthodontic headgear directly contact oral tissue. Altering the composition of the

materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that extraoral orthodontic headgear should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5500, to read as follows:

§ 872.5500 Extraoral orthodontic headgear.

(a) *Identification.* An extraoral orthodontic headgear is a device that is used, in conjunction with an orthodontic appliance, to exert pressure on the teeth from outside the mouth. The headgear has a strap that wraps around the patient's neck or head and an inner bow portion that is fastened to the orthodontic applicance in the patient's mouth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39939 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2961]

Medical Devices; Classification of Preformed Orthodontic Space Maintainers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed orthodontic space maintainers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed orthodontic space maintainers:

1. Identification: A preformed orthodontic space maintainer is a metal device that is used to preserve the space between teeth. The device is welded to the orthodontic bands affixed to the teeth adjacent to the space, preventing movement of the adjacent teeth into the empty space.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that preformed orthodontic space maintainers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, preformed orthodontic space maintainers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that preformed orthodontic space maintainers be classified into class II

(performance standards). The properties of the materials used to form preformed orthodontic space maintainers depend upon the proper composition of these materials. Moreover, preformed orthodontic space maintainers directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that preformed orthodontic space maintainers should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5510, to read as follows:

§ 872.5510 Preformed orthodontic space maintainer.

(a) *Identification.* A preformed orthodontic space maintainer is a metal device that is used to preserve the space between teeth. The device is welded to the orthodontic bands affixed to the teeth adjacent to the space, preventing movement of the adjacent teeth into the empty space.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39940 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2962]

Medical Devices; Classification of Orthodontic Pliers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic pliers into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic pliers:

1. Identification: Orthodontic pliers are a device used to shape and to adjust wires and bands used in orthodontic treatment.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic pliers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic pliers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that orthodontic pliers be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by this device.

In response to the Panel's recommendation that manufacturers of orthodontic pliers be exempt from

section 510(k) of the act (21 U.S.C. 360 (k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premaket notification under section 510(a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification manufacturers of orthodontic pliers, the agency cannot make the required findings. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufactuers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of orthodontic pliers be exempt from records and reports regulations under section 59 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel's recommendation that manufacturers of orthodontic pliers be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of orthodontic pliers having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5520,to read as follows:

§ 872.5520 Orthodontic pliers.

(a) *Identification.* Orthodontic pliers are a device used to shape and to adjust wires and bands used in orthodontic treatment.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39941 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 872

[Docket No. 78N–3025]

Medical Devices; Classification of Preformed Tooth Positioners

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed tooth positioners into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed tooth positioners:

1. Identification: A preformed tooth positioner is a plastic device used to prevent a patient's teeth from shifting position or to move teeth to a final position after orthodontic appliances (braces) have been removed. The device is an impression of a perfected bite. The patient bites down on the device for several hours a day to force the teeth

into a final position or to maintain the teeth in their corrected position.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that preformed tooth positioners be classified into class I because the Panel believes that general controls are sufficient to ensure the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures and the good manufacturing practice regulation because it is a simple device that presents no undue risks to health when used in a normal manner and for the purposes recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, preformed tooth positioners in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that preformed tooth positioners be classified into class II (performance standards). Preformed tooth positioners are composed of materials with certain properties, properties that depend upon the correct compostion of these materials. Moreover, preformed tooth positioners directly contact oral tissue. Altering the composition of the materials used in the device or contaminating the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. Performance standards are necessary to assure that the materials in the device are nontoxic and of adequate strength to prevent movement of teeth and to assure that the device fits properly. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that preformed tooth positioners should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and as new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5575, to read as follows:

§ 872.5575 Preformed tooth positioner.

(a) *Identification.* A preformed tooth positioner is a plastic device used to prevent a patient's teeth from shifting position or to move teeth to a final position after orthodontic appliances (braces) have been removed. The device in an impression of a perfected bite. The patient bites down on the device for several hours a day to force the teeth into a final position or to maintain the teeth in their corrected position.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39942 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2963]

Medical Devices; Classification of Orthodontic Expansion Screw Retainers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic expansion screw retainers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the

classification of orthodontic expansion screw retainers:

1. Identification: An orthodontic expansion screw retainer is a device used to exert pressure on the teeth during orthodontic treatment. The retainer has an adjustable screw that, when turned, expands the device laterally and, thereby, enlarges an area of the oral cavity, such as the palate.

2. Recommended classification: Class I (general controls). The Panel recommends that orthodontic expansion screw retainers be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

(3) Summary of reasons for recommendation: The Panel recommends that orthodontic expansion screw retainers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic expansion screw retainers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that orthodontic expansion screw retainers be classified into class II (performance standards). The properties of the materials used to form orthodontic expansion screw retainers depend upon the proper composition of these materials. Moreover, orthodontic expansion screw retainers directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. Because the agency has determined that orthodontic expansion screw retainers should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5530, to read as follows:

§ 872.5530 Orthodontic expansion screw retainer.

(a) *Identification.* An orthodontic expansion screw retainer is a device used to exert pressure on the teeth during orthodontic treatment. The retainer has an adjustable screw that, when turned, expands the device laterally and thereby enlarges an area of the oral cavity, such the palate.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39943 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2964]

Medical Devices; Classification of Orthodontic Springs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic springs into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the

development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic springs:

1. Identification: An orthodontic wire spring is a metal device that is attached to the orthodontic bands affixed to adjacent teeth and is used to apply pressure to teeth to correct their position.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic springs be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic springs in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that orthodontic springs be classified into class II (performance standards). The properties of the materials used to form orthodontic springs depend upon the proper composition of these materials. Moreover, orthodontic springs directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that orthodontic springs should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5540, to read as follows:

§ 872.5540 Orthodontic spring.

(a) *Identification.* An orthodontic spring is a metal device that is attached to the orthodontic bands affixed to adjacent teeth and is used to apply pressure to teeth to correct their position.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39944 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2965]

Medical Devices; Classification of Teething Rings

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fluid-filled teething rings into class II (performance standards) and classifying nonfluid-filled teething rings into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the fluid-filled teething rings be classified into class I (general controls). The Panel recommendation did not include a recommended classification for nonfluid-filled teething rings. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying teething rings. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, Md 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the

development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fluid-filled teething rings:

1. Identification: A fluid-filled teething ring is a soft plastic device containing a liquid, such as water. Prior to use, the liquid may be chilled by refrigerating the device. The device is used by infants to soothe gums during the teething process.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(i)) and from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that fluid-filled teething rings be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The device materials that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, fluid-filled teething rings in the practice of dentistry.

5. Risks to health: Infection: If the fluid in the device becomes contaminated and the teething ring ruptures, the patient may develop an infection.

Proposed Classification

With respect to fluid-filled teething rings, FDA disagrees with the Panel recommendation and is proposing that these rings be classified into class II (performance standards). Contamination of the fluid in the device has the potential for causing infection, if the teething ring ruptures. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risk to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that fluid-filled teething rings should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device by exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

FDA has revised the identification of the device to clarify that the regulation applies only to products intended for use as an aid in teething, and to include nonfluid-filled teething rings as well as fluid-filled teething rings. Because nonfluid-filled teething rings do not present a risk of infection due to contaminated fluid, FDA is proposing to classify them into class I. FDA is also proposing to exempt nonfluid-filled teething rings from the premarket notification requirement under section 510(k) of the act and Subpart E of Part 807 of the regulations (21 CFR Part 807, Subpart E) and from most provisions of the GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)) and Part 820 of the regulations. The agency has determined that is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning a nonfluid-filled teething ring. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new types of nonfluid-filled teething rings.

FDA is proposing that a manufacturer of a nonfluid-filled teething ring who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a nonfluid-filled teething ring, even when it is not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of nonfluid-filled teething rings must still be required to comply with the general requirements concerning records to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of a nonfluid-filled teething ring that it labeled or otherwise represented as sterile is, in the manufacture of this device, subject to the GMP regulation in its entirety.

Teething rings may also be subject to regulation by the Consumer Product Safety Commission under the Federal Hazardous Substances Act (15 U.S.C. 1261–1275).

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5550, to read as follows:

§ 872.5550 Teething ring.

(a) *Identification.* A teething ring is a device intended for use by infants to soothe gums during the teething process.

(b) *Classification.* (1) Class I (general controls), if the teething ring does not contain a liquid, such as water. This nonfluid-filled teething ring is exempt from the premarket notification procedures in Subpart E of Part 807. If the nonfluid-filled device is not labeled or otherwise represented as sterile, it also is exempt from the good manufacturing practice regulation in Part 820, with the exception of §820.180, regarding general requirements concerning records, and § 820.198,

regarding compliant files. (2) Class II (performance standards), if the teething ring contains a liquid, such as water.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39945 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2966]

Medical Devices; Classification of Orthodontic Tubes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic tubes into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic tubes:

1. Identification: An orthodontic tube is a metal device that is used in orthodontics to attach a wire or headgear to bands cemented to the teeth. The tube is welded to a band or bonded to the last tooth and allows insertion of an arch wire or headgear appliance.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic tubes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, record and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic tubes in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that orthodontic tubes be classified into class II (performance standards). The properties of the materials used to form orthodontic tubes depend upon the correct composition of these materials. Moreover, orthodontic tubes directly contact oral tissue. Altering the composition of the materials used in the device or contaimination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insuffient to control the risks to health presented by the device. A performance standard would provide reasonable assurance for the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency had determined that orthodontic tubes should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513), 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5560, to read as follows:

§ 872.5560 Orthodontic tube.

(a) *Identification.* An orthodontic tube is a metal device that is used in orthodontics to attach a wire or headgear to bands cemented to the teeth. The tube is welded to a band or bonded to the last tooth and allows

insertion of an arch wire or headgear appliance.

(b) *Classification.* Class II (performance standards).

Interested persons may on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39946 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2967]

Medical Devices; Classification of Orthodontic Ligature Tucking Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic ligature tucking instruments into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of orthodontic ligature tucking instruments:

1. Identification: An orthodontic ligature tucking instrument is a device used to push the end of a ligature under the arch wire so that soft tissues are not irritated by these ends. A ligature is the wire that fastens an orthodontic arch wire to the orthodontic band on a tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic ligature tucking instruments be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with orthodontic ligature tucking instruments in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that orthodontic ligature tucking instruments be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of orthodontic ligature tucking instruments be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of orthodontic ligature tucking instruments, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necesary for the protection of the public health that FDA receive premarket notification submissions concerning orthodontic ligature tucking instruments. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semi-annual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of orthodontic ligature tucking instruments be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption

from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of orthodontic ligature tucking instruments be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of orthodontic ligature tucking instruments must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of orthodontic ligature tucking instruments must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5570, to read as follows:

§ 872.5570 Orthodontic ligature tucking instrument.

(a) *Identification.* An orthodontic ligature tucking instrument is a device used to push the end of a ligature under the arch wire so that soft tissues are not irritated by these ends. A ligature is the wire that fastens an orthodontic arch wire to the orthodontic band on a tooth.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individual may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday thorugh Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39947 Filed 12-29-80 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2968]

Medical Devices; Classification of Orthodontic Wires

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying orthodontic wires into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of orthodontic wires:

1. Identification: An orthodontic wire is a device that is incorporated into an orthodontic appliance and is used to exert pressure on teeth in order to alter their position.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C.360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that orthodontic wires be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device

has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, orthodontic wires in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that orthodontic wires be classified into class II (performance standards). The properties of the materials used to form orthodontic wires depend upon the proper composition of these materials. Moreover, orthodontic wires directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that orthodontic wires should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation idntifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart F by adding new § 872.5580, to read as follows:

§ 872.580 Orthodontic wire.

(a) *Identification.* An orthodontic wire is a device that is incorporated into an orthodontic appliance and is used to exert pressure on teeth in order to alter their position.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except the individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39948 filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2969]

Medical Devices; Classification of Abrasive Disks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying abrasive disks into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of abrasive disks:

1. Identification: An abrasive disk is a device constructed of various abrasives, such as diamond chips, that are glued to shellac-based paper. The device is used to remove excessive restorative material, such as gold, and to smooth rough surfaces from oral restorations, such as crowns. The device is attached to a shank that is held by a handpiece.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that abrasive disks be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply

with records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, abrasive disks in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that abrasive disks be classified into class II (performance standards). The properties of the materials used to form abrasive disks depend upon the proper composition of these materials. Moreover, abrasive disks directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that abrasive disks should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6010, to read as follows:

§ 872.6010 Abrasive disk.

(a) *Identification.* An abrasive disk is a device constructed of various abrasives, such as diamond chips, that are glued to shellac-based paper. The device is used to remove excessive restorative material, such as gold, and to smooth rough surfaces from oral restorations, such as crowns. The device is attached to a shank that is held by a handpiece.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated. November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39949 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2970]

Medical Devices; Classification of Abrasive Points

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying abrasive points into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 104–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of abrasive points:

1. Identification: An abrasive point is a device used to remove excessive restorative material, such as gold, and to remove rough surfaces on oral restorations, such as amalgam fillings. The device may be constructed of diamond or silica particles molded into different shapes and fused to a shank that is held by a handpiece.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that abrasive points be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to

health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, abrasive points in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that abrasive points be classified into class II (performance standards). The properties of the materials used to form abrasive points depend upon the proper composition of these materials. Moreover, abrasive points directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that abrasive points should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6020, to read as follows:

§ 872.6020 Abrasive point.

(a) *Identification.* An abrasive point is a device used to remove excessive restorative material, such as gold, and to remove rough surfaces on oral restorations, such as amalgam fillings. The device may be constructed of diamond or silica particles molded into different shapes and fused to a shank that is held by a handpiece.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39950 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2971]

Medical Devices; Classification of Oral Cavity Abrasive Polishing Agents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oral cavity abrasive polishing agents into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of oral cavity abrasive polishing agents:

1. Identification: An oral cavity abrasive polishing agent is a device in paste or powder form that contains an abrasive material, such as silica pumice, and is used to remove debris from the teeth. The abrasive polish is applied to the teeth by a handpiece attachment (prophylaxis cup).

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that oral cavity abrasive polishing agents be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel

based its recommendation on the Panel members' personal knowledge of, and clinical experience with, oral cavity abrasive polishing agents in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that oral cavity abrasive polishing agents be classified into class II (performance standards). The properties of the materials used to form oral cavity abrasive polishing agents depend upon the proper composition of these materials. Moreover, oral cavity abrasive polishing agents directly contact oral tissue. Altering the composition of materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that oral cavity abrasive polishing agents should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble of the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 State. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6030, to read as follows:

§ 872.6030 Oral cavity abrasive polishing agent.

(a) *Identification.* An oral cavity abrasive polishing agent is a device in paste or powder form that contains an abrasive material, such as silica pumice, and is used to remove debris from the teeth. The abrasive polish is applied to the teeth by a handpiece attachment (prophylaxis cup).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39951 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2972]

Medical Devices; Classification of Polishing Agent Strips

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying polishing agent strips into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of polishing agent strips:

1. Identification: A polishing agent strip is a device composed of a plastic strip to which an abrasive material is affixed. The device is used to polish restorative materials, such as amalgam or silicate, especially in areas between the teeth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that polishing agent strips be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and

clinical experience with, polishing agent strips in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that polishing agent strips be classified into class II (performance standards). The properties of the materials used to form polishing agent strips depend upon the correct composition of these materials. Moreover, the polishing agent strips directly contact oral tissue. Altering the composition of the materials used in the device or contamination of the materials with other substances may cause adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that polishing agent strips should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6035, to read as follows:

§ 872.6035 Polishing agent strip.

(a) *Identification.* A polishing agent strip is a device composed of a plastic strip to which an abrasive material is affixed. The device is used to polish restorative materials, such as amalgam or silicate, especially in areas between the teeth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk, (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39952 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2973]

Medical Devices; Classification of Polishing Wheels

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying polishing wheels into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of polishing wheels:

1. Identification: A polishing wheel is a device composed of a material such as hard rubber, that is used to polish restorative materials in readily accessible areas of the oral cavity. The device is held by a dental handpiece.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that polishing wheels be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, polishing wheels in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that polishing wheels be classified into Class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

FDA disagrees with the Panel's recommendation that manufacturers of

polishing wheels be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements in found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of polishing wheels be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of polishing wheels must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of polishing wheels must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667 and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6040, to read as follows:

§ 872.6040 Polishing wheel.

(a) *Identification.* A polishing wheel is a device composed of a material such as hard rubber, that is used to polish restorative materials in readily accessible areas of the oral cavity. The device is held by a dental handpiece.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records,and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39953 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2974]

Medical Devices; Classification of Paper Saliva Absorbers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying paper saliva absorbers into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of paper saliva absorbers:

1. Identification: A paper saliva absorber is a device made of paper that is used to absorb moisture from the oral cavity during dental procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that paper saliva absorbers be exempt from premarket notification procedures under section 510(k) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that paper saliva absorbers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, paper saliva absorbers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that paper saliva absorbers be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of paper saliva absorbers be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of paper saliva absorbers, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of paper saliva absorbers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel recommendation that manufacturers of paper saliva absorbers be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of paper saliva absorbers having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6050, to read as follows:

§ 872.6050 Paper saliva absorber.

(a) *Identification.* A paper saliva absorber is a device made of paper that is used to absorb moisture from the oral cavity during dental procedures.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that the individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39954 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2975]

Medical Devices; Classification of Ultraviolet Activators for Polymerization

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ultraviolet activators for polymerization into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards

to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ultraviolet activators for polymerization:

1. Identification: An ultraviolet activator for polymerization is a device that produces ultraviolet radiation which is used to polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of the light through a rod.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ultraviolet activators for polymerization be classified into class II becasue the amount of ultraviolet light emitted by the device must be controlled to prevent possible eye damage to users. The design and output characteristics of this device should meet a generally acceptable satisfactory level of performance. Also, the electrical properties or the device must be controlled to ensure electrical safety. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry. The Panel also based its recommendation on a report published in the *Journal of the American Dental Association* (Ref. *1*). The report states the ultraviolet radiation of 320–400 nanometers (nm) is usually innocuous to human skin. However, ultraviolet light radiation in the 320–400 nm range can cause erythema (redness of the skin produced by congestion of the capillaries) and pigmentation in persons naturally susceptible to ultraviolet light and persons ingesting certain drugs or other chemicals that act as photosensitizing agents.

5. Risks to health: (a) Adverse skin reaction: A phototoxic or photoallergic skin reaction (erythema and pigmentation) may occur after moderate to excessive exposure to ultraviolet radiation emitted by the device.

(b) Eye damage: Eye damage may be caused by exposure to ultraviolet radiation emitted by the device.

(c) Electrical shock: Improper electrical design of the device may cause electrical shock to the patient or user.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ultraviolet activators for polymerization be classified into class II (performance standards). A performance standard for this device would control the exposure of the patient to unnecessary ultraviolet light radiation. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Council on Dental Materials and Devices, "Guidelines on the Use of Ultraviolet Radiation in Dentistry," *Journal of the American Dental Association*, Volume 92:775–776, April 1976.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6070, to read as follows:

§ 872.6070 Ultraviolet activator for polymerization.

(a) *Identification.* An ultraviolet activator for polymerization is a device that produces ultraviolet radiation which is used to polymerize (set) resinous dental pit and fissure sealants or restorative materials by transmission of the light through a rod.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39955 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2976]

Medical Devices; Classification of Air Brushes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying air brushes into class III

(premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of air brushes:

1. Identification: An air brush is an AC-powered device used in conjunction with articulation paper. The device uses air-driven particles to roughen the surfaces of dental restorations; uneven areas of the restorations are then identified by use of articulation paper.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that air brushes be classified into class III because the device presents a potential unreasonable risk of illness or injury. Use of the device may cause soft and hard tissue damage or cause inhalation or harmful particulate matter by creating excessive abrasive particles in the mouth. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel also believes that sufficient data do not exist to establish an adequate performance standard for this device because statisfactory performance has never been demonstrated. Therefore, the Panel recommends that the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and, thus, assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Inhalation of particles: Improper design of the device could create excessive abrasive particles which could be inhaled by the patient.

(b) Tissue trauma: The device could cause unnecessary trauma to hard and soft tissue structures of the mouth due to the abrasive nature of the particulates.

(c) Adverse tissue reaction: If the materials used in the device are not biocompatible, the patient may have an adverse tissue reaction.

(d) Electrical shock: Improper design or a malfunction of the device may cause electrical shock to the patient or user.

Proposed Classfication

FDA agrees with the Panel recommendation and is proposing that air brushes be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness or injury because use of the device to roughen surfaces of dental restorations may cause the patient to inhale harmful particles or to suffer trauma to hard and soft tissues of the mouth. The agency believes that sufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6080, to read as follows:

§ 872.6080 Air brush.

(a) *Identification.* An air brush is an AC-powered device used in conjunction with articulation paper. The device uses air-driven particles to roughen the surfaces of dental restorations. Uneven areas of the restorations are then identified by use of articulation paper.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39956 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2977]

Medical Devices; Classification of Anesthetic Warmers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthetic warmers into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthetic warmers:

1. Identification: An anesthetic warmer is an AC-powered device into which tubes containing anesthetic solution are placed in order to warm them prior to the administration of the anesthetic.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that anesthetic warmers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, anesthetic warmers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthetic warmers be classified into Class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of anesthetic warmers be exempt from section 510(k) of the act (21 U.S.C. 360), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of anesthetic warmers, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of anesthetic warmers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel's recommendation that manufacturers of anesthetic warmers be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (2 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of anesthetic warmers having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6100, to read as follows:

§ 872.6100 Anesthetic warmer.

(a) *Identification.* An anesthetic warmer is an AC-powered device into which tubes containing anesthetic solution are placed in order to warm them prior to the administration of the anesthetic.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug

Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39957 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2978]

Medical Devices; Classification of Articulation Paper

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying articulation paper into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of articulation paper:

1. Identification: Articulation paper is a device composed of paper coated with an ink dye that is placed between the patient's upper and lower teeth when the teeth are in the bite position. The articulation paper is used to locate uneven or high areas.

2. Recommended classification: Class I (general controls): The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that articulation paper be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, articulation paper in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that articulation paper be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of articulation paper be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of articulation paper, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of articulation paper be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of articulation paper be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general

requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of articulation paper must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of articulation paper must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and compliants about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6140, to read as follows:

§ 872.6140 Articulation paper.

(a) *Identification.* Articulation paper is a device composed of paper coated with an ink dye that is placed between the patient's upper and lower teeth when the teeth are in the bite position. The articulation paper locates uneven or high areas.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that the individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39958 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2979]

Medical Devices, Classification of Base Plate Shellacs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying base plate shellacs into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elswhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of base plate shellacs:

1. Identification: Base plate shellac is a device composed of shellac that is used to rebuild the occlusal rim of full or partial dentures.

2. Recommend classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that base plate shellacs be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, base plate shellac in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that base plate shellacs be classified into class II (performance standards). The properties of the materials used to form base plate shellacs depend upon the proper composition of these materials. Moreover, base plate shellacs directly

contact oral tissues. Altering the composition of the materials or contamination of the materials with other substances may lead to adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that base plate shellacs should be classified into Class II rather than Class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under Section 519, and the good manufacturing practice regulation under Section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each devices panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewehre in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6200, to read as follows:

§ 872.6200 Base plate shellac.

(a) *Identification.* Base plate shellac is a device composed of shellac that is used to rebuild the occlusal rim of full or partial dentures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39959 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2980]

Medical Devices; Classification of Dental Chairs with Operative Units

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is isssuing for public comment a proposed regulation classifying dental chairs with operative units into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental chairs with operative units:

1. Identification: A dental chair with operative unit is a device that consists of an AC-powered chair or lounger in which the patient is positioned during dental procedures. Attached to the chair is an AC-powered operative unit that supplies power to, and serves as the base for, dental handpieces, lights, and other devices and that holds syringes for air and water.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: Panel recommends that dental chairs with operative units be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that devices contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures and records and reports requirements because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental chairs with operative units in the practice of dentistry.

5. Risks to health: Electrical shock: Improper electrical design of the device may cause electrical shock to the patient.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that dental chairs with operative units be classified into class II (performance standards). This decision is based on the potential for electric shock posed by the power supply of the device. The agency believes that a performance standard is necessary for this device to ensure electrical safety and that general

controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that dental chairs with operative units should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k) and records and reports requirements under section 519 of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 7019(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6250, to read as follows:

§ 872.6250 Dental chair with operative unit.

(a) *Identification.* A dental chair with operative unit is a device that consists of an AC-powered chair or lounger in which the patient is positioned during dental procedures. Attached to the chair is an AC-powered operative unit that supplies power to, and serves as the base for, dental handpieces, lights, and other devices and that holds syringes for air and water.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39960 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2981]

Medical Devices; Classification of Dental Chairs Without Operative Units

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental chairs without operative units into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classfiying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental chairs without operative units:

1. Identification: A dental chair without operative unit is a device that consists of an AC-powered chair or lounger in which the patient is positioned during dental procedures. The Chair does not have an operative unit device attached.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental chairs without operative units be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for may years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with the premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental chairs without operative units in the practice of dentistry.

5. Risks to health; Electrical shock: Improper electrical design of the device may cause electrical shock to the patient.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that dental chairs without operative units be classified into class II (performance standards). This decision is based on the potential for electric shock posed by the power supply of the device. The Agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health

presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Because the agency has determined that dental chairs without operative units should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6260, to read as follows:

§ 872.6260 Dental chair without operative unit.

(a) *Identification.* A dental chair without operative unit is a device that consists of an AC-powered chair or lounger in which the patient is positioned during dental procedures. The chair does not have an operative unit device attached.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39961 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR PART 872

[Docket No. 78N-2982]

Medical Devices; Classification of Cotton Rolls

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cotton rolls into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305) Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Greg Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cotton rolls:

1. Identification: A cotton roll is a tube shaped device composed of cotton fibers that is used to absorb moisture in the oral cavity during dental procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(dk) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360l), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that cotton rolls be classified into class I because the Panel believed that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, cotton rolls in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cotton rolls be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of cotton rolls be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing and premarket notification by manufacturers of cotton rolls, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from

manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of cotton rolls be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees wih the Panel's recommendation that manufacturers of cotton rolls be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of cotton rolls having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6280, to read as follows:

§ 872.6280 Cotton roll.

(a) *Identification.* A cotton roll is a tube shaped device composed of cotton fibers that is used to absorb moisture in the oral cavity during dental procedures.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39962 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2983]

Medical Devices; Classification of Prophylaxis Cups

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prophylaxis cups into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of prophylaxis cups:

1. Identification: A prophylaxis cup is a device made of rubber that is held by a dental handpiece and used to apply polishing agents during prophylaxis (cleaning). The dental handpiece spins the rubber cup holding the polishing agent and the user applies it to the teeth to remove debris.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that prophylaxis cups be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, prophylaxis cups in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that prophylaxis cups be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

FDA disagrees with the Panel's recommendation that manufacturers of prophylaxis cups be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel's recommendation that manufacturers of prophylaxis cups be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of prophylaxis cups having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 862 in Subpart G by adding new § 872.6290, to read as follows:

§ 872.6290 Prophylaxis cup.

(a) *Identification.* A prophylaxis cup is a device made of rubber that is held by a dental handpiece and used to apply polishing agents during prophylaxis (cleaning). The dental handpiece spins the rubber cup holding the polishing agent and the user applies it to the teeth to remove debris.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk, (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39963 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 872

[Docket No. 78N–2984]

Medical Devices; Classification of Rubber Dams

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rubber dams into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rubber dams:

1. Identification: A rubber dam is a device composed of a thin sheet of latex with a hole in the center that is used to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity. The device is streched around a tooth by inserting the tooth through the hole in the center.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good

manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that rubber dams be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, rubber dams in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rubber dams be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of rubber dams be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing and premarket notification by manufacturers of rubber dams, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of rubber dams be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of rubber dams be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of rubber dams must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manaufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of rubber dams must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6300, to read as follows:

§ 872.6300 Rubber dam.

(a) *Identification.* A rubber dam is a device composed of a thin sheet of latex with a hole in the center that is used to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity. The device is stretched around a tooth by inserting the tooth through the hole in the center.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated November 19, 1980

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39964 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2985]

Medical Devices; Classification of Rubber Dam Clamps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rubber dam clamps into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rubber dam clamps:

1. Identification: A rubber dam clamp is a device used to anchor a rubber dam (a barrier used to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity).

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that rubber dam clamps be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is base: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, rubber dam clamps in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rubber dam clamps be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of rubber dam clamps be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of rubber dam clamps, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of rubber dam clamps be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of rubber dam clamps be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of rubber dam clamps must still be required to

comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of rubber dam clamps must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6310, to read as follows:

§ 872.6310 Rubber dam clamp.

(a) *Identification.* A rubber dam clamp is a device used to anchor a rubber dam (a barrier used to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity).

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39965 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2986]

Medical Devices; Classification of Rubber Dam Frames

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rubber dam frames into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rubber dam frames:

1. Identification: A rubber dam frame is a plastic or metal device used to stretch and apply a rubber dam (a barrier used to isolate a tooth from fluids in the mouth during procedures, such as filling a cavity).

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that rubber dam frames be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, rubber dam frames in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rubber dam frames be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel recommendation that manufacturers of rubber dam frames be exempt from section 510(k) of the act (21 U.S.C. 360), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of rubber dam frames, the agency cannot make the required finding. In

order to conduct necessary inspections, and, thereby, to protect the public health, the agency must be able to identify the firms manufacturing this device. Likewise, the agency must receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of rubber dam frames be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of rubber dam frames be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of rubber dam frames must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of rubber dam frames must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about products defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6320, to read as follows:

§ 872.6320 Rubber dam frame.

(a) *Identification.* A rubber dam frame is a plastic or metal device used to stretch and apply a rubber dam (a barrier used to isolate a tooth from fluids in the mouth during dental procedures, such as filling a cavity).

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39966 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2987]

Medical Devices, Classification of Ultraviolet Detectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ultraviolet detectors into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. after considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administraton, 8757 Georgia Ave., Silver spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendations

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation.

The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ultraviolet detectors:

1. Identification: An ultraviolet detector is a device that provides a source of ultraviolet light which is used to identify otherwise invisible material, such as dental plaque, present in or on teeth.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that ultraviolet detectors be classified into class II because the amount of ultraviolet light emitted by the device must be controlled to prevent eye damage. The design and ouput characteristics of this device should meet a generally acceptable satisfactory level of performance. Also, the electrical properties of the device must be controlled to assure electrical safety. The Panel believes that general controls alone would not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry. The Panel also based its recommendation on a report published in the *Journal of the American Dental Association* (Ref. *1*). The report stated that ultraviolet radiation of 320–400 nanometers (nm) is usually innocuous to human skin. However, ultraviolet light radiation in the 320–400 nm can cause erythema (redness of the skin produced by congestion of the capillaries) and pigmentation in persons naturally susceptible to ultraviolet light and persons ingesting certain drugs or other chemicals that act as photosensitizing agents.

5. Risks to health: (a) Adverse skin reaction: A phototoxic or photoallergic skin reaction (erythema and pigmentation) may occur after moderate to excessive exposure to ultraviolet radiation emitted by the device.

(b) Eye damage: Eye damage may be caused by exposure to ultraviolet radiation emitted by the device.

(c) Electrical shock: Improper electrical design of the device may cause electrical shock to the patient or users.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ultraviolet detectors be classified into Class II (performance standards). A performance standard for this device would control the exposure of the patient to unnecessary ultraviolet light radiation. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Reference

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m., to 4 p.m., Monday through Friday.

1. Council on Dental Materials and Devices, "Guidelines on the Use of Ultraviolet Radiation in Dentistry," *Journal of the American Dental Association,* Volume 92:775–776, April 1976.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360, (a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6350, to read as follows:

§ 872.6350 Ultraviolet detector.

(a) *Identification.* An ultraviolet detector is a device that provides a source of ultraviolet light which is used to identify otherwise invisible material, such as dental plaque, present in or on teeth.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39967 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2988]

Medical Devices; Classification of Oral Cavity Evacuators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oral cavity evacuators into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides

background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of oral cavity evacuators:

1. Identification: An oral cavity evacuator is a hand-held device that consists of a plastic tube attached to a suction unit and is used to remove fluids from the oral cavity during dental procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that oral cavity evacuators be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, oral cavity evacuators in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that oral cavity evacuators be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of oral cavity evacuators be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing and premarket notification by manufacturers of oral cavity evacuators, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of oral cavity evacuators be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposed device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel's recommendation that manufacturers of oral cavity evacuators be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of oral cavity evacuators having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6370, to read as follows:

§ 872.6370 Oral cavity evacuator.

(a) *Identification.* An oral cavity evacuator is a hand-held device that consists of a plastic tube attached to a suction unit and is used to remove fluids from the oral cavity during dental procedures.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39968 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 872

[Docket No. 78N-2989]

Medical Devices; Classification of Dental Floss

AGENCY: Food and Drug Administration.

ACTION: Proposed rule

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental floss into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommentation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental floss:

1. Identification: Dental floss is a string-like device made of cotton or other fibers that is intended to be used to remove plaque and food particles from between the teeth to reduce tooth decay. The fibers of the device may be coated with wax for easier use.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360 (k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental floss be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental floss in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental floss be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of dental floss be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing and premarket notification under section 510(a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing and premarket notification by manufacturers of dental floss, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of signficant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of dental floss be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorizd, wholly or in part, by 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR § 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel's recommendation that manufacturers of dental floss be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulation and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of dental floss having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6390, to read as follows:

§ 872.6390 Dental floss.

(a) *Identification.* Dental floss is a string-like device made of cotton or other fibers that is intended to be used to remove plaque and food particles from between the teeth to reduce tooth decay. The fibers of the device may be coated with wax for easier use.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39969 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2990]

Medical Devices; Classification of Forceps for an Articulation Paper

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying forceps for an articulation paper into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of forceps for an articulation paper:

1. Identification: Forceps for an articulation p aper are a device used to hold articulation paper in the proper position between the patient's upper and lower teeth when the teeth are in the bite position. The articulation paper locates uneven or high areas.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that forceps for an articulation paper be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, forceps for an articulation paper in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that forceps for an articulation paper be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of forceps for an articulation paper be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of forceps for an articulation paper, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning forceps for an articulation paper. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of forceps for an articulation paper be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other

regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of forceps for an articulation paper be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of forceps for an articulation paper must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of forceps for an articulation paper must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the maufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elswhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6400, to read as follows:

§ 872.6400 Forceps for an articulation paper.

(a) *Identification.* Forceps for an articulation paper are a device used to hold articulation paper in the proper position between the patient's upper and lower teeth when the teeth are in the bite position. The articulation paper locates uneven or high areas.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested parties may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39970 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2991]

Medical Devices; Classification of Forceps for Dental Dressings

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying forceps for dental dressings into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of forceps for dental dressings:

1. Identification: Forceps for dental dressings are a handheld, tweezer-like device used to apply dressings to areas in the mouth during dental procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures

under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that forceps for dental dressings be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, forceps for dental dressings in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with Panel recommendation and is proposing that forceps for dental dressings be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of forceps for dental dressings be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing of manufacturers of forceps for dental dressings, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning forceps for dental dressings. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of forceps for dental dressings be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of forceps for a dental dressing be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of forceps for dental dressings must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of forceps for dental dressings must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6410, to read as follows:

§ 872.6410 Forceps for dental dressings.

(a) *Identification.* Forceps for dental dressings are a hand-held, tweezer-like device used to apply dressings to areas in the mouth during dental procedures.

(b) *Classification.* Class I (general controls). The device is exempt from premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk, (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39971 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2992]

Medical Devices; Classification of Forceps for a Rubber Dam Clamp

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying forceps for a rubber dam clamp into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of forceps for a rubber dam clamp:

1. Identification: Forceps for a rubber dam clamp are a plier-like device that are used to spread a rubber dam clamp (a device used to anchor a rubber dam in place) during insertion and removal of the clamp.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that forceps for a rubber dam clamp be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, forceps for a rubber dam clamp in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that forceps for a rubber dam clamp be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of forceps for a rubber dam clamp be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of forceps for a rubber dam clamp, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of forceps for a rubber dam clamp be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of

forceps for a rubber dam clamp be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198)), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of forceps for a rubber dam clamp must still be required to comply with complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of forceps for a rubber dam clamp must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6420, to read as follows:

§ 872.6420 Forceps for a rubber dam clamp.

(a) *Identification.* Forceps for a rubber dam clamp are a plier-like device that are used to spread a rubber dam clamp (a device used to anchor a rubber dam in place) during insertion and removal of the clamp.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that the individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39972 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2993]

Medical Devices; Classification of Guards for an Abrasive Disk

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying guards for an abrasive disk into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of guards for abrasive disks:

1. Identification: A guard for an abrasive disk is a metal device that clips onto the dental handpiece. The guard shields soft tissue from injury by an abrasive disk when the disk is being used during the contruction of a restoration.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedure under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that guards for an abrasive disk be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, the records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, guards for an

abrasive disk in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that guards for an abrasive disk be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of guards for an abrasive disk be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510(a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing and premarket notification by manufacturers of guards for an abrasive disk, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of guards for an abrasive disk be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of guards for an abrasive disk be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of guards for an abrasive disk must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of guards for an abrasive disk must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6465, to read as follows:

§ 872.6465 Guard for an abrasive disk.

(a) *Identification.* A guard for an abrasive disk is a metal device that clips onto the dental handpiece. The guard shields soft tissue from injury by an abrasive disk when the disk is being used during the construction of a restoration.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 802.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Firday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39973 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2994]

Medical Devices; Classification of Heat Sources for Bleaching Teeth

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying heat sources for bleaching teeth into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into

class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of heat sources for bleaching teeth:

1. Identification: A heat source for bleaching teeth is an AC-powered device used to apply heat to a tooth after the tooth is coated with a bleaching agent. The heat source may be either a light or an electric heater.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that heat sources for bleaching teeth be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, heat sources for bleaching teeth in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that heat sources for bleaching teeth be classified into class II (performance standards). This device directs heat energy at oral tissue. This heat may cause burns to the patient if it is too intense and the device may be ineffective if it does not have sufficient intensity. The electrical properties of the device must also be controlled to prevent electrical shock to the patient or user. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that heat sources for bleaching teeth should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6475, to read as follows:

§ 872.6475 Heat source for bleaching teeth.

(a) *Identification.* A heat source for bleaching teeth is an AC-powered device used to apply heat to a tooth after the tooth is coated with a bleaching agent. The heat source may be either a light or an electric heater.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39974 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N–2996]

Medical Devices; Classification of Oral Irrigation Units

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oral irrigation units into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a

device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of oral irrigation units:

1. Identification: An oral irrigation unit is an AC-powered device intended to be used to remove food particles from between the teeth and promote good periodontal (gum) condition by means of a pressurized water stream.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that oral irrigation units be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, oral irrigation units in the practice of dentistry.

5. Risks to health: Infection and tissue trauma: Infection and trauma to soft tissues may result from the pressure of the water stream driving microorganisms into the gum pockets surrounding the user's teeth.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that oral irrigation units be classified into class II (performance standards). The agency believes that the design and performance characteristics of the device which regulate the output pressure of the water stream must be controlled to prevent infection and trauma to soft tissues. Excessive pressure may drive microorganisms and debris into the gum pockets surrounding the user's teeth, causing infection. The agency believes that general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Because the agency has determined that oral irrigation units should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6510, to read as follows:

§ 872.6510 Oral irrigation unit.

(a) *Identification.* An oral irrigation unit is an AC-powered device intended to be used to remove food particles from between the teeth and promote good periodontal (gum) condition by means of a pressurized water stream.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39975 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2997]

Medical Devices; Classification of Dental Matrix Bands

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental matrix bands into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental matrix bands:

1. Identification: A dental matrix band is a device made of stainless steel that is used as a mold and is placed around a tooth to provide support for restorative materials while filling a tooth.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental matrix bands be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simply device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental matrix bands in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental matrix bands be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of dental matrix bands be exempt from section 510(k) of the act (21 U.S.C. 360), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510(a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of dental matrix bands, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, and to receive premarket notification from manufacturers to conduct necessary inspection to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of dental matrix bands be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements is found in the device good manufacturing practice (GMP) regulation published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of dental matrix bands be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of dental matrix bands must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of dental matrix bands must still be required to comply with the general requirements concerning records, in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6550, to read as follows:

§ 872.6550 Dental matrix band.

(a) *Identification.* A dental matrix band is a device made of stainless steel that is used as a mold and is placed around a tooth to provide support for restorative materials while filling a tooth.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39976 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-2998]

Medical Devices; Classification of Matrix Retainers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying matrix retainers into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of matrix retainers:

1. Identification: A matrix retainer is a device used to fasten together the ends of a matrix band (a mold placed around a tooth to provide support for restorative materials) and to tighten the matrix band around the tooth during restoration and filling.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that matrix retainers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and report requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, matrix retainers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that matrix retainers be classified into Class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of matrix retainers be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of matrix retainers, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections, and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices, for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of matrix retainers be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain

classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of matrix retainers be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of matrix retainers must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of matrix retainers must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding § 872.6560, to read as follows:

§ 872.6560 Matrix retainer.

(a) *Identification.* A matrix retainer is a device used to fasten together the ends of a matrix band (a mold placed around to tooth to provide support for restorative materials) and to tighten the matrix band around the tooth during restoration and filling.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practices regulation in Part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 39977 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–2999]

Medical Devices; Classification of Impression Tubes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying impression tubes into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of impression tubes.

1. Identification: An impression tube is a device consisting of a hollow copper tube that is used to take an impression of a single tooth. The hollow tube is filled with impression material. One end of the tube is sealed with a softened material, such as wax; the remaining end is slipped over the tooth to make the impression.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that impression tubes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this

device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personnel knowledge of, and clinical experience with, impression tubes in the practice of dentistry.

5. Risks to health. None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that impression tubes be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of impression tubes be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification 510(a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of impression tubes, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of signficant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of impression tubes be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements is found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of impression tubes be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of impression tubes must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of impression tubes must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6570, to read as follows:

§ 872.6570 Impression tube.

(a) *Identification.* An impression tube is a device consisting of a hollow copper tube that is used to take an impression of a single tooth. The hollow tube is filled with impression material. One end of the tube is sealed with a softened material, such as wax; the remaining end is slipped over the tooth to make the impression.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39978 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–3000]

Medical Devices; Classification of Mouth Mirrors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mouth mirrors into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mouth mirrors:

1. Identification: A mouth mirror is a hand-held metal or glass device that is used as a visual aid to reflect oral structures during examination and treatment of the teeth and the oral cavity.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that mouth mirrors be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, mouth mirrors in the practice of dentistry.

5. Risks of health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that mouth mirrors be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of mouth mirrors be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510 (a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of mouth mirrors, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning mouth mirrors. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products with this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of mouth mirrors be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of mouth mirrors be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of mouth mirrors must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of mouth mirrors must

still be required to comply with the general requirements concerning records in § 820.189 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6600, to read as follows:

§ 872.6600 Mouth mirror.

(a) *Identification.* A mouth mirror is a hand-held metal or glass device that is used as a visual aid to reflect oral structures during examination and treatment of the teeth and the oral cavity.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39979 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–3001]

Medical Devices; Classification of Saliva Ejector Mouthpieces

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying saliva ejector mouthpieces into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of saliva ejector mouthpieces:

1. Identification: A salivia ejector mouthpiece is a device consisting of a plastic tube that is used to remove saliva continuously from the oral cavity during dental treatment. The tube is looped over the patient's lips and is attached to a suction unit.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i)), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that saliva ejector mouthpieces be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, saliva ejector mouthpieces in the practice of denstistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that saliva ejector mouthpieces be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of saliva ejector mouthpieces be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of saliva ejector mouthpieces, the

agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections, and receive premarket notification from manufacturers to assure that FDA learns of new devices, and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of saliva ejector mouthpieces be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of saliva ejector mouthpieces be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes that manufacturers of saliva ejector mouthpieces must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency believes that manufacturers of saliva ejector mouthpieces must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6620, to read as follows:

§ 872.6620 Saliva ejector mouthpiece.

(a) *Identification.* A saliva ejector mouthpiece is a device consisting of a plastic tube that is used to remove saliva continuously from the oral cavity during dental treatment. The tube is looped over the patient's lips and is attached to a suction unit.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk, (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39980 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3002]

Medical Devices; Classification of Dental Operative Units

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental operative units into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental operative units:

1. Identification: A dental operative unit is an AC-powered device that supplies power to, and serves as the base for, dental handpieces, lights, or other dental devices and holds syringes for air and water. It can be attached to the dental chair or cabinet or located on a portable cart.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental operative units be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental operative units in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that dental operative units be classified into class II (performance standards). Dental operative units indirectly contact patients because air and water supplied through the unit are used to clean the operating area of debris. If the unit is not designed properly, contamination of the air and water may occur, thereby putting the patient at risk of harm. A performance standard is necessary to control the electrical design of the device to prevent electrical shock to the patient or user. The agency believes that performance standards are necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that dental operative units should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that is device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart E by adding new § 872.6640, to read as follows:

§ 872.6640 Dental operative unit.

(a) *Identification.* A dental operative unit is an AC-powered device that supplies power to, and serves as the base for, dental handpieces, lights, or other dental devices and holds syringes for air and water. It can be attached to the dental chair or cabinet or located on a portable cart.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated November 19, 1980

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39981 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–3003]

Medical Devices; Classification of Suction Operative Units

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying suction operative units into class II (performance standards.) FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of suction operative units:

1. Identification: A suction operative unit is an AC-powered device that is attached to a dental operative unit and is used to remove fluids from the oral cavity by suction supplied by tubing to a saliva ejector mouthpiece or an oral cavity evacuator.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that suction operative units be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with the premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, suction operative units in the practice of dentistry.

5. Risks to health: Electrical shock: Improper electrical design of the device may cause electrical shock to the patient or user.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that suction operative units be classified into class II (performance standards). The agency believes that the amount of suction generated by the device must be controlled to prevent injury to soft tissues, and that the electrical design of the device must be controlled to prevent electrical shock to the patient or user. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6645, to read as follows:

§ 872.6645 Suction operative unit.

(a) *Identification.* A suction operative unit is an AC-powered device used to remove fluids from the oral cavity by suction supplied by tubing to a saliva ejector mouthpiece or an oral cavity evacuator.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39982 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3004]

Medical Devices; Classification of Massaging Picks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying massaging picks into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of massaging picks:

1. Identification: A messaging pick is a pointed device made of wood or plastic that is intended to be used manually to stimulate and massage the gums to promote good periodontal (gum) condition. The end of the pick is placed at the base of the teeth and moved gently.

2. Recommended classification: Class I (general controls). The Panel

recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that massaging picks be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, massaging picks in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that massaging picks be classifed into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of massaging picks be exempt from section 510(k) of the act (21 U.S.C. 360), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listings and premarket notification by manufacturers of massaging picks, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of massaging picks be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of massaging picks be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of massaging picks must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency believes that manufacturers of massaging picks must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6650, to read as follows:

§ 872.6650 Massaging pick.

(a) *Identification.* A massaging pick is a pointed device made of wood or plastic that is intended to be used manually to stimulate and massage the gums to promote good periodontal (gum) condition. The end of the pick is placed at the base of the teeth and moved gently.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.280, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk, (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may

submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39983 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3005]

Medical Devices; Classification of Porcelain Powder for Clinical Use

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying porcelain powder for clinical use into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of porcelain powder for clinical use:

1. Identification: Porcelain powder for clinical use is a device consisting of a mixture of kaolin, felspar, quartz, or other substances that is used in the production of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers. The device is used in restorative dentistry by heating the powder mixture to a high temperature in an oven to produce a hard prosthesis with a glass-like finish.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that porcelain powder for clinical use be classified into class II because the composition of the porcelain powder must be controlled. The fluorescing agents in the porcelain powder for clinical use may contain radioactive components which may decay, resulting in the production of prosthetic devices that emit radiation. The Panel believes that general controls alone would not provide sufficient control over this characteristic. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: (a) Exposure to radiation: The patient may be exposed to radiation emitted by prostheses made from porcelain powder that contains radioactive ingredients. (b) Adverse tissue reaction: If the materials used in the construction of the device are not biocompatible, the patient may have an adverse tissue reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that procelain powder for clinical use be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. Exposure of surrounding tissue to the ionizing radiation emitted by the radioactive material that may be present in dental products fabricated from porcelain powder for clinical use may result in acute tissue damage, if the radiation is sufficiently intense, or in neoplastic (abnormal changes), if radiation is chronically received at lower levels. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6660, to read as follows:

§ 872.6660 Porcelain powder.

(a) *Identification.* Porcelain powder for clinical use is a device consisting of a mixture of kaolin, felspar, quartz, or other substances that is used in the production of artificial teeth in fixed or removable dentures, of jacket crowns, facings, and veneers. The device is used in restorative dentistry by heating the powder mixture to a high temperature in an oven to produce a hard prosthesis with a glass-like finish.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39984 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 872

[Docket No. 78N-3006]

Medical Devices; Classification of Silicate Protectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying silicate protectors into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of silicate protectors:

1. Identification: A silicate protector is a device made of silicone that is applied with an absorbent tipped applicator to the surface of a new restoration to exclude temporarily fluids from its surface.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that silicate protectors be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, record and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, silicate protectors in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that silicate protectors be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of silicate protectors be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of silicate protectors, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections, and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of silicate protectors be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until there regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of silicate protectors be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of silicate

protectors must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of silicate protectors must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding § 872.6670, to read as follows:

§ 872.6670 Silicate protector.

(a) *Identification.* A silicate protector is a device made of silicone that is applied with an absorbent tipped applicator to the surface of a new restoration to exclude temporarily fluids from its surface.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 39965 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–3007]

Medical Devices; Classification of Dental Retractors (All Types)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental retractors (all types) into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental retractors (all types):

1. Identification: A dental retractor (any type) is a device used to fold back oral tissues by pulling back the cheeks at the lips to aid operating procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that dental retractors (all types) be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, record and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental retractors in the practice of dentistry.

5. Risks to health: Infection: If the materials used in the device cannot be sterilized, infection to the patient may occur.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that dental retractors (all types) be classified into class II (performance standards). Dental retractors may be reused, and therefore, have a potential for transmitting microorganisms between patients. For this reason, the device must be capable of sterilization. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient

information to establish a performance standard for this device.

Because the agency has determined that dental retractors (all types) should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6680, to read as follows:

§ 872.6680 Dental retractor (any type).

(a) *Identification.* A dental retractor (any type) is a device used to fold back oral tissues by pulling back the cheeks at the lips to aid operating procedures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39986 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–3008]

Medical Devices; Classification of Dental Retractor Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental retractor accessories into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental retractor accessories:

1. Identification: A dental retractor accessory is a device, such as a spring, that is used with a dental retractor (a device used to fold back oral tissue during operating procedures) to aid in pulling back the cheek as far as possible.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f).

3. Summary of reasons for recommendation: The Panel recommends that dental retractor accessories be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental retractor accessories in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that dental retractor accessories be classified into class II (performance standards). Dental retractor accessories may be reused, and therefore, have a potential for transmitting microorganisms between patients. For this reason, the device must be capable of sterilization. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that dental retractor accessories should be classified into class II rather than

class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Futher information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6690, to read as follows:

§ 872.6690 Dental retractor accessory.

(a) *Identification.* A dental retractor accessory is a device, such as a spring, that is used with a dental retractor (a device used to fold back oral tissue during operating procedures) to aid in pulling back the cheek as far as possible.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39987 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 872

[Docket No. 78N–3009]

Medical Devices; Classification of Boiling Water Sterilizers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying boiling water sterilizers into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of boiling water sterilizers:

1. Identification: A boiling water sterilizer is an AC-powered device used to sterilize dental and surgical instruments by submersion of the instruments into boiling water.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that boiling water sterilizers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, boiling water sterilizers in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that boiling water sterilizers be classified into class II (performance standards). This device is used to sterilize instruments which directly contact the patients' oral tissues. If the water is inadequately heated, the instruments will not be properly sterilized, possibly resulting in the transmission of microorganisms between patients. Also, the electrical design of the device must be controlled to prevent electrical shock to the user. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that boiling water sterilizers should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43

FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6710, to read as follows:

§ 872.6710 Boiling water sterilizer.

(a) *Identification.* A boiling water sterilizer is an AC-powered device used to sterilize dental and surgical instruments by submersion of the instruments into boiling water.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39988 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–3011]

Medical Devices; Classification of Endodontic Dry Heat Sterilizers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying endodontic dry heat sterilizers into class III (premarket approval). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of endodontic dry heat sterilizers:

1. Identification: An endodontic dry heat sterilizer is a device used to sterilize endodontic and other dental instruments by the application of dry heat. The heat is supplied through glass beads which have been heated by electricity.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that endodontic dry heat sterilizers be classified into class III because the device presents a potential unreasonable risk of illness or injury. In tests of the device, it has failed to sterilize adequately various endodontic and dental instruments. Such failure may be a result of faulty thermostats which register higher temperatures than those generated within the device or may be caused by the inability of glass beads to sterilize adequately and uniformly despite sufficient heat. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that it is not possible to establish an adequate performance standard for this device because satisfactory performance has never been demonstrated. Therefore, the device should be subject to premarket approval to assure that manufacturers of this device demonstrate satisfactory performance of the device and thus assure its safety and effectiveness. The Panel believes that further study is needed to determine the causes of this device's ineffectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device in the practice of dentistry.

5. Risks to health: Infection: The inability of the device to sterilize adequately endodontic and other dental instruments may lead to the transmission of micro-organisms among patients and subsequent spread of infection.

Proposed Classification

The agency has sought other information concerning the application of endodontic dry heat sterilizers in dentistry. Some of the literature indicates that endodontic dry heat sterilizers are more effective than other methods of sterilization such as isopropyl alcohol (70 percent), glutoraldehyde solution (buffered to 7.4), or sterile saline solution used with gauze sponges to wipe the instruments (Ref. 1). However, Dayoub, et al., (Ref. 2) found that a large degree of variation occurs among currently marketed endodontic dry heat sterilizers in terms of reaching and maintaining claimed temperature levels. Koehler and Hefferren (Ref. 3) found that large temperature gradients exist within the same endodontic dry heat sterilizer, which causes uneven heat transfer to instruments being sterilized.

FDA agrees with the Panel recommendation and is proposing that endodontic dry heat sterilizers be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness of injury to the patient because the device may fail to sterilize dental instruments adequately. In addition, the device is purported or represented to be for a use (sterilization of endodontic and other dental instruments) that is of substantial importance in preventing impairment of human health. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device

and that insufficient information exists to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Hubbard, T. M., et al., "Chairside Decontamination of Endodontic Files," *Oral Surgery*, (40):1, 148–152, July, 1975.

2. Dayoub, M. B., et al., "Endodontic Dry-Heat Sterilizer Effectiveness," *Journal of Endodontics*, (2):11.

3. Koehler, H. M., et al., "The Temperature Relations of Dental Instruments Heated in Root-Canal Instrument Sterilizers," *Journal of Dental Research*, 41:182, Jan.–Feb., 1962.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6730, to read as follows:

§ 872.6730 Endodontic dry heat sterilizer.

(a) *Identification.* An endodontic dry heat sterilizer is a device used to sterilize endodontic and other dental instruments by the application of dry heat. The heat is supplied through glass beads which have been heated by electricity.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4.62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39989 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3012]

Medical Devices; Classification of Air or Water Syringe Units

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying air or water syringe units into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of air or water syringe units:

1. Identification: An air or water syringe unit is a device consisting of a tube to deliver air or water to the patient's mouth that is used for the irrigation or drying of tooth or gum tissue. The device may be attached to a dental operative unit.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that air or water syringe units be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, air or water syringe units in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that air or water syringe units be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of air or water syringe units be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of air or water syringe units, the agency cannot make the required finding. To protect the public health, the agency

needs to be able to identify the firms manufacturing this device, to conduct necessary inspection and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant notifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of air or water syringe units be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirement, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel's recommendation that manufacturers of air or water syringe units be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of air or water syringe units having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6750, to read as follows:

§ 872.6750 Air or water syringe unit.

(a) *Identification.* An air or water syringe unit is a device consisting of a tube to deliver air or water to the patient's mouth that is used for the irrigation or drying of tooth or gum tissue. The device may be attached to a dental operative unit.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39990 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3014]

Medical Devices; Classification of Cartridge Syringes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cartridge syringes into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cartridge syringes:

1. Identification: A cartridge syringe is a device used to inject anesthetic agents subcutaneously or intramuscularly. The device consists of a metal syringe body into which a disposable, previously filled, glass carpule (a cylindrical cartridge) containing anesthetic is placed. After attaching a needle to the syringe body and activating the carpule by partially inserting the plunger on the syringe, the device is used to administer an injection to the patient.

2. Recommended classification Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the food manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that cartridge syringes be

classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, cartridge syringes in the practice of dentistry.

5. Risks to health: Adverse reaction: If the syringe is incapable of being aspirated, the drug may be injected directly into a blood vessel, thus causing an adverse reaction in the patient.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that cartridge syringes be classified into class II (performance standards).

FDA has reviewed the Panel recommendation and has sought other information and data describing the use of cartridge syringes in dentistry. Some of the literature discusses injection of local anesthetic agents used in dentistry into blood vessels. Schiano et al. (Ref. 1) found that 11 percent of mandibular (lower jawbone) blocks, 14.3 percent of sphenopalative blocks (in the region of the sphenoid and parietal bone), and 15.0 percent of posterior super alveolar nerve blocks (nerve at the back of the mouth) were positive, or showed presence of blood when aspirated, indicating the needle's, and drug's, entry into blood vessels. Although the incidence of fatalities from this event has been low (less than one death per 1 million administrations of local anesthetic (Refs. 1 and 2)), adverse responses to the anesthetic, such as headaches, nausea, and vomiting, occur in much higher frequency (Ref. 3). The agency believes that the device may present a potential unreasonable risk to the patient's health if the mechanism for aspiration is inadequate. That mechanism enables the practitioner to determine whether a blood vessel has been penetrated during injection procedures. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that cartridge syringes should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Schiano, A. M. and R. C. Strambi, "Frequency of Accidental Intravascular Injection of Local Anesthetic in Dental Practice," *Oral Surgery, Oral Medicine and Oral Pathology*, February 1964.

2. Seldin, H. M., "Survey of Anesthetic Fatalities in Oral Surgery and a Review of the Etiologic Factors in Anesthetic Deaths," *Journal of the American Dental Society of Anesthesiology, Inc.*, 5(6), February 1958.

3. Proch, R. C., "Post Injection Complications in Local Anesthesia and Their Treatment," *Journal of Kansas City District Dental Society*, Volume 34, April 1958.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6770, to read as follows:

§ 872.6770 Cartridge syringe.

(a) *Identification.* A cartridge syringe is a device used to inject anesthetic agents subcutaneously or intramuscularly. The device consists of a metal syringe body into which a disposable, previously filled, glass carpule (a cylindrical cartridge) containing anesthetic is placed. After attaching a needle to the syringe body and activating the carpule by partially inserting the plunger on the syringe, the device is used to administer an injection to the patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39991 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3016]

Medical Devices; Classification of Periodontic or Endodontic Irrigating Syringes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying periodontic or endodontic irrigating syringes into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–

62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of periodontic or endodontic irrigating syringes:

1. Identification: A periodontic or endodontic irrigating syringe is a device used for the irrigation of tissues in the mouth such as gums in periodontic therapy and root canals in teeth in endodontic therapy.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that periodontic or endodontic irrigating syringes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, periodontic or endodontic irrigating syringes in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that periodontic or endodontic irrigating syringes be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of periodontic or endodontic irrigating syringes be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of periodontic or endodnotic irrigating syringes, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modification of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of periodontic or endodontic irrigating syringes be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of periodontic or endodontic irrigating syringes be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of periodontic or endodontic irrigating syringes must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of periodontic or endodontic irrigating syringes must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 2166, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the

general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6800, to read as follows:

§ 872.6800 Periodontic or endodontic irrigating syringe.

(a) *Identification.* A periodontic or endodontic irrigating syringe is a device used for the irrigation of tissues in the mouth such as gums in periodontic therapy and root canals in teeth in endodontic therapy.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180., regarding general requirements, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39992 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–3017]

Medical Devices; Classification of Restorative or Impression Material Syringes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying restorative or impression material syringes into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of restoration or impression material syringes:

1. Identification: A restorative or impression material syringe is a device used in the placement of impression material (alginate) or restorative material (amalgam) in the oral cavity. It consists of a hollow tube syringe body with a plunger at one end and a narrow opening at the opposite end, through which the impression or restorative material is forced by the plunger.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that restorative or impression material syringes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no unreasonable risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, restorative or impression material syringes in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that restorative or impression material syringes be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of restorative or impression material syringes be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of restorative or impression material syringes, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of restorative or impression material syringes be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the dvice good manufacturing practice (GMP)

regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of restorative or impression material syringes be exempt from the device food manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of restorative or impression material syringes must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of restorative or impression material syringes must still be required to comply with general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulations is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6810, to read as follows:

§ 872.6810 Restorative or impression material syringe.

(a) *Identification.* A restorative or impression material syringe is a device used in the placement of impression material (alginate) or restorative material (amalgam) in the oral cavity. It consists of a hollow tube syringe body with a plunger at one end and a narrow opening at the opposite end, through which the impression or restorative material is forced by the plunger.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 8320.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39993 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3018]

Medical Devices; Classification of Rubber Tips for Oral Hygiene

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rubber tips for oral hygiene into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rubber tips for oral hygiene:

1. Identification: A rubber tip for oral hygiene is a device made of rubber that is intended to be used manually to stimulate and massage the gums to promote good periodontal (gum) condition. It is attached to a metal or plastic handle or to the handle of a toothbrush.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that rubber tips for oral hygiene be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, rubber tips for oral hygiene in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

The agency agrees with the Panel recommendation and is proposing that rubber tips for oral hygiene be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of rubber tips for oral hygiene be exempt from section 510(k) of the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration and device listing under section 510(a) through (j) of the act, but exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration and listing by manufacturers of rubber tips for oral hygiene, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device and to conduct necessary inspections. The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning rubber tips for oral hygiene. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

FDA disagrees with the Panel's recommendation that manufacturers of rubber tips for oral hygiene be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of rubber tips for oral hygiene be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of rubber tips for oral hygiene must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of rubber tips for oral hygiene must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register**.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6850, to read as follows:

§ 872.6850 Rubber tip for oral hygiene.

(a) *Identification.* A rubber tip for oral hygiene is a device made of rubber that is intended to be used manually to stimulate and massage the gums to promote good periodontal (gum) condition. It is attached to a metal or plastic handle or to the handle of a toothbrush.

(b) *Classification.* Class I (general controls). The device is exempt from the

premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39994 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3019]

Medical Devices; Classification of Manual Toothbrushes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual toothbrushes into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of manual toothbrushes:

1. Identification: A manual toothbrush is a device that is intended to be used to remove adherent plaque and food debris from the teeth to reduce tooth decay. It is composed of a shaft with either natural or synthetic bristles at one end.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that manual toothbrushes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, manual toothbrushes in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that manual toothbrushes be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of manual toothbrushes be exempt from section 510(k) the act (21 U.S.C. 360(k)), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510 (a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 520 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of manual toothbrushes, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, to conduct necessary inspections and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers or manual toothbrushes be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21

CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that manufacturers of manual toothbrushes be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of manual toothbrushes must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of manual toothbrushes must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6855, to read as follows:

§ 872.6855 Manual toothbrush.

(a) *Identification.* A manual toothbrush is a device that is intended to be used to remove adherent plaque and food debris from the teeth to reduce tooth decay. It is composed of a shaft with either natural or synthetic bristles at one end.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, regarding general requirements concerning records and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39995 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3020]

Medical Devices; Classification of Powered Toothbrushes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered toothbrushes into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered toothbrushes:

1. Identification: A powered toothbrush is an AC or battery-powered device that is intended to be used to remove plaque and food particles from the teeth to reduce tooth decay. It consists of a handle containing a motor that provides mechanical vibrations to a toothbrush that is inserted in one end.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that powered toothbrushes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements, and the good manufacturing practice regulation, because this is a simple device that presents no undue risks to

health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel Members' personal knowledge of, and clinical experience with, powered toothbrushes in the practice of dentistry.

5. Risks to health: Electrical shock: Improper electrical design of the device may cause electrical shock to the patient.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that power toothbrushes be classified into class II (performance standards). The agency believes that a level of vibration must be controlled to prevent injury to soft tissue and excessive abrasion to teeth, and that the electrical design of the device must be controlled to prevent electrical shock. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that powered toothbrushes should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the premarket notification procedures under section 510(k), the records and reports requirements under section 519, and the good manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6865, to read as follows:

§ 872.6865 Powered toothbrush.

(a) *Identification.* A powered toothbrush is an AC or battery-powered device that is intended to be used to remove plaque and food particles from the teeth to reduce tooth decay. It consists of a handle containing a motor that provides mechanical vibrations to a toothbrush that is inserted in one end.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39996 Filed 12–29–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 872

[Docket No. 78N–3021]

Medical Devices; Classification of Disposable Fluoride Trays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying disposable fluoride trays into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of disposable fluoride trays:

1. Identification: A disposable fluoride tray is a device made of styrofoam that is used for the topical application of fluoride to the teeth. To employ the tray, the patient bites down on the tray which has been filled with a fluoride solution.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that disposable fluoride trays be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, disposable fluoride trays in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that

disposable fluoride trays be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

FDA disagrees with the Panel's recommendation that manufacturers of disposable fluoride trays be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

FDA disagrees with the Panel's recommendation that manufacturers of disposable fluoride trays be exmpt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f). The agency believes that compliance with this regulation is necessary to assure the quality of this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of disposable fluoride trays having defects that could harm users.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the Federal Register of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the Federal Register.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart B by adding new § 872.6870, to read as follows:

§ 872.6870 Disposable fluoride tray.

(a) *Identification.* A disposable fluoride tray is a device made of styrofoam that is used for the topical application of fluoride to the teeth. To employ the tray, the patient bites down on the tray which has been filled with a fluoride solution.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before March 2, 1981 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39997 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 872

[Docket No. 78N-3022]

Medical Devices; Classification of Preformed Impression Trays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed impression trays into class I (general controls). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of preformed impression trays:

1. Identification: A preformed impression tray is a metal or plastic device that is used to hold impression material, such as alginate, during the making of an impression of a patient's teeth or alveolar process (bony tooth sockets). The impression is used to reproduce the structure of a patient's teeth and gums.

2. Recomended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), records and reports requirements under section 519 of the act (21 U.S.C. 360i), and the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that preformed impression trays be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The materials used in the device

that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with premarket notification procedures, records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, preformed impression trays in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that preformed impression trays be classified into class I (general controls). The agency believes that general controls are sufficient to control the risks to health presented by the device.

In response to the Panel's recommendation that manufacturers of preformed impression trays be exempt from section 510(k) of the act (21 U.S.C. 360), FDA is proposing that these manufacturers be subject to registration, device listing, and premarket notification under section 510(a) through (k) of the act. Under section 510(g)(4) of the act, the agency may exempt a manufacturer from section 510 only if it finds that compliance with this section is not necessary for the protection of the public health. In the case of registration, listing, and premarket notification by manufacturers of preformed impression trays, the agency cannot make the required finding. To protect the public health, the agency needs to be able to identify the firms manufacturing this device, and to receive premarket notification from manufacturers to assure that FDA learns of new devices and of significant modifications of existing devices for which premarket approval is required.

FDA disagrees with the Panel's recommendation that manufacturers of preformed impression trays be exempt from records and reports regulation under section 519 of the act (21 U.S.C. 360i). The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation, published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempt from the requirements, and FDA will issue exemptions that are appropriate. The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from requirements of the device GMP regulation. The exemption will not extend to two device GMP requirements, § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files.

In response to the Panel's recommendation that maunfacturers of preformed impression trays be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacure of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of preformed impression trays must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of preformed impression trays must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6880, to read as follows:

§ 872.6880 Preformed impression tray.

(a) *Identification.* A preformed impression tray is a metal or plastic device that is used to hold impression material, such as alginate, during the making of an impression of a patient's teeth or alveolar process (body tooth sockets). The impression is used to reproduce the structure of a patient's teeth and gums.

(b) *Classification.* Class I (general controls). This device is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–39998 Filed 12–29–80; 8:45 am]

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21 CFR Part 872

[Docket No. 78N-3023]

Medical Devices; Classification of Intraoral Dental Waxes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intraoral dental waxes into class II (performance standards). FDA is also publishing the recommendation of the Dental Device Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by March 2, 1981. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gregory Singleton, Bureau of Medical Devices (HFK-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7536.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Dental Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of intraoral dental waxes:

1. Identification: Intraoral dental wax is a device made of wax that is used to construct patterns from which custom made metal dental prostheses, such as crowns and bridges, are cast. In orthodontic dentistry, the device is used to make a pattern of the patient's bite so that crowns and bridges have the proper biting surface contact.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) and from the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that intraoral dental waxes be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device has been used in dentistry for many years. The device materials that contact the body have known and acceptable properties. The Panel believes that manufacturers of this device should not be required to comply with records and reports requirements and the good manufacturing practice regulation because this is a simple device that presents no undue risks to health when used in a normal manner and for the purpose recommended.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, intraoral dental waxes in the practice of dentistry.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that intraoral dental waxes be classified into class II (performance standards). The properties of the materials used to form intraoral dental waxes depend upon the proper composition of these materials. Moreover, intraoral dental waxes directly contact oral tissue. Altering the composition of the materials used in the device or the contamination of the materials with other substances may lead to adverse tissue reactions, thus placing the patient unnecessarily at risk. The agency believes that a performance standard is necessary for this device because general controls alone are insufficent to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Because the agency has determined that intraoral dental waxes should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the Panel recommendation that this device be exempt from the records and reports requirements under section 519 and the food manufacturing practice regulation under section 520(f) of the act.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). This proposed classification regulation identifies each device panel by the former name. Further information regarding the device advisory committees and list of their new names may be found in the preamble to the general provisions, published elsewhere in this issue of the **Federal Register.**

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371 (a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 872 in Subpart G by adding new § 872.6890, to read as follows:

§ 872.6890 Intraoral dental wax.

(a) *Identification.* Intraoral dental wax is a device made of wax that is used to construct patterns from which custom made metal dental prostheses, such as crowns and bridges, are cast. In orthodontic dentistry, the device is used to take a pattern of the patient's bite so that crowns and bridges have the proper biting surface contact.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 2, 1981, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

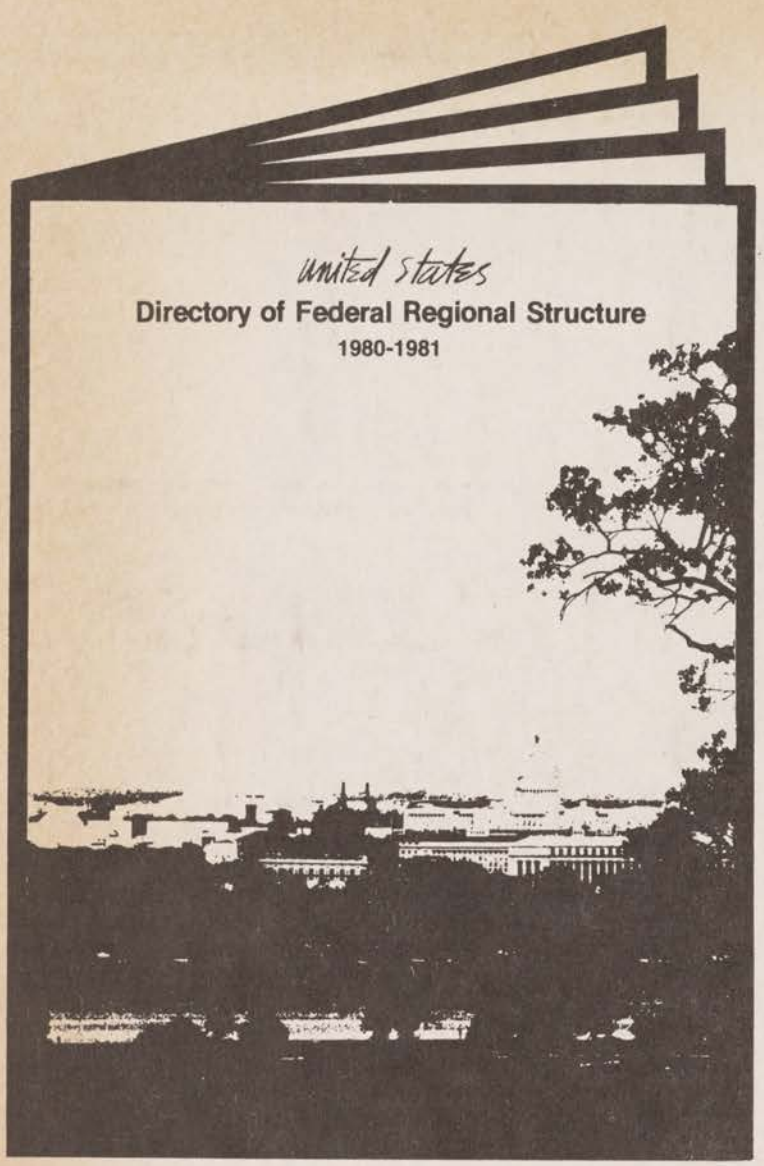
Dated: November 19, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-39999 Filed 12-29-80; 8:45 am]

BILLING CODE 4110-03-M



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Part IV

Department of Labor

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 12–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions are effective from their date of publication in the **Federal Register** without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

Modifications and Supersedeas Decisions to General Wage Determination Decisions

Modifications and supersedeas decisions to general wage determination decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the modifications and supersedeas decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24–70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's orders 13–71 and 15–71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing general wage determination decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and supersedeas decisions are effective from their date of publication in the **Federal Register** without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Office of Government Contract Wage Standards, Division of Government Contract Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Determination Decision.

New General Wage Determination Decisions

None.

Modifications to General Wage Determination Decisions

The numbers of the decisions being modified and their dates of publication in the **Federal Register** are listed with each State.

Arkansas:	
AR80–4079	Nov. 7, 1980.
AR80–4080	Oct. 31, 1980.
AR80–4082	Nov. 7, 1980.
Florida:	
FL79–1039	Feb. 16, 1979.
FL79–1110	July 20, 1979.
Kentucky: KY80–1093	Aug. 22, 1980.
Maine: ME80–2069	Aug. 15, 1980.
Montana:	
MT80–5141	Nov. 21, 1980.
MT80–5142	Do.
MT80–5143	Do.
Mississippi: MS80–1121	Dec. 12, 1980.
North Dakota: ND80–5132	Oct. 10–1980.
New Jersey: NJ80–3024	May 2, 1980.
Pennsylvania:	
PA80–3011	Feb. 22, 1980.
PA80–3012	Feb. 15, 1980.
PA80–3029	Apr. 25, 1980.
PA80–3055	Oct. 3, 1980.
PA80–3056	Sept. 12, 1980.
PA80–3058	Oct. 3, 1980.
PA80–3059	Oct. 3, 1980.

Supersedeas Decisions to General Wage Determination Decisions

The numbers of the decisions being superseded and their dates of publication in the **Federal Register** are listed with each State. Supersedeas decision numbers are in parentheses following the numbers of the decisions being superseded.

Alabama:	
AL79–1079 (AL81–1122)	May 4, 1979.
AL80–1014 (AL81–1123)	Feb. 1, 1980.
AL78–1094 (AL81–1124)	Nov. 13, 1978.
AL78–1045 (AL81–1125)	May 5, 1978.
AL77–1064 (AL81–1126)	May 13, 1977.
AL77–1071 (AL81–1127)	June 3, 1977.
AL79–1121 (AL81–1128)	Oct. 5, 1979.
AL77–1063 (AL81–1129)	May 13, 1977
AL77–1066 (AL81–1130)	Do.
AL79–1150 (AL81–1131)	Dec. 28, 1979.
AL79–1152 (AL81–1132)	Do.
AL80–1043 (AL81–1133)	Jan. 25, 1980.
AL79–1151 (AL81–1134)	Dec. 28, 1979.
New York: NY80–3002 (NY80–3079)	Jan. 18, 1980.

North Carolina:
NC80-1022 (NC81-1135) ..... Jan. 4, 1980.
NC78-1035 (NC81-1137) ..... Apr. 14, 1978.
NC80-1021 (NC81-1138) ..... Jan. 4, 1980.
NC80-1019 (NC81-1139) ..... Do.
NC80-1024 (NC81-1140) ..... Do.
NC80-1026 (NC81-1141) ..... Do.
NC78-1036 (NC81-1142) ..... Apr. 14, 1978.
NC80-1025 (NC81-1143) ..... Jan. 4, 1980.
NC77-1135 (NC81-1144) ..... Nov. 11, 1977.
NC80-1023 (NC81-1145) ..... Jan. 4, 1980.
NC78-1027 (NC81-1146) ..... Mar. 24, 1978.
NC78-1037 (NC81-1147) ..... Apr. 14, 1980.
NC79-1125 (NC81-1148) ..... Sept. 7, 1979.
NC78-1061 (NC81-1149) ..... July 7, 1978.
NC79-1107 (NC81-1151) ..... Aug. 17, 1979.
NC80-1017 (NC81-1152) ..... Jan. 4, 1980.
South Carolina: SC78-1087 (SC81-1150) .... Oct. 13, 1978.

Cancellation of General Wage Determination Decisions

The general wage decisions listed below are cancelled. Agencies with construction projects pending to which one of the cancelled decisions would have been applicable should utilize the project determination procedure by submitting Form SF-308. See Regulations Part 1 (29 CFR), § 1.5. Contracts for which bids have been opened shall not be affected by this notice. Also consistent with 29 CFR 1.7(b)(2), the incorporation of one of the cancelled decisions in contract specifications, the opening of bids is within ten (10) days of this notice, need not be affected.

LA77-4031—Ouachita Parish, Louisiana, dated February 18, 1977 in 42 FR 10237—Residential Construction
AZ80-5123—Maricopa County, Arizona, dated August 1, 1980 in 45 FR 51393—Residential Construction

This is to advise all interested parties that the Department of Labor intends to withdraw 14 days from the date of this notice the following general wage determination: AZ80-5124—Pima County, Arizona, dated August 1, 1980, in 45 FR 51388—Residential Construction.

Signed at Washington, D.C., this 19th day of December 1980.

Dorothy P. Come,

Assistant Administrator, Wage and Hour Division.

BILLING CODE 4510-27-M

MODIFICATION P. 1

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #AR80-4079-Mod.#2					
45FR74344-November 7, 1980					
Garland, Hot Springs and Clark Counties, Arkansas					
CHANGE:					
ELECTRICIANS:					
Electricians	$11.57		3%+1.00		1/4%
Cable splicers	11.695		3%+1.00		1/4%
DECISION #AR80-4080-Mod.#3					
45FR72439-October 31, 1980					
Jefferson County, Arkansas					
CHANGE:					
ELECTRICIANS:					
Electricians	12.35	.55	3%+1.35		1/4%
Cable splicers	12.475	.55	3%+1.35		1/4%
DECISION #AR80-4082-Mod.#2					
45FR74345-November 7, 1980					
Union & Ouachita Counties, Arkansas					
CHANGE:					
ELECTRICIANS:					
Electrical contracts over $20,000.00:					
Electricians	13.18		3%		1/4%

MODIFICATION P. 2

Decision #FL79-1039 - Mod #5	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
(44 FR 10228 - February 16, 1979)					
Volusia County (except Cape Kennedy Space Flight Center and Cape Canaveral Air Force Station, Florida)					
Change:					
Asbestos Workers	12.59	.55	1.10		.08
Boilermakers	11.75	1.275	1.10		.04
Electricians:					
Base Zone (within 40 miles Daytona Beach					
Electricians	10.04	.50	3% + .83		.05
Cable Splicers	10.29	.50	3% + .83		.05
Zone I (all work beyond 40 miles from Daytona Beach and not accessible by public roads & including power generation plants and industrial over 3,000,000 total permit):					
Electricians	11.42	.50	3% + .83		.05
Cable Splicers	11.67	.50	3% + .83		.05
Elevator Constructors:					
Mechanic	10.455	1.045	.82	a+b	.035
Helper	7.32	1.045	.82	a+b	.035
Ironworkers	11.28	.80	.90	.65	.05
Millwrights	12.17	.70	.70		.10
Painters					
Brush & Roller	8.95	.50	.45		.06
Paperhangers, Sandblasters & Spray	9.45	.50	.45		.06
Plumbers:					
Commercial	11.45	.60	.60		.05
Industrial	14.40	.60	.60		.05
Roofers					
Roofers	8.90	.35	.25		
Kettlemen	7.45	.35	.25		

Decision #FL79-1039 - Mod. #5 cont.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Sheet Metal Workers	10.96	.55+3%	.44		.08
Sprinkler Fitters	12.40	.85	1.20		.10

DECISION NO. FL79-1110- MOD. #8
(44FR 42858 - July 20, 1979)
Dade County, Florida

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Elevator Constructors					
Mechanic	12.84	1.195	.95		.035
Helper	8.99	1.195	.95		.035
Probationary Helper	6.42				
Millwrights	12.17	.70	.70		.10
Sprinkler Fitters	12.40	.85	1.20		.10

DECISION NO. KY80-1093 - MOD. #2
(45FR 56287-56290, August 22, 1980)
Boone, Cambell, Kenton, and Pendleton Counties, KY.

Change:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Boilermakers	12.50	1.275	1.20	2.00	.04
Bricklayers & Stonemasons	14.945	.80	.45		.02
Sheet Metal Workers Pendleton County	14.19	1.607	1.61		.16

MODIFICATION P. 5

DECISION NO. ME80-2069 - (45 FR 54614 - August 15, 1980) Cumberland County, Maine	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
Sheet Metal Workers	$ 9.46	.62	.465		.07

MODIFICATION P. 6

DECISION NO. MT80-5141 Mod. No. 1
(45 FR 77286 November 21, 1980)

STATEWIDE, MONTANA	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
Electricians					
Area 2					
Electricians	$14.55	.70	3%+.75		½%
Cable Splicers	15.00	.70	3%+.75		½%
Plumbers					
Area 4	15.90	1.00	1.10		.20

DECISION NO. MT80-5142 Mod. #1
(45 FR 77295 November 21, 1980)

STATEWIDE, MONTANA	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
Asbestos Workers	$16.69	.78	1.45		.04
Electricians					
Area 2					
Electricians	14.55	.70	3%+.75		½%
Cable Splicers	15.00	.70	3%+.75		½%
Laborers					
Flathead, Glacier National Park, Lincoln, and that area of Lake and Sanders Cos. lying 5 miles north of the 5th parallel.					
Group 1	9.90	.70	.60	.20	.05
Group 2	10.05	.70	.60	.20	.05
Group 3	10.20	.70	.60	.20	.05
Laborers					
Daniels, Garfield, Petroleum, Phillips, Richland, Roosevelt, Sheridan, and Valley Counties.					
Group 1	9.80	.70	.60	.20	.05
Group 2	10.05	.70	.60	.20	.05
Group 3	10.15	.70	.60	.20	.05
Group 4	10.20	.70	.60	.20	.05
Group 5	10.30	.70	.60	.20	.05
Group 6	10.35	.70	.60	.20	.05
Plumbers					
Area 4	15.90	1.00	1.10		.20
Carpenters					
Area 6					
Carpenters	11.28	.80	.75		.02
Millwrights	12.28	.80	.75		.02
Pildrivermen	11.53	.80	.75		.02

DECISION NO. MT80-5142 Mod. #1 cont'd

ADD:

POWER EQUIPMENT OPERATORS Big Horn, Carter, Custer, Fallon, Musselshell, Powder River, Rosebud, Treasure, Yellowstone, Stillwater, Carbon, Sweetgrass, Golden VAlley, Petroleum, Garfield, and Prairie Counties.	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
A-Frame Truck Crane Oper.	$11.94	.87	.75	.50	.07
Air Compressor Oper., single	11.68	.87	.75	.50	.07
Asphalt Paving Machine Oper.	12.19	.87	.75	.50	.07
Air Doctor	12.19	.87	.75	.50	.07
Belt Finishing Operator	11.86	.87	.75	.50	.07
Bit Grinder	12.19	.87	.75	.50	.07
Bituminous Mixer Operator	12.19	.87	.75	.50	.07
Bulldozer Operator	12.19	.87	.75	.50	.07
Boring Machine Oper., small	11.75	.87	.75	.50	.07
Boring Machine Oper., large	12.19	.87	.75	.50	.07
Cableway Operator	12.71	.87	.75	.50	.07
Cement Silo Operator	11.96	.87	.75	.50	.07
Concrete Batch Plant Oper.	12.08	.87	.75	.50	.07
Concrete Finish Machine, paving	12.19	.87	.75	.50	.07
Concrete Float Operator and Spreader	12.19	.87	.75	.50	.07
Conveyor Operator	11.89	.87	.75	.50	.07
Chip & Gravel Spreader	11.89	.87	.75	.50	.07
Crane Operator, to & including 80' boom	12.35	.87	.75	.50	.07
Crane Operator, 81' to 130' boom	12.50	.87	.75	.50	.07
Crane Operator, 131' to 150' boom	12.55	.87	.75	.50	.07
Crane Operator, 151' to 170' boom	12.60	.87	.75	.50	.07
(An additional 5¢ per hour is added for each 20' of boom)					
All cranes with jibs, an additional 25¢ per hour is added to above crane rates.					

DECISION NO. MT80-5142 Mod. #1 (cont'd)

POWER EQUIPMENT OPERATORS:
(Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Crane Oiler-Driver, rubber tired	$11.74	.87	.75	.50	.07
Electric Overhead Crane Operator	12.38	.87	.75	.50	.07
Crusher and/or Screening Plant Operator, portable	12.19	.87	.75	.50	.07
Crusher and/or Screening Plant Tender, if over 2 units	11.68	.87	.75	.50	.07
Crusher and/or Screening Plant Operator, Stationary	12.08	.87	.75	.50	.07
Distributor Operator	12.19	.87	.75	.50	.07
Drilling Machine Operator, does not include Jack-hammer, Wagondriller, Waterliner	12.09	.87	.75	.50	.07
Euclid Loader & similar type	12.28	.87	.75	.50	.07
Tractor, rubber-tired, Industrial	11.63	.87	.75	.50	.07
Elevating Grader	12.19	.87	.75	.50	.07
Field Equipment Serviceman	12.09	.87	.75	.50	.07
Fireman	11.75	.87	.75	.50	.07
Fork Lift, on construction site	11.98	.87	.75	.50	.07
Front End Loader, rubber-tired, under 1 yd	11.88	.87	.75	.50	.07
Front End Loader, lyd. and including 3 yds.	12.19	.87	.75	.50	.07
Front End Loader, rubber-tired, over 3 yds. and including 5 yds.	12.32	.87	.75	.50	.07
Front End Loader, rubber-tired, over 5 yds. and including 10 yds.	12.42	.87	.75	.50	.07
Front End Loader, rubber-tired, over 10 yds. and including 15 yds.	12.52	.87	.75	.50	.07
Front End Loader, rubber-tired, over 15 yds. (Factory struck rating, not to include sideboards)	11.89	.87	.75	.50	.07

DECISIONS NO. MT80-5142 Mod. #1

POWER EQUIPMENT OPERATORS: (cont'd)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Grade Setter	$11.65	.87	.75	.50	.07
Heavy Duty Drills-Rotary-Quarry Master	12.19	.87	.75	.50	.07
Heavy Duty Rotary Drill Tender	11.64	.87	.75	.50	.07
Helicopter Hoist Operator	12.69	.87	.75	.50	.07
Herman Nelson Heaters & Similar type	11.65	.87	.75	.50	.07
Hoist Operator, single drum	11.94	.87	.75	.50	.07
Hoist Operator, two or more drums	12.19	.87	.75	.50	.07
Hot Plant Operator	12.19	.87	.75	.50	.07
Hot Plant Fireman	12.19	.87	.75	.50	.07
Industrial Locomotive	12.19	.87	.75	.50	.07
LeTourneau Operator, single and similar type	12.32	.87	.75	.50	.07
LeTourneau Operator, tandem and similar type	12.49	.87	.75	.50	.07
Loaders, Barber Green & similar types	11.10	.87	.75	.50	.07
Mechanic and/or Welder on job	12.29	.87	.75	.50	.07
Mechanic and/or Welder Tender	11.64	.87	.75	.50	.07
Mixer Operator, concrete, 3 bags or under	11.75	.87	.75	.50	.07
Mixer Operator, concrete, 4 bags or over	12.00	.87	.75	.50	.07
Mixermobile	12.28	.87	.75	.50	.07
Motor Patrol Operator	12.32	.87	.75	.50	.07
Mucking Machine Operator	12.19	.87	.75	.50	.07
Oiler	11.64	.87	.75	.50	.07
Pavement breaker, Emsco & similar type	12.19	.87	.75	.50	.07
Paver Mixer Operator	12.19	.87	.75	.50	.07
Power Saw Operator-self-propelled, multiple cut	12.19	.87	.75	.50	.07
Pumpcrete or Grout Machine Operator	12.19	.87	.75	.50	.07
Pumpman	11.69	.87	.75	.50	.07
Quad Cat	12.49	.87	.75	.50	.07

DECISION NO. MT80-5142 Mod. #1

POWER EQUIPMENT OPERATORS:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Retort Operator	$11.75	.87	.75	.50	.07
Roller Operator, grade or finish	11.88	.87	.75	.50	.07
Roller Operator, finish high type pavement	12.19	.87	.75	.50	.07
Ross & similar type carriers, on construction site	12.19	.87	.75	.50	.07
Roller, 25 ton or over	12.19	.87	.75	.50	.07
Screed Operator	12.19	.87	.75	.50	.07
Shovels, including all attachments under 1 yd.	12.19	.87	.75	.50	.07
Shovels, including all attachments 1 yd. to and including 4 yds.	12.38	.87	.75	.50	.07
Shovels, over 4 yds.	12.68	.87	.75	.50	.07
Shovel Oiler for shovel over 4 yds. (.50¢ per hour under shovel operator)					
Stiff Leg & Guy Derrick Operator	12.68	.87	.75	.50	.07
Tournapull, DW 20, 21, & similar type	12.38	.87	.75	.50	.07
Scraper, twin engine	12.42	.87	.75	.50	.07
Scraper, tandem, 3 engine	12.68	.87	.75	.50	.07
Track type tractor, with or without attachments incl. track-type loader, front end up to & incl. 5 yds.	12.19	.87	.75	.50	.07
Track type front end loaders, over 5 yds. to and incl. 10 yds.	12.42	.87	.75	.50	.07
Track type front end loaders, over 10 yds. to and incl. 15 yds.	12.52	.87	.75	.50	.07
Track type front end loaders, over 15 yds.	12.62	.87	.75	.50	.07
Traxcavator, & Athey type loader	12.19	.87	.75	.50	.07

DECISION NO. MT80-5142 Mod. # 1

POWER EQUIPMENT OPERATORS:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Trench Machine Operator	$12.13	.87	.75	.50	.07
Wagner Roller & Similar type	12.19	.87	.75	.50	.07
Winch Truck Operator with hydraulic boom	12.09	.87	.75	.50	.07
Tower Crane	12.68	.87	.75	.50	.07
Automatic Finegrader, Gurries and similar type	12.32	.87	.75	.50	.07
Concrete Conveyor, under 40'	11.77	.87	.75	.50	.07
Concrete Conveyor, over 40'	12.52	.87	.75	.50	.07
Concrete Pump	12.52	.87	.75	.50	.07
Raygo Giant	12.77	.87	.75	.50	.07
Quad Loader & similar type	12.77	.87	.75	.50	.07
Leadman: 25¢ per hour above highest paid oper.					
Elevator Constructor Helper	9.54	1.045	.82	a	.035
Probationary Helper	6.82	1.045	.82	a	.035

DECISION NO. MT80-5143 Mod. #1
(45 FR 77311 November 21,1980)

Cascade, Deer Lodge, Hill, Gallatin, Glacier, Missoula, Silver Bow, and Valley Counties	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
Asbestos Workers	$16.69	.78	1.45		.04
Carpenters					
Area 8					
Carpenter	11.28	.80	.75		.02
Millwrights	12.28	.80	.75		.02
Piledrivermen	11.53	.80	.75		.02
Ironworkers					
Area 2	13.21	.90	1.45		.04
Laborers					
Valley County					
Group 1	9.80	.70	.60	.20	.05
Group 2	10.05	.70	.60	.20	.05
Group 3	10.15	.70	.60	.20	.05
Group 4	10.20	.70	.60	.20	.05
Group 5	10.30	.70	.60	.20	.05
Group 6	10.55	.70	.60	.20	.05
ADD:					
Elevator Constructors					
Helper	9.54	1.045	.82	a	.035
Probationary Helper	6.82	1.045	.82	a	.035

DECISION NO. MS80-1121, Mod. #1
(December 12, 1980, 45 FR 81975)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
Description of Work to read: Heavy Construction (including Water & Sewer Lines) excluding all work in conjunction with the Tennesse Tombigbee Waterway Project.					

DECISION NO. ND80-5132 - Mod #1
(45 Fr 67525 - Oct. 10, 1980)

Burleigh, Cass, Grand Forks, Morton, Richland, Steele, Traill, Walsh, and Ward Counties, North Dakota	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
LABORERS:					
Building Construction:					
Grand Forks, Steele, and Traill Counties					
Group 1	$8.22	.50	.15		
Group 2	8.37	.50	.15		
Group 3	8.57	.50	.15		
Burleigh and Morton Counties					
Group 1	7.85	.50	.15		
Group 2	7.95	.50	.15		
Group 3	8.05	.50	.15		
Cass and Richland Counties					
Group 1	7.89	.50	.15		
Group 2	7.99	.50	.15		
Group 3	8.04	.50	.15		
Ward County					
Group 1	7.89	.50	.15		
Group 2	7.99	.50	.15		
Group 3	8.14	.50	.15		

DECISION NO. NJ80-3024 - MOD. #3 (45 FR 29515 - May 2, 1980) Bergen, Essex, Hudson and Passaic Counties, New Jersey	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
ASBESTOS WORKERS	15.04	1.41	1.67		.04
DOCKBUILDERS & PILEDRIVERMEN	13.25	1.85	1.78	1.01	.05
ELECTRICIANS & CABLE SPLICERS:					
Other Residential Construction:					
Bergen & Hudson Cos.	15.35	12%	9%+.58		.5%
GLAZIERS:					
Essex & Hudson Counties	13.45	1.00	2.00		.05
IRONWORKERS-STRUCURAL, ORNAMENTAL & REINFORCING	13.35	1.05	2.85	1.15	.11
LABORERS:					
Zone 6					
Group 1	8.50	.75	1.25		.10

DECISION NO. PA80-3011 MOD. NO. 5 (45 FR 12118 - February 22, 1980) Greene, Somerset & Potter Counties, Pennsylvania	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
Truck Drivers:					
Zone 1					
Class 1	$8.27	a	b		
Class 2	8.35	a	b		
Class 3	8.42	a	b		
Class 4	8.17	a	b		
DECISION NO. PA80-3012 MOD. NO. 5 (45 FR 10595 - February 15, 1980) Armstrong, Allegheny, Beaver, Butler, Fayette, Indiana, Washington, Westmoreland Counties, Pennsylvania					
CHANGE:					
Painters:					
Zone 1					
Commercial					
Brush	13.33	.90	.80		.03
Paperhangers	13.33	.90	.80		.03
Spray	13.83	.90	.80		.03
Industrial					
Brush	13.88	.90	.80		.03
Spray	14.38	.90	.80		.03

DECISION NO. PA80-3029
MOD. NO. 6
(45 FR 28069 - April 25, 1980)
Lebanon County, Pennsylvania

CHANGE:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Electricians:					
That portion of Lebanon County which extends South and East of Interstate Route 81	$11.59	.65	3%+.67		1/4%
Painters:					
West of Route 72					
Brush	10.27	.45	.38		.02
Structural Steel	10.72	.45	.38		.02
Spray	11.02	.45	.38		.02
Plumbers:					
East of Route 501	13.83	.85	1.40		.14
West of Route 501	11.80	1.00	1.00		.12
Steamfitters:					
East of Route 501	13.86	.80	1.45		.11
West of Route 501	11.80	1.00	1.00		.14

DECISION NO. PA80-3055
MOD. NO. 2
(45 FR 65902 - October 3, 1980)
Bucks, Chester, Delaware, Montgomery & Philadelphia Counties, Pennsylvania

CHANGE:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Glaziers					
Zone 1	$11.93	.95	1.80		.01
Plumbers					
All other work					
Zone 1	14.23	.85	1.40		.14
Zone 2	13.83	.85	1.40		.14
Steamfitters					
Zone 1	14.26	.80	1.45		.11
Zone 2	13.86	.80	1.45		.11

AREA COVERED BY STEAMFITTERS ZONES

ZONE - 1 - Chester, Delaware, Montgomery, Philadelphia Counties, Remainder of Bucks County

ZONE - 2 - Bucks County; Townships of Bridgton, Durham, Haycock, Milford, Nockamixon, Richland, East Rockhill, West Rockhill and Springfield

DECISION NO. PA80-3056
MOD. NO. 1
(45 FR 60748 - September 12, 1980)
Lackawanna, Susquehanna, Wayne and Wyoming Counties, Pennsylvania

CHANGE:

Bricklayers & Stonemasons:					
Susquehanna & Wyoming Cos.	11.35	1.05	.95		
Carbondale in Lackawanna Co.	11.85	1.50	.40		

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION NO. PA80-3058					
MOD. NO. 1					
(45 FR 65898 - October 3, 1980)					
Lawrence & Mercer Counties, Pennsylvania					
CHANGE:					
Soft floor layers:					
Lawrence County	$12.30	.76	.81	.51	.05
Sheet metal workers	13.75	1.12	1.66		.23
DECISION NO. PA80-3059					
MOD. NO. 1					
(45 FR 65895 - October 3, 1980)					
Erie County, Pennsylvania					
CHANGE:					
Electricians	14.55	.72	3%+.28	.75	½ of 1%
Painters:					
Brush	11.10	.60	.50		.02
Structural Steel	11.85	.60	.50		.02
Spray	11.60	.60	.50		.02
Plumbers	14.12	.75	1.05		.06
Steamfitters	14.12	.75	1.05		.06
Sheet metal workers	13.75	1.12	1.66		.23

STATE: ALABAMA

COUNTIES: Calhoun, Cherokee, DeKalb, Cleburne, and Etowah.

DECISION NUMBER: AL81-1122

DATE: Date of Publication

Supersedes Decision No.: AL79-1079, May 4, 1979 in 44 FR 26405

DESCRIPTION OF WORK: Residential construction consisting of single family homes and apartments up to and including four stories

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air conditioning/heating mechanic	$ 3.75				
Bricklayers	7.00				
Carpenters	6.15				
Concrete finishers	4.50				
Drywall finishers	6.00				
Drywall hangers	6.00				
Electricinas	10.45				
Insulators	4.65				
Laborers	3.35				
Painters:					
brush	6.00				
Plumbers & Pipefitters	7.95	.40	.35		
Power Equipment Operators:					
bulldozer	5.00				
Roofers	8.00				
Sheet Metal workers	4.35				
Soft floor layers	6.25				
Welders - receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: ALABAMA COUNTY: MONTGOMERY
DECISION NUMBER: AL81-1123 DATE: Date of Publication
Supersedes Decision No.: AL80-1014, February 1, 1980 in 45 FR 7441
DESCRIPTION OF WORK: Building Construction(does not include residential construction consisting of single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air conditioning mechanics	5.72				
Bricklayers	7.15				
Carpenters	5.66				
Form setters	3.35				
Cement masons	4.15				
Electricians	7.58				
Elevator constructors	10.56	.895	.69	a+b	.03
Glaziers	7.15	.50	.40		
Ironworkers, structural & ornamental	4.40				
Ironworkers, reinforcing	4.00				
Laborers:					
Laborers	3.35				
Asphalt raker	3.75				
Pipelayers	4.00				
Lathers	6.75				
Painters:					
Brush	5.90				
Sandblasters and spray	7.80		.40		
Plasterers	5.75				
Plumbers & pipefitters	6.60				
Roofers	4.67				
Kettlemen	3.50				
Sheet metal workers	5.81				
Soft floor layers	5.41				
Sprinkler fitters	6.45				
Tile setters	6.00				
Truck drivers	3.75				
Welders - rate for craft					
POWER EQUIPMENT OPERATORS:					
Asphalt rollers	4.75				
Asphalt spreader	5.25				
Backhoe	4.90				
Bulldozers	6.00				
Crane operator	6.61				
Finishing machine	4.00				
Front end loader	4.85				
Motor grader	6.00				
Motor patrol	8.51				
Piledriver	5.50				
Screed operator	3.50				
Tractor	3.75				

FOOTNOTES:
a. Six paid holidays

b. Employer contributes 8% of basic hourly rate for over 5 years service and 6% for 6 months to 5 years service as vacation pay credit.

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: ALABAMA
DECISION NUMBER: AL81-1124
COUNTIES: *See below
DATE: Date of Publication
Supersedes Decision NO.: AL78-1094, November 13, 1978 in 43 FR 52633
DESCRIPTION OF WORK: Residential construction consisting of single family homes and apartments up to and including four stories

*Counties: Autauga, Bullock, Butler, Chilton, Clarke, Conecuh, Coosa, Crenshaw, Dallas, Elmore, Lowndes, Monroe, Montgomery, Pike, and Wilcox.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air conditioning mechanics	$5.69				
Bricklayers	6.13				
Carpenters	4.50				
Cement Masons	4.50				
Drywall finishers	4.55				
Drywall hangers	4.50				
Electricians	8.53				
Laborers	3.35				
Painters:					
brush	5.35				
Plumbers & Pipefitters	5.87				
Power Equipment Operators:					
backhoe	4.00				
bulldozer	4.36				
loader	4.00				
motor grader	4.00				
Roofers	7.00				
Soft floor layers	3.35				
Tile setters	4.94				

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: ALABAMA
DECISION NUMBER: AL81-1125
COUNTIES: *See below
DATE: Date of Publication
Supersedes Decision No.: AL78-1045, May 5, 1978 in 43 FR 19541
DESCRIPTION OF WORK: Residential construction consisting of single family homes and apartments up to and including four stories

*Counties: Barbour, Coffee, Covington, Dale, Geneva, Henry, Houston, and Russell.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air conditioning mechanic	$5.25				
Bricklayers	5.00				
Carpenters	4.16				
Cement Masons	4.00				
Drywall finishers	5.50				
Drywall hangers	5.00				
Electricians	3.50				
Insulators	3.35				
Laborers	3.35				
Painters:					
brush	5.00				
Plumbers & Pipefitters	4.05				
Power Equipment Operators:					
bulldozer	3.63				
Roofers	4.25				
Sheet Metal workers	4.29				
Soft floor layers	3.35				
Truck drivers	3.50				
Welders - receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: ALABAMA
DECISION NUMBER: AL81-1126
COUNTIES: *See below
DATE: Date of publication
Supersedes Decision No.: AL77-1064, May 13, 1977 in 42 FR 24553
DESCRIPTION OF WORK: Heavy construction

*Counties: Autauga, Barbour, Bibb, Bullock, Butler, Chambers, Chilton, Coffee, Coosa, Covington, Crenshaw, Dale, Dallas, Elmore, Geneva, Hale, Henry, Houston, Lee, Lowndes, Macon, Montgomery, Perry, Pike, Russell, and Tallapoosa.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Carpenters:					
carpenters	$3.75				
piledrivermen	4.00				
Cement Masons	3.60				
Electricians	9.30	.40	1%		
Ironworkers:					
structural, ornamental, & reinforcing	8.25	.40	.47		
Laborers:					
unskilled	3.35				
asphalt rakers	3.35				
Painters	3.90				
Power Equipment Operators:					
asphalt distributor	3.60				
asphalt roller	3.60				
asphalt spreader	3.60				
backhoe	4.15				
bulldozer	6.28				
crane, derrick, & dragline	4.15				
front end loader	3.35				
motor patrol	5.79				
oiler-greaser	6.91	.30	.20		.10
pump	7.57	.30	.20		.10
scraper	7.91	.30	.20		.10

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: ALABAMA
DECISION NUMBER: AL81-1127
COUNTIES: *See below
Supersedes Decision No.: AL77-1071, June 3, 1977 in 42 FR 28728
DESCRIPTION OF WORK: Sewer and Water Line construction

*Counties: Calhoun, Etowah, Greene, Jefferson, Pickens, St. Clair, Shelby, Sumter, Talladega, Tuscaloosa, and Walker.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Carpenters	$5.00				
Cement Masons	5.25				
Laborers:					
unskilled	3.35				
drillers, wagon drill	3.95				
asphalt rakers	3.85	.20	.30		
powdermen, blasters	3.60				
Power Equipment Operators:					
air compressor	4.00				
backhoe	5.23				
bulldozer	5.50				
cranes, derrick, dragline	5.25				
front end loader	5.00				
motor patrol	5.60				
roller	5.60				
Truck drivers	3.71				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

STATE: ALABAMA
DECISION NUMBER: AL81-1128
Supersedes Decision No.: AL79-1121, October 5, 1979 in 44 FR 57623
DESCRIPTION OF WORK: Sewer, Water, and Storm Drainage construction

COUNTIES: *See below
DATE: Date of publication

*Counties: Baldwin, Choctaw, Clarke, Conecuh, Escambia, Marengo, Mobile, Monroe, Washington, and Wilcox.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Carpenters	$5.00				
Cement Masons	5.50				
Cement finishers	5.50				
Ironworkers:					
structural and reinforcing	5.70				
Laborers:					
unskilles	3.68				
mortar mixers	3.75				
pipelayers	3.75				
Power Equipment Operators:					
backhoe	5.79				
bulldozer	5.31				
crane	5.86				
loader	4.25				
Truck drivers:					
truck drivers	3.35				
multi-rear axle	4.25				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: ALABAMA
DECISION NUMBER: AL81-1129
Supersedes Decision No.: AL77-1063, May 13, 1977 in 42 FR 24553
DESCRIPTION OF WORK: Sewer and Water Line construction

COUNTIES: *See below
DATE: Date of publication

*Counties: Autauga, Barbour, Bibb, Bullock, Butler, Chambers, Chilton, Coffee, Coosa, Covington, Crenshaw, Dale, Dallas, Elmore, Geneva, Hale, Henry, Houston, Lee, Lowndes, Macon, Montgomery, Perry, Pike, Russell, and Tallapoosa.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$4.75				
Carpenters	5.75				
Laborers:					
unskilled	3.35				
air tool operators	3.40				
pipelayers	3.35				
Plumbers & Pipefitters	5.00				
Power Equipment Operators:					
backhoe	4.63				
bulldozer	4.50				
trenching machine	4.66				
front end loader	4.37				
Truck drivers	3.35				
Welders-receive rate prescribed fro craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: ALABAMA
DECISION NUMBER: AL81-1130
Supersedes Decision No.: AL77-1066, May 13, 1977 in 42 FR 24554
DESCRIPTION OF WORK: Sewer and Water Line construction

COUNTIES: *See below
DATE: Date of publication

*Counties: Blount, Cherokee, Clay, Cleburne, Colbert, Cullman, DeKalb, Fayette, Franklin, Jackson, Lamar, Lauderdale, Lawrence, Limestone, Madison, Marion, Marshall, Morgan, Randolph, and Winston.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Cement Masons	$5.80				
Ironworkers	8.80				
Laborers:					
unskilled	3.35				
pipelayers	3.50				
Power Equipment Operators:					
air compressor	6.00				
backhoe	5.00				
bulldozer	5.25				
drilling machine	6.00				
loader	4.91				
mechanic	5.83				
trenching machine	5.00				
Truck drivers	3.65				

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: ALABAMA
DECISION NUMBER: AL81-1131
Supersedes Decision No.: AL79-1150, December 28, 1979, 44 FR 77104
DESCRIPTION OF WORK: Highway construction (excluding tunnels, buildingsstructures in rest area projects and railroad construction; bascule, suspension, and spandrel arch bridges; bridges designed for commercial navigation; bridges involving marine construction; and other major bridges)

COUNTY: Jefferson

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$ 3.65				
Carpenters	5.66				
Concrete finishers	5.23				
Concrete saw	3.35				
Electricians	12.05	.55	3% + .40		1½%
Ironworkers:					
structural	9.25				
reinforcing	5.19				
Laborers:					
air tool operators	3.35				
asphalt rakers	4.35				
concrete laborers	4.00				
pipelayers	3.45				
powdermen and blasters	4.00				
saw	3.50				
side rail or form setters	5.00				
unskilled	3.35				
wagon drill	4.00				
Painters	5.75				
Piledrivermen	5.60				
Power Equipment Operators:					
aggregate spreader	4.10				
air compressor	3.35				
asphalt distributor	5.51				
asphalt spreader	6.65				
asphalt mixer and pug mills & batch plants	3.95				
asphalt plant driers	3.95				
bulldozer	6.00				
bull floats	3.35				
concrete mixers(3 bags & under)	3.35				
concrete mixers(over 3 bags)	3.95				
concrete paving machine	3.95				
concrete paving finishing machine	3.95				
concrete paving spreaders	3.95				
cranes, clamshells, backhoe derricks, dragline or shovels	6.55				
conveyors	3.35				
crusher & screening plants	3.95				
drilling machines	5.00				
elevating graders, gradalls, or trenching	6.28				
firemen	3.35				
form graders	3.35				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators:(con't)					
hoist(2 drums or 2 cages or more)	3.95				
hoist(1 drum)	3.35				
mechanics	6.00				
motor patrols	6.60				
oilers & greasemen	5.94				
paving subgraders	3.35				
piledrivers	4.55				
pumps	3.35				
pumpcretes	3.35				
rollers(self-propelled)	5.72				
rollers(self-propelled on asphalt bases & pavements)	6.00				
scale operators	3.35				
scalemen	3.35				
scrapers	6.00				
seeding & mulching machines	4.00				
striping machines(paint)	4.75				
tractors & loaders(farm rubber tired)	3.50				
tractors & loaders(80 h.p.or less, draw-bar capacity)	4.98				
tractors & loaders(over 80 h.p.)	6.00				
Truck drivers:					
under 1½ tons	3.35				
single-rear axle	3.35				
multi-rear axle or heavy duty, off-road sinlge axle	3.48				
winch truck & A-frame	3.70				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: ALABAMA COUNTIES: *See below
DECISION NUMBER: AL81-1132 DATE: Date of publication
Supersedes Decision No.: AL79-1152, December 28, 1979 in 44 FR 77107
DESCRIPTION OF WORK: Highway Construction (excluding tunnels, building structures in rest area projects and railroad construction; bascule, suspension and spandrel arch bridges; bridges designed for commercial navigation; bridges involving marine construction; and other major bridges)

*Counties: Calhoun, Etowah, St. Clair, Shelby, Talladega, Tuscaloosa and Walker.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$ 3.65				
Carpenters	5.27				
Concrete finishers	4.75				
Concrete saw	3.35				
Electricians	12.05	.55	3% + .40		½%
Ironworkers:					
structural	5.80				
reinforcing	4.50				
Laborers:					
air tool operators	3.35				
asphalt rakers	4.60				
concrete laborers	3.35				
pipelayers	3.50				
powdermen and blasters	4.00				
saw	3.50				
side rail or form setters	3.72				
unskilled	3.35				
wagon drill	4.00				
Painters	5.50				
Piledrivermen	5.40				
Power Equipment Operators:					
aggregate spreader	4.10				
air compressor	3.35				
asphalt distributor	5.25				
asphalt spreader	5.25				
asphalt mixer and pug mill & batch plant	3.95				
asphalt plant driers	3.95				
bulldozers	5.72				
bull floats	3.35				
concrete mixer(3 bags & under)	3.35				
concrete mixer(over 3 bags)	3.95				
concrete paving machine	3.95				
concrete paving finishing machine	3.95				
concrete paving spreader	3.95				
cranes, clamshells, backhoes derricks, draglines or shovels	5.58				
conveyors	3.35				
crusher and screening plant	3.95				
drilling machine	5.00				
elevating graders, gradalls or trenching	4.75				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators:(con't)					
firemen	3.35				
form graders	3.35				
hoist(2 drums or 2 cages or more)	3.95				
hoist(1 drum)	3.35				
mechanic	6.00				
motor patrol	5.91				
oiler and greasemen	4.00				
paving subgraders	3.35				
piledrivers	3.66				
pumps	3.35				
pumpcretes	3.35				
rollers(self-propelled)	4.00				
rollers(self-propelled on asphalt bases and pavements)	4.11				
scale operators	3.35				
scalemen	3.35				
scrapers	6.00				
seeding and mulching machine	4.00				
striping machine(paint)	4.10				
tractors & loaders(80 h.p. or less, draw-bar capacity)	4.00				
tractors & loaders(over 80 h.p.)	5.17				
Truck drivers:					
under 1½ tons	3.35				
single-rear axle	3.35				
multi-rear axle or heavy duty, off-road, single axle	3.35				
winch truck and A-frame	3.35				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: ALABAMA COUNTIES: *See below
DECISION NUMBER: AL81-1133 DATE: Date of publication
Supersedes Decision No.: AL80-1043, January 25, 1980 in 45 FR 6293
DESCRIPTION OF WORK: Highway Construction (excluding tunnels, building structures in rest area projects and railroad construction; bascule, suspension and spandrel arch bridges; bridges designed for commercial navigationl bridges involving marine construction; and other major bridges)

*Counties: Autauga, Baldwin, Barbour, Bibb, Blount, Bullock, Butler, Chambers, Cherokee, Chilton, Choctaw, Clark, Clay, Coffee, Colbert, Conecuh, Coosa, Covington, Crenshaw, Cullman, Cleburne, Dale, Dallas, DeKalb, Elmore, Escambia, Fayette, Franklin, Geneva, Greene, Hale, Henry, Houston, Jackson, Lamar, Lauderdale, Lawrence, Lee, Limestone, Lowndes, Macon, Madison, Marengo, Marion, Marshall, Monroe, Montgomery, Morgan, Perry, Pickens, Pike, Randolph, Russell, Sumter, Tallapoosa, Washington, Wilcox, and Winston.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$3.65				
Carpenters	4.90				
Concrete finishers	4.40				
Concrete saw	3.35				
Electricians	5.80				
Ironworkers:					
structural	5.80				
reinforcing	4.50				
Laborers:					
air tool operators	3.35				
asphalt rakers	3.75				
concrete laborers	3.35				
pipelayers	3.75				
powdermen and blasters	4.00				
saw	3.50				
side rail or form setters	3.72				
unskilled	3.35				
wagon drill	4.00				
Painters	5.50				
Piledrivermen	4.80				
Power Equipment Operators:					
aggregate spreader operator	4.10				
air compressors	3.35				
asphalt distributor	4.25				
asphalt spreader	4.75				
asphalt mixer and pug mills & batch plants	3.35				
asphalt plant driers	3.95				
bulldozer	4.64				
bull floats	3.35				
concrete mixer(3 bags & under)	3.35				
concrete mixer(over 3 bags)	3.95				
concrete paving machine	3.95				
concrete paving finishing machine	3.95				
concrete paving spreader	3.95				
cranes, clamshells, backhoe derricks, draglines or shovels	5.22				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators:(con't)					
conveyors	3.35				
crusher and screening plant	3.95				
drilling machine	5 00				
elevating graders, gradalls or trenching	3.85				
firemen	3.35				
form graders	3.35				
hoist(2 drum or 2 cages or more)	3.95				
hoist(1 drum)	3.35				
mechanics	5.36				
motor patrols	5.00				
oilers and greasemen	3.60				
paving subgraders	3.35				
piledrivers	4.85				
pumps	3.35				
pumpcretes	3.35				
roller(self-propelled)	4.17				
roller(self-propelled, on asphalt bases and pavements)	4.43				
scale operators	3.35				
scalemen	3.35				
scrapers	4.32				
seeding and mulching machine	4.00				
striping machine(paint)	4.31				
tractors & loaders(farm rubber tired)	3.35				
tractors & loaders(80 h.p. or less, draw-bar capacity)	3.78				
tractors & loaders(over 80 h.p.)	4.00				
Truck drivers:					
under 1½ tons	3.35				
single-rear axle	3.35				
multi-rear axle or heavy duty, off-road, single axle	3.35				
winch trucks and A-frame	3.35				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

STATE: ALABAMA COUNTY: Mobile
DECISION NUMBER: AL81-1134 DATE: Date of publication
Supersedes Decision No.: AL79-1151, December 28, 1979, 44 FR 77106
DESCRIPTION OF WORK: Highway construction (excluding tunnels, building structures in rest area projects and railroad construction; bascule, suspension and spandrel arch bridges; bridges designed for commercial navigation; bridges involving marine construction; and other major bridges)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$ 3.65				
Carpenters	5.00				
Concrete finishers	5.50				
Concrete saw	3.35				
Electricians	12.05	.55	3% + .40		.05
Ironworkers:					
Reinforcing	6.00				
Structural	6.50				
Laborers:					
Air tool operators	3.35				
Asphalt rakers	3.75				
Concrete laborers	4.00				
Pipelayers	3.75				
Powdermen and blasters	4.00				
Saw	3.50				
Side rail and form setters	5.00				
Unskilled	3.35				
Wagon drill	4.00				
Painters	5.75				
Piledrivermen	6.75				
Power Equipment Operators:					
Asphalt spreader operator	4.10				
Air compressor	3.35				
Asphalt distributor	5.00				
Asphalt spreader	5.38				
Asphalt mixers and pug milles & batch plants	3.95				
Asphalt plant driers	3.95				
Bulldozers	4.50				
Bull floats	3.44				
Concrete mixer(3 bags and under)	3.44				
Concrete mixer(over 3 bags)	3.95				
Concrete paving machine	3.95				
Concrete paving finishing machine	3.95				
Concrete paving spreader	3.95				
Cranes, clamshells, backhoe derricks, draglines or shovels	7.00				
Conveyors	3.35				
Crusher and screening plants	3.95				
Drilling machine	5.00				
Elevating graders, gradalls or trenching	5.25				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment operators:(con't)					
Firemen	3.35				
Form graders	3.35				
Hoist(2 drums or 2 cages or more)	3.95				
Hoist(1 drum)	3.44				
Mechanics	6.41				
Motor patrols	5.85				
Oilers and greasemen	4.00				
Paving subgraders	3.35				
Piledrivers	4.85				
Pumps	3.35				
Pumpcretes	3.35				
Roller(self-propelled)	3.50				
Roller(self-propelled on asphalt bases and pavements)	5.08				
Scale operators	3.35				
Scalemen	3.35				
Scrapers	4.50				
Seeding and mulching machines	4.00				
Striping machine(paint)	4.00				
Tractors and loaders(farm rubber tired)	3.50				
Tractors and loaders(80 h.p. or less, draw-bar capacity)	4.00				
Tractors and loaders(over 80 h.p.)	4.75				
Truck drivers:					
Under 1½ tons	3.35				
Single-rear axle	3.35				
Multi-rear axle or heavy duty, off road, single axle	3.83				
Winch traucks and A-Frame	3.35				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATES: CONNECTICUT, DELAWARE, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA & RHODE ISLAND
DECISION NO.: NY80-3079 DATE: DATE OF PUBLICATION
Supersedes Decision No. NY80-3002 dated January 18, 1980, in 45 FR 3866
DESCRIPTION OF WORK: All Dredging on the Atlantic Coast from the Canadian Border to the southerly border of the State of Maryland & tributary waters emptying into the Atlantic Ocean, the Cheaspeake & Delaware Canal, Baltimore City & Baltimore County, Md.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DIPPER & CLAMSHELL DREDGES:					
Operator	12.45	.73	.70	7%+a	
Engineer	12.36	.73	.70	7%+a	
Craneman	12.13	.73	.70	7%+a	
Maintenance Engineer	11.96	.73	.70	7%+a	
Welder	11.80	.73	.70	7%+a	
Mate	11.25	.73	.70	7%+a	
Fireman and Oiler	10.42	.73	.70	7%+a	
Deckhand, Handyman and Tug Deckhand	10.18	.73	.70	7%+a	
Scowman and Rodman	10.07	.73	.70	7%+a	
HYDRAULIC DREDGES:					
Leverman	12.25	.73	.70	7%+a	
Engineer and Derrick Operator	12.13	.73	.70	7%+a	
Maintenance Engineer	11.96	.73	.70	7%+a	
Boilerman; Dredge Carpenter; Dredge Blacksmith; Electricians and Dredge Welder	11.80	.73	.70	7%+a	
Spider Barge Operator	11.69	.73	.70	7%+a	
Mate	11.25	.73	.70	7%+a	
Fireman and Oiler	10.42	.73	.70	7%+a	
Tug Deckhand	10.18	.73	.70	7%+a	
Deckhand; Handyman; Shoreman and Rodman	10.07	.73	.70	7%+a	
COMPANY LEAD DREDGEMAN:					
Lead Dredgeman	12.25	.73	.70	7%+a	
TUG Boats over 400 H.P. (with master or captain having license endorsed for 200 miles off shore):					
Tug Engineer	11.75	.73	.70	7%+a	
Tug Deckhand	10.23	.73	.70	7%+a	
TUG Boats over 400 H.P. (without master or Captain having license endorsed for 200 miles off shore):					
Tug Engineer	11.32	.73	.70	7%+a	
Tug Deckhand	10.18	.73	.70	7%+a	

DECISION NO. NY80-3079

FOOTNOTES:
a. Paid holidays include New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day, Washington's Birthday and Veterans Day.

SUPERSEDEAS DECISION

STATE: NORTH CAROLINA COUNTY: Orange
DECISION NUMBER: NC81-1135 DATE: Date of publication
Supersedes Decision No.: NC80-1022, January 4, 1980, 45 FR 1372
DESCRIPTION OF WORK: Building Construction (does not include single family homes and apartments up to and including 4 stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$6.25				
Carpenters	4.83				
Cement Masons	5.00				
Electricians	5.00				
Glaziers	5.22				
Ironworkers:					
ornamental & reinforcing	5.21				
structural	5.21				
Laborers	3.35				
Painters	4.12				
Plumbers & Pipefitters	5.00				
Power Equipment Operators:					
backhoe	4.37				
front end loader	4.25				
roller	3.75				
Roofers	4.00				
Sheet Metal workers	4.50				
Tile setters	6.50				
Truck drivers	3.35				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: NORTH CAROLINA

COUNTIES: Chatham, Harnett, Lee, and Moore

DECISION NUMBER: NC81-1137

DATE: Date of publication

Supersedes Decision No.: NC78-1035, April 14, 1978, 43 FR 16095

DESCRIPTION OF WORK: Building Construction (does not include single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air conditioning mechanics	$ 4.46				
Bricklayers	5.50				
Carpenters	4.14				
Cement masons	3.74				
Drywall mechanics	5.00				
Electricians	4.85				
Glaziers	3.64				
Laborers	3.35				
Lathers	6.00				
Painters:					
brush	4.00				
Plumbers & Pipefitters	5.50				
Power Equipment Operators:					
bulldozer	3.75				
tractor	3.50				
Roofers	4.05				
Sheet metal workers	4.85				
Sprinkler fitters (Chatham and Lee counties)	11.00	.85	1.20		.08
Tile setters	5.25				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: NORTH CAROLINA

COUNTIES: Camden, Currituck, Dare, Pasquotank, Perquimans, and Tyrell

DECISION NUMBER: NC81-1138

DATE: Date of publication

Supersedes Decision No.: NC80-1021, January 4, 1980, 45 FR 1369

DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos workers	$7.00				
Bricklayers	7.00				
Carpenters	3.72				
Cement masons	4.25				
Electricians	4.25				
Glaziers	4.00				
Ironworkers:					
structural	4.50				
Laborers:					
mortar mixer	3.50				
pipelayer	5.00				
unskilled	3.35				
Painters	3.85				
Plasterers	5.00				
Plumbers	4.25				
Power Equipemnt Operators:					
crane	5.00				
mechanic	6.45				
Roofers	3.50				
Sheet metal workers	3.75				
Terrazzo workers	4.00				
Tile setters	5.50				
Truck drivers	3.35				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

STATE: NORTH CAROLINA COUNTY: Wake
DECISION NUMBER: NC81-1139 DATE: Date of publication
Supersedes Decision No.: NC80-1019, January 4, 1980, 45 FR 1373
DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air conditioning mechanics	$5.25				
Bricklayers	6.00				
Carpenters	4.99				
Cement masons	4.00				
Drywall mechanics	5.20				
Electricians	4.96				
Elevator constructors	7.82	.745	.69	a	.025
Glaziers	6.00				
Ironworkers:					
reinforcing	5.50				
structural & ornamental	5.00				
Laborers:					
air tool operator(jackhammers, vibrators)	3.75				
mason tender	3.35				
mortar mixer	3.50				
pipelayer	3.35				
unskilled	3.35				
Lathers	7.40				
Marble setters	6.50				
Painters	4.00				
Pipefitters	5.20	.13		.10	
Plasterers	6.25				
Plumbers	4.91				
Power Equipment Operators:					
backhoe	3.94				
bulldozer	4.50				
crane	5.55				
finishing machine	4.50				
front end loader	3.75				
motor grader	4.75				
roller	4.00				
scraper	4.00				
tractor	4.00				
Roofers:					
roofers	4.04				
water proofers	4.65				
Sheet metal workers	4.90				
Soft floor layers	5.08				
Terrazzo workers	6.50				
Tile setters	7.00				
Truck drivers	3.35				
Welders-receive rate prescribed for craft to which it is incidental					

FOOTNOTE:
a. Employer contributes 6% of basic hourly rate for 6 months to 5 years service and 8% for over 5 years of service as vacation pay credit; also six paid holidays

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: NORTH CAROLINA

COUNTIES: Edgecombe, Greene, Johnston, Nash, and Wilson

DECISION NUMBER: NC81-1140

DATE: Date of publication

Supersedes Decision No.: NC80-1024, January 4, 1980, 45 FR 1369

DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including four storie)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$ 6.00				
Carpenters	4.36				
Cement masons	3.66				
Electricians	3.60				
Glaziers	4.22				
Ironworkers:					
structural	3.35				
Laborers:					
pipelayer	3.50				
unskilled	3.35				
Lathers	6.95				
Painters:					
brush	4.00				
Plasterers	5.65				
Plumbers & Steamfitters	3.70				
Power Equipment Operators:					
backhoe	3.50				
blade grader	3.35				
bulldozer	3.42				
cranes, derricks & draglines	4.29				
distributor	3.75				
finishing machine	3.36				
motor grader	3.35				
pump	3.35				
scraper	3.54				
shovel	3.75				
screed	3.50				
trenching machine	4.00				
Roofers	3.46				
Sheet metal workers	3.35				
Soft floor layers	5.10				
Sprinkler fitters(Wilson co.)	11.00	.85	1 20		.08
Tile setters	5.29				
Truck drivers	3.35				

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: NORTH CAROLINA

COUNTY: Cumberland

DECISION NUMBER: NC81-1141

DATE: Date of publication

Supersedes Decision No.: NC80-1026, January 4, 1980, 45 FR 1368

DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos workers	$ 6.50				
Boilermakers	6.25				
Bricklayers	6.00				
Carpenters:					
carpenters	6.05				
millwrights	6.50				
Cement masons	5.25				
Electricians	6.50				
Glaziers	4.39				
Ironworkers:					
structural & reinforcing	6.50				
Laborers:					
pipelayer	3.72				
plasterer tender	3.35				
unskilled	3.35				
Lathers	5.00				
Painters:					
brush	4.75				
spray	5.00				
Plasterers	5.85				
Plumbers & Pipefitters	6.50				
Power Equipment Operators:					
bulldozer	4.00				
cranes, derricks & draglines	5.53				
forklift	4.40				
front end loader	3.37				
grader	3.90				
mechanic	5.95				
motor grader	3.98				
roller(asphalt)	3.45				
saw operator	4.00				
scraper	3.75				
Roofers	5.00				
Sheet metal workers	4.82				
Sprinkler fitters	11.00	.85	1.20		.08
Soft floor layers	4.32				
Terrazzo workers	4.63				
Tile setters	5.28				
Truck drivers	3.35				

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

STATE: NORTH CAROLINA COUNTY: Guilford
DECISION NUMBER: NC81-1142 DATE: Date of publication
Supersedes Decision No.: NC78-1036, April 14, 1978, 43 FR 16095
DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$ 6.14				
Carpenters	5.23				
Cement masons	4.67				
Drywall installers	6.00				
Electricians	5.36				
Elevator constructors	7.82	.745	.56	a	.025
Glaziers	4.85				
Ironworkers:					
structural & ornamental	5.50				
reinforcing	5.00	.25		.10	.05
Laborers:					
mason tenders	3.68				
mortar mixers	3.71				
pipelayers	4.25				
unskilled	3.35				
Painters:					
brush	4.17				
Plasterers	6.25				
Plumbers & Steamfitters	5.75				
Power Equipment Operators:					
backhoe	4.45				
bulldozer	4.25				
crane, derrick, & dragline	6.00				
distributor	4.75				
finishing machine	4.75				
fork lift operator	4.00				
front end loader	4.25				
motor grader	4.76				
roller	4.03				
Roofers	4.32				
Sheet metal workers	4.85				
Soft floor layers	4.02				
Sprinkler fitters	11.00	.85	1.20		.08
Tile setters	5.19				
Terrazzo workers	5.76				
Truck drivers	3.76				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

STATE: NORTH CAROLINA COUNTY: Durham
DECISION NUMBER: NC81-1143 DATE: Date of publication
Supersedes Decision No.: NC80-1025, January 4, 1980, 45 FR 1371
DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos workers	$ 5.25				
Bricklayers	6.00				
Carpenters	5.00				
Cement masons	4.75				
Electricians	5.00				
Glaziers	5.25				
Ironworkers:					
structural & ornamental	5.50				
reinforcing	5.50				
Laborers:					
mortar mixers	3.35				
unskilled	3.35				
Lathers	6.95				
Marble setters	5.25				
Painters:					
brush	3.76				
Plasterers	6.35				
Plumbers & Pipefitters	5.33				
Power Equipment Operators:					
backhoe	3.75				
bulldozer	3.90				
finishing machine	3.85				
front end loader	4.25				
motor grader	4.39				
roller	4.10				
scraper(pan)	4.01				
tractor	3.90				
Roofers	4.00				
Sheet metal workers	4.81				
Soft floor layers	4.31				
Sprinkler fitters	11.00	.85	1.20		.08
Terrazzo workers	6.00				
Tile setters	5.20				
Truck drivers	3.35				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: NORTH CAROLINA COUNTY: Granville
DECISION NUMBER: NC81-1144 DATE: Date of publication
Supersedes Decision No.: NC77-1135, November 11, 1977, 42 FR 58928
DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$6.00				
Carpenters	4.31				
Cement masons	4.30				
Drywall hangers	6.00				
Electricians	5.00				
Ironworkers:					
structural	5.07				
reinforcing	4.75				
Laborers	3.35				
Painters:					
brush	4.38				
spray	4.50				
Plumbers & Pipefitters	5.30				
Power Equipment Operators:					
backhoe	5.00				
bulldozer	4.00				
loader	4.13				
Roofers	4.75				
Sheet metal workers	5.00				
Tile setters	6.50				
Truck drivers	3.63				

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: NORTH CAROLINA COUNTIES: Cartaret, Craven, Jones, Lenior, Onslow, and Pamlico
DECISION NUMBER: NC81-1145 DATE: Date of publication
Supersedes Decision No.: NC80-1023, January 4, 1980, 45 FR 1372
DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$5.50				
Carpenters	4.50				
Cement masons	4.23				
Electricians	4.56				
Glaziers	3.55				
Ironworkers:					
structural	4.75				
reinforcing	4.25				
Laborers:					
pipelayers	4.35				
plasterer tenders	3.50				
unskilled	3.35				
Painters	5.00				
Plasterers	6.00				
Plumbers & Pipefitters	5.51				
Power Equipment Operators:					
backhoe	4.50				
motor grader	4.00				
roller	5.00				
Roofers	5.52				
Sheet metal workers	3.88				
Sprinkler fitters(Onslow co.)	5.375				
Sprinkler fitters(Cartaret co.)	11.00	.85	1.20		.08
Soft floor layers	5.10				
Tile setters	6.00				
Truck drivers	3.35				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

STATE: NORTH CAROLINA COUNTIES: Gaston, Lincoln, Mecklenburg, and Union

DECISION NUMBER: NC81-1146 DATE: Date of publication

Supersedes Decision No.: NC78-1027, March 24, 1978, 43 FR 12602

DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air conditioning/heating mechanics	$ 4.88				
Asbestos workers	4.85				
Bricklayers	5.93				
Carpenters	5.04				
Cement masons	4.83				
Electricians	6.12				
Elevator constructors	7.53	.745	.56	a	.025
Glaziers	4.83				
Ironworkers:					
structural	5.52				
reinforcing	4.83				
Laborers:					
mason tenders	3.35				
mortar mixers	3.50				
pipelayers	4.10				
plasterer tenders	3.35				
unskilled	3.35				
Lathers	7.40				
Painters:					
brush	4.46				
Plasterers	6.51				
Plumbers, Pipefitters & Steamfitters	6.19				
Power Equipment Operators:					
backhoe	3.98				
bulldozer	4.00				
crane, derrick, & dragline	5.26				
finishing machine	4.00				
forklift	3.35				
front end loader	4.50				
motor grader	4.29				
pan operator	3.85				
roller	3.43				
scraper	3.85				
shovel	4.00				
tractor	4.76				
Roofers	4.57				
Sheet metal workers	5.23				
Soft floor layers	4.50				
Sprinkler fitters(Mecklenburg & Union cos.)	11.00	.85	1.20		,08

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Stone masons	4.25				
Terrazzo workers	4.00				
Tile setters	5.38				
Truck drivers	3.46				
Water proofing mechanics	3.35				

Footnote:

a. employer contributes 6% of basic hourly rate for 6 months to 5 years service and 8% for over 5 years service as vacation pay credit: also six paid holidays.

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: NORTH CAROLINA COUNTY: New Hanover
DECISION NUMBER: NC81-1147 DATE: Date of publication
Supersedes Decision No.: NC78-1037, April 14, 1978, 43 FR 16096
DESCRIPTION OF WORK: Building Construction (excluding single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos workers	$ 5.75				
Bricklayers	6.00				
Carpenters	5.00				
Cement Masons	4.50				
Electricians	5.25				
Ironworkers:					
structural & ornamental	5.30				
Laborers:					
air tool operators	3.50				
unskilled	3.35				
Painters:					
brush	4.50				
Plumbers & Steamfitters	6.50				
Power Equipment Operators:					
bulldozer	5.00				
crane	4.75				
forklift	4.50				
Roofers	4.00				
Sheet metal workers	5.00				
Sprinkler fitters	11.00	.85	1.20		.08
Terrazzo workers	4.75				
Tile setters	5.00				
Truck drivers	3.35				
Welders-receive rate prescribed for craft to which it is incidental					

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: NORTH CAROLINA COUNTIES: Statewide
DECISION NUMBER: NC81-1148 DATE: Date of publication
Supersedes Decision No.: NC79-1125, September 7, 1979, 44 FR 52577
DESCRIPTION OF WORK: Water and Sewer construction projects and Heavy construction projects excluding Dam construction projects

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Bricklayers	$4.47				
Carpenters	5.16				
Cement masons	5.01				
Fence erectors	4.04				
Ironworkers:					
structural	4.81				
Laborers:					
asphalt rakers	3.95				
pipelayers	3.98				
powdermen	5.95				
unskilled	3.37				
Manhole builders	4.00				
Millwrights	4.00				
Painters	5.50				
Piledrivermen	6.29				
Plumbers & Pipefitters	5.25				
Power Equipment Operators:					
asphalt paver	3.98				
backhoe	4.99				
boom operator	4.00				
bulldozer	4.50				
compactor	3.75				
crane	5.87				
dragline	5.50				
drill:					
air	4.81				
well	4.50				
loader	4.48				
mechanic	5.16				
motor grader	4.25				
oiler	3.75				
pump operator	3.75				
roller	3.35				
scraper(pan)	4.25				
screed	4.08				
tractor	4.75				
trenching machine	5.00				
Truck drivers	3.67				

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

STATE: NORTH CAROLINA COUNTIES: Statewide
DECISION NUMBER: NC81-1149 DATE: Date of publication
Supersedes Decision No.: NC78-1061, July 7, 1978, 43 FR 29463
DESCRIPTION OF WORK: Highway construction projects (excluding tunnels, building structures in rest area projects and railroad construction; bascule, suspension and spandrel arch bridges; bridges designed for commercial navigation; bridges involving marine construction; and other major bridges)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asphalt rakers	$3.76				
Builders - curb & gutter	3.44				
Carpenters	4.76				
Carpenters helpers	3.74				
Concrete finishers	4.35				
Electricians	5.59				
Form setters(road)	4.01				
Ironworkers:					
reinforcing	5.24				
Laborers	3.35				
Lutemen	3.35				
Masons	4.83				
Mechanics	4.81				
Mechanics' helpers	3.35				
Oilers	3.72				
Piledriver leadsmen	4.86				
Pipelayers	3.60				
Powdermen	3.50				
Power Equipment Operators:					
asphalt distributor	4.11				
aspahlt plant	4.00				
asphalt paver	4.32				
bulldozer	4.22				
bulldozer(utility)	3.83				
concrete finsihing machine	4.56				
concrete paver	5.51				
concrete saw	5.00				
concrete spreader	4.82				
crane, backhoe, dragline, and shovel:					
1 yd. & under	4.43				
over 1 yd.	4.76				
curb machine(concrete)	4.29				
drill operator	3.86				
greasemen	3.81				
hydro seeder	4.10				
loader operator	4.01				
motor grader:					
fine	4.81				
rough	3.83				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators:(con't)					
power tool operator	4.18				
roller:					
rough	3.35				
finish	3.90				
scraper	3.95				
screed(asphalt)	4.12				
sign erector	4.75				
stone spreader	4.20				
subgrader machine	4.00				
sweeper	3.35				
tractor(crawler)	3.89				
tractor(utility)	3.35				
Truck drivers:					
single axle(rear)	3.35				
multi rear axle	3.35				
concrete	3.58				
heavy duty	3.35				
Welders	4.55				

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDEAS DECISION

STATE: NORTH CAROLINA

COUNTIES: Bladen, Columbus, Richmond, Robeson, and Scotland

DECISION NUMBER: NC81-1151

DATE; Date of publication

Supersedes Decision No.: NC79-1107, August 17, 1979, 44 FR 48584

DESCRIPTION OF WORK: Residential construction (including single family homes and apartments up to and including four stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air conditioning mechanics	$4.81				
Bricklayers	6.00				
Carpenters	4.73				
Cement masons	5.65				
Drywall finishers	4.00				
Drywall hangers	5.00				
Electricians	4.59				
Insulation installer	3.53				
Laborers:					
mason tenders	3.35				
pipelayers	3.35				
unskilled	3.35				
asphalt raker	4.25				
Painters:					
brush	3.71				
spray	4.00				
Paperhangers	3.35				
Plumbers & Pipefitters	4.93				
Power Equipment Operators:					
backhoe	4.69				
bulldozer	5.16				
grader	4.25				
loader	4.33				
paver	3.72				
roller	3.42				
screed	4.25				
tractor	5.25				
Roofers	5.00				
Sheet metal workers	4.55				
Soft floor layers	5.29				
Truck drivers	3.35				

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

SUPERSEDES DECISION

STATE: NORTH CAROLINA

COUNTIES: Beaufort, Bertie, Chowan, Dare, Edgecombe, Franklin, Halifax, Hertford, Hyde, Martin, Nash, Northampton, Pitt, Tyrrell, Vance, Warren, and Wilson

DECISION NUMBER: NC81-1152

Supersedes Decision No.: NC80-1017, January 4, 1980, 45 FR 1370

DESCRIPTION OF WORK: Residential Construction consisting of single family homes and apartments up to and including four stories

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Acoustical spray applicators	$4.10				
Air conditioning/heating mechanics	4.50				
Bricklayers	6.00				
Carpenters	4.98				
Carpet layers	5.00				
Cement masons	4.90				
Drywall finishers	5.00				
Drywall hangers	5.00				
Electricians	4.50				
Insulation installers	3.66				
Ironworkers:					
structural	5.20				
reinforcing	5.20				
Laborers:					
asphalt rakers	3.55				
mortar mixers	3.35				
pipelayers	4.00				
unskilled	3.35				
Painters:					
brush	4.25				
Plumbers & Pipefitters	5.02				
Power Equipment Operators:					
back hoe	4.50				
bulldozer	4.90				
distributor(asphalt)	4.24				
forklift	4.25				
grader	4.50				
loader	4.64				
pans-scraper	4.25				
paver	4.25				
roller	4.40				
screed	4.21				
tractor	4.00				
Roofers	4.71				
Sheet metal workers	4.50				
Soft floor layers	5.00				
Tile setters	6.00				
Truck drivers	3.46				

Unlisted classifications needed for work not included within the scope of this classification may be added only after award as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

STATE: SOUTH CAROLINA

COUNTIES: BERKELEY, CHARLESTON, & DORCHESTER

DECISION NUMBER: SC81-1150

DATE: DATE OF PUBLICATION

Supersedes Decision Number SC78-1087, dated October 13, 1978, in 43 FR 47443.

DESCRIPTION OF WORK: BUILDING CONSTRUCTION PROJECTS (does not include single family homes and apartments up to and including four (4) stories).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
AIR CONDITIONING & HEATING MECHANICS	$ 6.80				
BOILERMAKERS	12.75	1.275	1.10		.04
BRICKLAYERS	8.25				
CARPENTERS	6.47				
CEMENT MASONS	6.39				
ELECTRICIANS	10.45	.55	3% + .50	a	½ of 1%
IRONWORKERS	10.00	.60	1.00		.05
LABORERS	3.71				
MILLWRIGHTS	9.60	.45	.35		
PAINTERS	4.66				
PLASTERERS	7.00				
PLUMBERS & PIPEFITTERS	10.00	.55	.50		.10
ROOFERS	5.07				
SHEET METAL WORKERS	5.80				
SOFT FLOOR LAYERS	4.93				
SPRINKLER FITTERS	11.00	.85	1.20		.08
TILE SETTERS	6.46				
TRUCK DRIVERS	4.02				
WELDERS - Rate for craft.					
POWER EQUIPMENT OPERATORS:					
Backhoe	5.86				
Bulldozer	5.01				
Crane, derrick, dragline	8.50	.60	.55		
Motor grader	7.75				
Oiler	7.25				
Piledriver	5.49				

FOOTNOTE:

a. One Paid Holiday (8 Hours Pay): Labor Day, provided the employee is on the employer's payroll the last regular working day preceeding Labor Day.

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR. 5.5 (a)·(1) (ii)).

[FR Doc. 80-40182 Filed 12-29-80; 8:45 am]

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federal register

Tuesday
December 30, 1980

Part V

Department of Labor

Office of Federal Contract Compliance Programs

Affirmative Action Obligations of Contractors and Subcontractors for Disabled Veterans, Veterans of the Vietnam Era, and Handicapped Workers; Proposed Rule

DEPARTMENT OF LABOR

Office of Federal Contract Compliance Programs

41 CFR Parts 60-1, 60-250 and 60-741

Obligations of Contractors and Subcontractors; Affirmative Action Obligations of Contractors and Subcontractors for Disabled Veterans and Veterans of the Vietnam Era and Handicapped Workers

AGENCY: Office of Federal Contract Compliance Programs, Department of Labor.

ACTION: Proposed Rule.

SUMMARY: These proposed amendments to Department of Labor regulations implementing sections 503 of the Rehabilitation Act of 1973, as amended, and 402 of the Vietnam Era Veterans Readjustment Assistance Act of 1974 will conform these regulations to the employment section of the Department of Labor regulations implementing section 504 of the Rehabilitation Act published on October 7, 1980 (45 FR 66706). It also deletes reporting requirements which are not necessary for proper performance under section 402, and it incorporates recent statutory changes in the definitions of disabled and Vietnam era veterans.

DATES: Comments are invited from other Federal agencies and the public. They must be received on or before March 2, 1981.

ADDRESSES: Comments should be sent to Director, Division of Program Policy, Office of Federal Contract Compliance Programs, 200 Constitution Avenue, NW., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: James Cisco, Acting Director, Division of Program Policy, Office of Federal Contract Compliance Programs, 200 Constitution Avenue, NW., Washington, D.C. 20210, telephone (202) 523-9426.

SUPPLEMENTARY INFORMATION:

Background

Section 503 of the Rehabilitation Act of 1973, as amended (hereinafter the Act), requires government contractors and subcontractors to take affirmative action to employ and advance in employment qualified handicapped individuals. Regulations implementing section 503 were published in the **Federal Register** on June 11, 1974 (39 FR 20566) and amended on April 19, 1976 (41 FR 16148). Section 504 of the Act prohibits discrimination against qualified handicapped individuals in any program or activity receiving Federal financial assistance. On April 28, 1976, the President issued Executive Order 11914, which, in section 1, delegated to the Department of Health, Education and Welfare (HEW) responsibility for coordinating agency implementation of section 504 so that consistent policies, practices and procedures are adopted among all the Federal departments with respect to enforcement of section 504. (Executive Order 11914 has been superseded by Executive Order 12250 which among other things, transferred HEW's lead agency role on section 504 to the Department of Justice.)

Section 402 of the Vietnam Era Veterans Readjustment Assistance Act of 1974 requires government contractors and subcontractors to take affirmative action to employ and advance in employment disabled and Vietnam era veterans. Regulations implementing Section 402 were published in the **Federal Register** on June 25, 1976 (41 FR 26386).

Those regulations were written to parallel the preexisting regulations issued pursuant to Section 503. Both regulations are presently identical, except where differences are necessary because of the nature of the protected class or differences in the statutes, to assure that covered contractors are bound to consistent requirements in both programs. Therefore, in an effort to retain consistency and avoid confusion and conflict, it is proposed to amend both regulations simultaneously.

Published as Part IV of this **Federal Register** are final regulations which consolidate and amend other provisions in the 503 and 402 regulations and generally renumber the various sections of Parts 60-250 and 60-741. Therefore references in this proposal are to the sections as renumbered in the final rule published today. Furthermore, because the purpose of the consolidation is to integrate the regulations of the various laws OFCCP enforces to the extent clarity permits, the definition changes proposed herein will appear in 41 CFR Part 60-1, when they are finally codified.

Section 2 of Executive Order 11914 required each Federal agency to issue rules, regulations and directives to implement section 504 consistent with the standards and procedures to be established by the Secretary of HEW. The rules, regulations and orders which HEW issued to implement section 504 could not be inconsistent with or duplicative of policies adopted by other Federal agencies relating to the handicapped, including those adopted in accordance with section 503.

HEW issued two sets of regulations under section 504. 45 CFR Part 85 sets forth the guidelines for Federal agency regulations, and 45 CFR Part 84 sets forth HEW's requirements with respect to its own programs of Federal financial assistance. The latter regulations are broader and more detailed than the guidelines for other Federal agencies.

In drafting its own regulations to implement section 504, which were proposed on January 4, 1980 (45 FR 1392), and published in final form on October 7, 1980, the Department of Labor generally followed HEW's guidelines and also incorporated substantial portions of HEW's regulations for its own programs when they were relevant to Department of Labor programs. However, there was some variance from the HEW guidelines and regulations based on the experiences of the handicapped community, employers and the public. Some parts of the existing section 503 and 402 regulations were incorporated in the 504 regulations, such as the requirement to review job qualifications and demonstrate that they are job related and consistent with business necessity. In the area of preemployment medical examinations, the Department of Labor section 504 regulations developed an approach which accomplishes the same objective as the HEW regulations while allowing more flexibility in the timing of the examination. That approach is adopted in these proposed amendments. The more detailed HEW definitions of handicapped individual and reasonable accommodation were included in the

504 regulations and are proposed to be adopted here.

One area in which the DOL regulations under section 504 departed from those under section 503 is the requirement in section 504 that every recipient must have an internal review procedure for handling complaints, and that complainants must utilize that procedure before filing with the Department of Labor. Published as Part VI of this **Federal Register** is a final rule amending the existing internal review procedures (41 CFR 60–741.25(b)) to permit a complainant to veto a referral of his or her complaint to the contractor's internal review procedure. This proposal does not affect that amendment. This distinction between the programs will not impose inconsistent requirements on contractors who are also covered under section 504, since compliance with the section 504 procedures by contractors would not constitute a violation of section 503.

With these proposed amendments to the section 503 regulations, the Department of Labor 503 and 504 regulations will not be inconsistent so that an employer which is both a government contractor and a recipient of Federal financial assistance from the Labor Department would not be subject to conflicting requirements with regards to employment.

The 504 regulations at 29 CFR 32.2(b), (45 FR 66709, Oct. 7, 1980), provide that government contractors who are also recipients and who are in compliance with section 503 shall be deemed in compliance with the employment provisions of section 504. The converse is not necessarily true, however. Section 504 prohibits discrimination against handicapped individuals, whereas section 503 goes beyond passive non-discrimination by mandating affirmative action to employ and advance in employment qualified handicapped individuals. Non-discrimination is just one element of an affirmative action effort.

In addition to amendments proposed to ensure uniformity in the handicapped and veterans enforcement programs, this proposal also deletes the existing obligation in the section 402 regulations for contractors to file quarterly reports of veterans hired with the appropriate local office of the state employment service. Accordingly, Federal contractors no longer need to submit or retain copies of these quarterly reports.

However, elimination of this reporting requirement does not affect the requirement that covered Federal contractors list suitable employment openings with an appropriate local office of the state employment service.

Summary of Proposed Regulations

There are several proposed amendments to the definitions section. The definitions of "disabled veteran" and "veteran of the Vietnam era" are being revised pursuant to recent statutory amendments extending coverage to greater numbers of disabled and Vietnam era veterans. The proposal also amends the definition of "handicapped individual" to conform to the definition under section 504.

This proposed amendment would modify the definitions of "qualified handicapped individual" and "qualified disabled veteran" to add the phrase "essential functions of the job". This would clarify the duty to make reasonable accommodations for handicapped individuals and disabled veterans qualified to perform the primary objectives of a job, but not all of its peripheral duties. Although it is not intended to require employers to conduct a formal job analysis for each job, addition of this phrase obligates employers to give careful consideration to reassignment of specific duties which a handicapped person or disabled veteran cannot perform and making other appropriate accommodations with respect to job functions which cannot reasonably be reassigned.

In applying the definition of qualified handicapped individual, contractors should be aware that the standards used to determine whether an individual is capable of safely and adequately performing the job shall be applied equally to all applicants and employees.

A definition of "reasonable accommodation" has also been added.

The proposal would also amend the affirmative action contract clauses at 41 CFR 60–741.3(a) and 41 CFR 60–250.3 by delineating in greater detail the types of employment activities covered under the regulations.

The proposed amendment would also conform 41 CFR 60–741.5(c) (3) and 41 CFR 60–250.5(c) (3), which deal with pre-employment medical examinations, to the Department's 504 regulations. They would restrict pre-employment inquiries into the medical status of an applicant to that information which is necessary to determine whether the applicant is capable of performing the requirements of the job or jobs for which the individual is applying. Where a number of jobs requiring different skills are available, information could be obtained under this proposal for proper job placement. However, contractors may no longer inquire on application forms into information which is neither job-related nor designed specifically for affirmative action purposes. Although pre-employment medical examinations may continue to be given if all applicants for the job are subject to them, the proposal would require that a medical examination follow a conditional decision to hire or be the last factor considered in the employment process.

The proposal also defines the role of the examining physician, which is to make an assessment of the employee's or applicant's functional abilities and limitations (e.g. no lifting over 30 pounds; 25 per cent reduction in peripheral vision) rather than to determine whether or not he or she should be hired or placed. The physician may advise and assist the placement officers, but actual decisions on suitability for jobs must be made by persons capable of evaluating physical or mental demands of particular jobs and matching applicants with appropriate jobs based upon those assessments. Because the pre-employment medical examination is a point in the screening process that is particularly susceptible to discrimination against the handicapped, the Department of Labor will scrutinize the practices of employers utilizing pre-employment medical examinations. In particular, the practices of employers which have not traditionally used such exams but institute them for the first time now will be closely examined to ensure that the requirements of these regulations are being carefully followed.

It is important to note that the purpose of conducting a medical examination under this proposal must be to determine an individual's current physical or mental ability, not to speculate about the long term possibility that the condition will progress or lead to inability to work. Thus, although an employer can consider disqualifying a person because his handicap creates a substantial risk of imminent injury, disqualification based on speculation about the risk of injury or speculation about inability to work at some imprecise time in the future is not permissible.

Although these amendments add no reporting requirements, and delete certain existing reporting requirements for veterans, they extend to three years the retention period for records regarding internal complaints. This consistent with the equivalent provision in the section 504 regulations, and will provide more adequate information to investigators regarding contractors' compliance practices.

An appendix is added to the regulations which gives examples of

several types of accommodation. This list is not all-inclusive, because accommodations arise in response to specific needs of particular employees or applicants, and cannot always be anticipated in advance. The entire purpose of accommodation involves matching individual needs with particular jobs at the point when they are needed. This appendix has a section not found in the appendix to the section 504 regulations dealing with architectural access. This section is added in these regulations because the nature of the 503 and 402 program differs from 504 in that they serve only employees and applicants of contractors, not program access for beneficiaries. Thus in section 503 and 402 architectural access is an element of the duty to provide reasonable accommodations rather than an independent obligation. We find this distinction necessary because, unlike section 504, 503 and 402 do not serve the general public. Therefore, they are designed to meet the specific needs of individuals at the time those needs arise. Since potential applicants or employees cannot be anticipated in advance, it would not be appropriate under section 503 and 402 to require costly renovations which might never be utilized. Therefore contractors must only renovate for access when an individual applies and is found qualified who needs architectural alterations. However, since employment offices and the employement process do serve the general public, they must be made accessible even in the absence of present handicapped employees or applicants. New construction and renovations and modifications of buildings must also meet appropriate desgin standards fot access at the time of construction or alteration.

It has been determined that this document does not contain a major proposal requiring preparation of a regulatory analysis under Executive Order 12044 (43 FR 12661) or under the Department's guidelines implementing Executive Order 12044 published at 44 FR 5570 on January 26, 1979.

In consideration of the foregoing, it is proposed to amend Parts 60–1, 60–250 and 60–741 of Chapter 60 of Title 41, Code of Federal Regulations, as set forth below.

Signed at Washington, D.C., this 22nd day of December 1980.

Ray Marshall,

Secretary.

PART 60–1—OBLIGATIONS OF CONTRACTORS AND SUBCONTRACTORS

1. The definitions of "Disabled veteran", "Handicapped individual", "Qualified disabled veteran" "Qualified handicapped individual" and "Veteran of the Vietnam era" at § 60–1.3 are revised and a new definition of "Reasonable accommodation" is added to read as follows:

§ 60–1.3 Definitions.

* * * * *

"Disabled veteran" means (a) a veteran who is entitled to compensation under laws administered by the Veterans' Administration, or (b) a person who was discharged or released from active duty because of a service-connected disability.

* * * * *

"Handicapped individual"

(a) "Handicapped individual" means any person who:

(1) Has a physical or mental impairment which substantially limits one or more major life activities; or

(2) Has a record of such an impairment; or

(3) Is regarded as having such an impairment

(b) As used in the preceding paragraph of this section, the phrase:

(1) "Physical or mental impairment" means

(i) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: Neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive; digestive; genito-urinary; hemic and lymphatic; skin and endocrine;

(ii) Any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

(2) "substantially limits" means the degree that the impairment affects an individual's employability. A handicapped individual who is likely to experience difficulty in securing, retaining, or advancing in employment would be considered substantially limited.

(3) "Major life activities" means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, working, and receiving education or vocational training.

(4) "Has a record of such an impairment" means that the individual has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activity.

(5) "Is regarded as having such an impairment" means that the individual

(i) Has a physical or mental impairment that does not substantially limit major life activities but that is treated by a contractor as constituting such a limitation;

(ii) Has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment; or

(iii) Has none of the impairments defined in paragraph (b)(1) of this section but is treated by a contractor as having an impairment.

* * * * *

"Qualified disabled veteran" means a disabled veteran as defined in §60–1.3 who is capable of performing the essential functions of the job or jobs for which he or she is being considered with reasonable accommodation to his or her disability.

"Qualified handicapped individual" means a handicapped individual as defined in § 60–1.3 who is capable of performing the essential functions of the job or jobs for which he or she is being considered with reasonable accommodation to his or her handicap.

"Reasonable accommodation" means the changes and modifications which can be made in the structure of a job or in the manner in which a job is performed unless it would impose an undue hardship on the conduct of the contractor's business. Reasonable accommodation may include:

(a) Making the facilities used by handicapped employees, including common areas used by all employees such as hallways, restrooms, cafeterias and lounges, readily accessible to and usable by handicapped workers and

(b) Job restructuring, part-time or modified work schedules, acquisition or modification of equipment or devices, the provision of readers or interpreters, and other similar actions.

* * * * *

"Veteran of the Vietnam era" means a person who (a) served on active duty for a period of more than 180 days, any part of which occurred between August 5, 1964 and May 7, 1975, and was discharged or released therefrom with other than a dishonorable discharge, or (b) was discharged or released from active duty for a service-connected

disability if any part of such active duty was performed between August 5, 1964 and May 7, 1975. However, no veteran may be considered to be a veteran of the Vietnam era under this paragraph after December 31, 1991.

(Sec. 503, Pub. L. 93-112, 87 Stat. 393 (20 U.S.C. 793), as amended by sec. 111, Pub. L. 93-516, 88 Stat. 1619 (29 U.S.C. 706) and sec. 112, Pub. L. 95-602, 92 Stat. 2984 (29 U.S.C. 790) and Executive Order 11758. Sec. 503(a), Pub. L. 92-540, 86 Stat. 1097 (38 U.S. 2012), as amended by sec. 402, Pub. L. 93-508, 88 Stat. 1593 (38 U.S.C. 2012) and sec. 508 and 509, Pub. L. 96-466, 94 Stat 2171 (38 U.S.C 2012))

PART 60-250—AFFIRMATIVE ACTION OBLIGATIONS OF CONTRACTORS AND SUBCONTRACTORS FOR DISABLED VETERANS AND VETERANS OF THE VIETNAM ERA

2. The authority citation for 41 CFR Part 60-250 is revised to read as follows:

Authority: Sec. 503(a), Pub. L. 92-540, 86 Stat. 1097 (38 U.S.C. 2012), as amended by sec. 508 and 509, Pub. L. 96-466, 94 Stat. 2171 (38 U.S.C. 2012).

3. Section 60-250.1 is revised to read as follows:

§ 60-250.1 Purpose and application.

The purpose of the regulations in this part is to assure compliance with section 402 of the Vietnam Era Veterans Readjustment Assistance Act of 1974, which requires government contractors to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era. The regulations in this part apply to all government contracts, including Federal deposit or share insurance, for the furnishing of supplies and services or for the use of personal property (including construction) in the amount of $10,000 or more. Contractors in compliance with this part which are also recipients of Federal financial assistance from the Department of Labor will be deemed in compliance with the employment provisions of the Department of Labor 504 regulations (see 29 CFR 32.2(b)).

4. Section 60-250.3 is revised to read as follows:

§ 60-250.3 Affirmative action clause.

Each agency and each contractor shall include the following affirmative action clause in each of its covered Government contracts (and modifications, renewals, or extensions thereof if not included in the original contract):

Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era

(a) The contractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment and otherwise treat qualified disabled veterans and veterans of the Vietnam era without discrimination based upon their disability or veterans status in all employment practices such as the following:

(1) Recruitment, advertising and the processing of applications for employment;

(2) Hiring, upgrading, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff and rehiring;

(3) Rates of pay or any other form of compensation and changes in compensation;

(4) Job assignments, job classifications, organizational structures, position descriptions, lines of prgression, and seniority lists;

(5) Leaves of absence, sick leave, or any other leave;

(6) Fringe benefits available by virtue of employment, whether or not administered by the contractor;

(7) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, and selection for leaves of absence to pursue training;

(8) Employer-sponsored activities including social or recreational programs; and

(9) Any other term, condition, or privilege of employment.

(b) The contractor agrees that all suitable employment openings of the contractor which exist at the time of the execution of this contract and those which occur during the performance of this contract, including those not generated by this contract and including those occuring at an estalishment of the contractor other than the one wherein the contract is being performed, but excluding those of independently operated corporate affiliates, shall be listed at an appropriate local office of the state employment service system wherein the opening occurs.

(c) Listings of employment openings with the employment service system pursuant to this clause shall be made at least concurrently with the use of any other recruiting source or effort and shall involve the normal obligations which attach to the placing of a bona fide job order, including the acceptance of referrals of veterans and non-veterans. This listing of employment openings does not require the hiring of any particular job applicant or hiring from any particular group of job applicants, and nothing herein is intended to relieve the contractor from any requirements in Executive Orders or regulations regarding nondiscrimination in employment.

(d) Documentation, including personnel records respecting job openings, recruitment and placement shall be made available.

(e) Whenever the contractor becomes contractually bound to the listing provision of this clause, it shall advise the employment service system in each state where it has establishments of the name and location of each hiring location in the state. As long as the contractor is contractually bound to these provisions and has so advised the state system, there is no need to advise the state system of subsequent contracts. The contractor may advise the state system when it is no longer bound by this contract clause.

(f) This clause does not apply to the listing of employment openings which occur and are filled outside of the 50 states, the District of Columbia, Puerto Rico, Guam and the Virgin Islands.

(g) The provisions of paragraphs (b), (c), (d), and (e) of this clause do not apply to openings which the contractor proposes to fill from within its own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement. This exclusion does not apply to a particular opening once an employer decides to consider applicants outside of its own organization or employer-union arrangement for that opening.

(h) As used in this clause: (1) "All suitable employment openings" includes, but is not limited to, openings which occur in the following job categories: Production and non-production; plant and office; laborers and mechanics; supervisory and nonsupervisory; technical; and executive, administrative, and professional openings as are compensated on a salary basis of less than $25,000 per year. This term includes full-time employment, temporary employment of more than 3 days' duration, and part-time employment. It does not include openings which the contractor proposes to fill from within its own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement nor openings in an educational institution which are restricted to students of that institution. Under the most compelling circumstances an employment opening may not be suitable for listing, including such situations where the needs of the Government cannot reasonably be otherwise supplied, where listing would be contrary to national security, or where the requirement of listing would otherwise not be in the best interest of the Government.

(2) "Appropriate office of the state employment service system" means the local office of the Federal-State national system of public employment offices with assigned responsibility for serving the area where the employment opening is to be filled, including the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

(3) "Openings which the contractor proposes to fill from within its own organization" means employment openings for which no consideration will be given to persons outside the contractor's organization (including any affiliates, subsidiaries, and the parent companies) and includes any openings which the contractor proposes to fill from regularly established "recall" lists.

(4) "Openings which the contractor proposes to fill pursuant to a customary and tranditional employer-union hiring arrangement" means employment openings which the contractor proposes to fill from union halls, which is part of the customary and traditional hiring relationship which exists between the contractor and representatives of its employees.

(i) The contractor agrees to comply with the rules, regulations, and relevant orders of

the Secretary of Labor issued pursuant to the Act.

(j) In the event of the contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(k) The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices in a form to be precribed by the Director, provided by or through the contracting officer. Such notice shall state the contractor's obligation under the law to take affirmative action to employ and advance in employment qualified disabled veterans and vererans of the Vietnam era and the rights of applicants and employees.

(l) The contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement of other contractual understanding, that the contractor is bund by the terms of the Vietnam Era Veterans Readjustment Assistance Act, and is committed to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era.

(m) The contractor will include the provisions of this clause in every subcontract or purchase order of $10,000 or more unless exempted by rules, regulations, or orders of the Secretary issued pursuant to the Act, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the Director of the Office of the Federal Contract Compliance Programs may direct to enforce such provisions, including action for non-compliance.

5. Paragraphs (a), (c) and (d) of § 60–250.5 are revised to read as follows:

§ 60–250.5 Affirmative action policy, practices and procedures.

(a) *General requirements.* Under the affirmative action obligation imposed by section 402 of the Act, contractors are required to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era at all levels of employment, including the executive level. Such action shall apply to all employment practices including, but not limited to, those practices specified in paragraph (a) of the affirmative action clause set forth in §60–250.3.

* * * * *

(c) *Job qualifications.* (1) The contractor shall provide in its affirmative action program, and shall adhere to, a schedule for the review of the appropriateness of all job qualifications to ensure that, to the extent job qualifications tend to exclude qualified disabled veterans because of their disability, they are related to the performance of the job and are consistent with business necessity and safe performance.

(2) Whenever a contractor applies job qualifications in the selection of applicants or employees for employment or other change in employment status such as promotion, demotion or training, which would tend to exclude qualified disabled veterans because of their disability, the qualifications shall be related to the specific job or jobs for which the individual is being considered and shall be consistent with business necessity and safe performance. The contractor shall have the burden to demonstrate that it has complied with the requirements of this paragraph.

(3) Except as provided in this section, a contractor may not conduct pre-employment medical examinations or make pre-employment inquiry of an applicant as to whether the applicant is a disabled veteran or as to the nature or the severity or a disability. A contractor may, however, make pre-employment inquiry into an applicant's ability to perform job-related functions.

(4) When a contractor is taking remedial action to correct the effects of past discrimination, when a contractor is taking voluntary action to overcome the effects of conditions that resulted in limited employment opportunities for qualified disabled veterans, or when a contractor is taking affirmative action under section 402 and the regulations in this part, the contractor may invite applicants for employment to indicate whether and to what extent they are disabled verterans if:

(i) The contractor states clearly on a written questionnaire used for this purpose or makes clear orally, if no written questionnaire is used, that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary or affirmative action efforts.

(ii) The contractor states clearly that the information is being requested on a voluntary basis, that it will be kept confidential as provided in paragraph (c)(6) of this section, that refusal to provide it will not subject the applicant or employee to any adverse treatment, and that it will be used only in accordance with this part.

(5) A contractor who routinely requires medical examinations as part of the employment selection process must demonstrate that each of the requirements of this subsection are met:

(i) The medical examination shall be performed by a physician qualified to make functional assessments of individuals in a form which will express residual capacity for work or training. Such an assessment does not require clinical determinations of disease or disability, but shall provide selecting or referring officials sufficient information regarding any functional limitations relevant to proper job placement or referrral to appropriate training programs. Factors which may be assessed may include, for example, use of limbs and extremities, mobility and posture, endurance and energy expediture, ability to withstand various working conditions and environments, use of senses and mental capacity.

(ii) The results of the medical examination shall be specific and objective so as to be susceptible to review by independent medical evaluators and shall be transmitted to the applicant or employee at the same time as the employing official;

(iii) The results of the medical examination shall not be used to screen out qualified applicants and employees but to determine proper placement and reasonable accommodation. The employing official using physical or mental information obtained pursuant to this section should be familiar with physical or mental activities involved in performing the job, and the working conditions and environment in which it is carried out. If the applicant is being considered for a variety of jobs having different requirements or skills, the employing official should make a functional assessment of the physical or mental demands of the jobs in order to match the applicant with the most suitable vacancy;

(iv) All potential employees for the job shall be subject to the medical examination;

(v) The procedures for using medical examinations or the medical information shall be constructed in such a manner that:

(A) A conditional job offer was made or the individual was conditionally placed in a job pool or conditionally placed on an eligibility list prior to the medical examination being performed; or

(B) The results of the medical examination were considered by the employing official only after a conditional decision to make a job offer or the individual had been placed conditionally in a job pool or conditionally placed on an eligibility list; that is, the medical results were the last factor evaluated by the employing official before a final decision to make an offer of employment was made.

(vi) Unless a conditional job offer is made prior to the medical examination, all potential employees for the job shall be informed at the time of the medical examination that:

(A) The results of the medical examination are the last factor

evaluated by the employing official before a final decision to make an offer of employment is made, and

(B) The medical examination results shall be transmitted to the employing official and to the applicant only after a conditional decision to make a job offer has been made.

(6) Information obtained in accordance with this section as to the medical condition or history of the applicant shall be collected and maintained on separate forms that shall be accorded confidentiality as medical records, except that:

(i) Employing officials may obtain the information after making a conditional decision to make a job offer to the applicant or the applicant was placed conditionally in a job pool or placed conditionally on an eligibility list.

(ii) Supervisors and managers may be informed regarding restrictions on the work or duties of disabled veterans and regarding necessary accommodations;

(iii) First aid and safety personnel may be informed, where appropriate, if the condition might require emergency care or treatment; and

(iv) Government officials investigating compliance with the Act shall be provided information upon request.

(d) *Reasonable accommodation.* (1) A contractor shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified disabled veteran unless the contractor demonstrates that the accommodation would impose an undue hardship on the conduct of the contractor's business.

(2) Reasonable accommodation may include:

(i) Making the facilities used by employees readily accessible to and usable by disabled veterans, and,

(ii) Job restructuring, part-time or modified work schedules, acquisition or modification of equipment or devices, the provision of readers or interpreters, and other similar actions.

(3) In determining pursuant to paragraph (d)(1) of this subsection whether an accommodation would impose an undue hardship on the conduct of a contractor's business, factors which may be considered include:

(i) The overall size of the contractor's operation with respect to the number of employees, number and type of facilities, and financial resources;

(ii) The type of the contractor's operation, including the composition and structure of the contractor's workforce; and

(iii) The nature and cost of the accommodation needed.

(4) A contractor may not deny any employment opportunity to a qualified handicapped employee or applicant if the basis for the denial is the need to make reasonable accommodation to the physical or mental limitations of the employee or applicant.

Note.—For further explanation and examples of reasonable accommodations, see Appendix C.

* * * * *

6–7. Section 60–250.31(a) is revised to read as follows:

§ 60–250.31 Recordkeeping.

(a) Each contractor shall maintain for a period not less than three years records regarding complaints and actions taken thereunder, and such employment or other records as required by the Director or by this part and shall furnish such information in the form required by the Director or as the Director deems necessary for the administration of the Act and regulations in this part.

* * * * *

8. A new Appendix C is added as follows:

Appendix C

Accommodations may take many forms based on the type of disability and the needs of the individual. In developing appropriate accommodations, the individual should be consulted as to particular needs.

The following is a list of possible types of accommodations provided for guidance and technical assistance.

Reasonable Accommodations for Employees

(a) Job restructuring means the procedure which includes:

(1) Identifying the separate tasks that comprise a job or group of jobs;

(2) Developing new position descriptions which retain some of the tasks of the original job; and

(3) Developing a career ladder which builds upward from the new positions which contain the lesser skilled tasks to regular jobs. A restructured job can be clearly different from the original one in terms of skills, knowledge, abilities, and work experience needed to perform the work. Job restructuring is intended to maximize the abilities of the particular handicapped person and is not intended to permit a contractor to under-employ or job-stereotype that person. A restructured job, for example, could be one in which the more highly skilled but physically less demanding duties are retained, e.g. operating controls and switches in a steel mill, and less skilled, physically taxing duties, e.g. lifting, pulling, are reassigned to non-handicapped employees.

(b) Modify job schedules, for example, by allowing for a flexible schedule a few days a week so that an employee may undergo medical treatment or therapy. Work-time may also be altered to permit disabled veterans to travel to and from work during non-rush hours. For employees who become unable to perform the duties of their positions because of a physical or mental condition, contractors may be required to grant liberal time off or leave without pay when paid sick leave is exhausted and when disability is of a nature that is likely to respond to treatment or hospitalization. See, e.g. 339 Federal Personnel Manual–1–3(b)(1).

(c) Relocate particular offices or jobs so that they are in facilities accessible to and usable by disabled veterans. For example, an employee with a respiratory ailment can be placed in a "nonsmoking" and/or well-ventilated office.

(e) Acquire or modify equipment or devices. For hearing-impaired employees, this may include placing amplifiers on telephone receivers, making telephone equipment compatible with hearing aids, providing flashing lights to supplement telephone rings, or installing telecommunications devices (TDD'S or TTY's). For blind employees, this may include providing tape recorders or dictating machines for those who cannot type. For wheelchair-users, this may include raising on blocks a desk that is otherwise to low for the employee, rather than purchasing a specially-made desk. A contractor is not obligated to acquire or modify equipment that enables an employee to perform a particular job until after an employee with a need for these modifications is hired.

(f) Provide readers, interpreters, and similar assistance as needed for deaf, blind and other handicapped employees. In most instances, this would not require a full-time assistant.

(g) Decrease reliance solely on one form of communication. For example, for deaf employees this may include supplementing job orientation sessions with written manuals and other visual materials. If appropriate, a visual warning system should be installed. It may also include providing flashing lights to supplement auditory signals such as sirens and alarm bells. For blind employees, this may include making some communications available in braille, enlarged print or cassette recordings. A contractor should tailor the accommodations listed above to the needs of the individual employees who have been hired for a particular job.

(h) Provide human relations-sensitivity training on issues pertaining to discrimination against disabled veterans to all employees.

(i) Conduct ongoing training and planning sessions with supervisors, managers, personnel, technical experts and disabled veterans advocates to implement and evaluate methods of reasonable accommodation.

Accommodation for Applicants

(a) Announce job vacancies in a form readily understandable by mentally disabled veterans and by persons with impaired vision or hearing, for example, by making the announcement available in braille or on cassette tapes. Contractors shall undertake to explain, as appropriate, job announcements to mentally disabled veterans. For example, this might entail notifying known mentally disabled veterans of openings for positions that they might be able to perform and taking specific steps to explain clearly the nature of the job and its benefits to that individual.

(b) Provide readers, interpreters, and other similar assistance during the application, testing, and interview process.

(c) Appropriately adjust or modify examinations so that the test results accurately reflect the applicant's skills, aptitudes or whatever other factor that test purports to measure, rather than reflecting the applicant's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure). This may require the extension of traditional time deadlines or allowing, for example, a blind person to answer an examination orally.

(d) If necessary, waive traditional tests and permit the applicant to demonstrate his or her skills through alternate techniques and utilization of adapted tools, aids, and devices.

Architectural Access

(a) Reasonable accommodation includes the duty to make the employment office, worksite and common areas accessible to handicapped applicants and employees. To the extent possible, employment offices, testing areas, waiting rooms and rest rooms serving the employment office should be accessible. A contractor whose only employment office is inaccessible and cannot reasonably be made accessible must develop an alternative method or sites for obtaining applications, conducting interviews and, where applicable, giving tests to disabled veteran applicants.

(b) When a disabled veteran qualifies for employment, the contractor must make the worksite and other common areas which the employee will use accessible unless such alterations would be unreasonable under the standards of these regulations. Common areas may include hallways, rest rooms, cafeterias, lounges, auditoriums, libraries, parking lots, credit-unions and other facilities generally have an affirmative action duty to ensure that any facilities constructed, acquired by purchase or lease or renovated after the effective date of its affirmative action program must be barrier-free, unless the contractor can establish that no mobility-impaired veteran could work in the affected worksite for reasons of business necessity. However, the business necessity reason which may relieve, for example, a coal mine, shipyard, logging camp or similar facility from the duty to be barrier free will not apply to the contractor's office jobs or other parts of the worksite where mobility-impaired workers may be qualified for jobs.

(d) For purposes of this appendix, newly built, acquired or renovated facilities will be deemed in compliance if they meet the standard for physical accessibility prescribed by the General Services Administration under the Architectural Barriers Act at 41 CFR 101-19.6. For specific employees, the contractor shall make whatever reasonable architectural modifications necessary which will enable the individual disabled veteran to work.

PART 60-741—AFFIRMATIVE ACTION OBLIGATIONS OF CONTRACTORS AND SUBCONTRACTORS FOR HANDICAPPED WORKERS

9. The authority citation for 41 CFR Part 60-741 is revised to read as follows:

Authority: Sec. 503, Pub. L. 93-112, 87 Stat. 393 (20 U.S.C. 793), as amended by sec. 111, Pub. L. 93-516, 88 Stat. 1619 (29 U.S.C. 706) and Sec. 122, Pub. L. 95-602, 92 Stat. 2984 (29 U.S.C. 790) and Executive Order 11758.

10. Section 60-741.1 is revised to read as follows:

§ 60-741.1 Purpose and application.

The purpose of the regulations in this part is to assure compliance with section 503 of the Rehabilitation Act of 1973, which requires government contractors to take affirmative action to employ and advance in employment qualified handicapped individuals. The regulations in this part apply to all government contracts and subcontractors, including Federal deposit or share insurance, for the furnishing of supplies and services or for the use of personal property (including construction) in excess of $2500. Contractors in compliance with this part which are also recipients of Federal financial assistance from the Department of Labor will be deemed in compliance with the employment provisions of the Department of Labor 504 regulations (see 29 CFR 32.2(b)).

11. Paragraph (a) of the affirmative action clause contained in § 60-741.3 is revised to read as follows:

§ 60-741.3 Affirmative action clause.

* * * * *

Affirmative Action for Handicapped Workers

(a) The contractor will not discriminate against any employee or applicant for employment because of physical or mental handicap in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment and otherwise treat qualified handicapped individuals without discrimination based upon their physical or mental handicap in all employment practices such as the following:

(1) Recruitment, advertising and the processing of applications for employment;

(2) Hiring, upgrading, promotion, award of tenure, demotion, transfer, layoff, termination, right of return from layoff and rehiring;

(3) Rates of pay or any other form of compensation and changes in compensation;

(4) Job assignments, job classifications, organizational structures, position descriptions, lines of progression, and seniority lists;

(5) Leaves of absence, sick leave, or any other leave;

(6) Fringe benefits available by virtue of employment, whether or not administered by the contractor;

(7) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, and selection for leaves of absence to pursue training;

(8) Employer-sponsored activities including social or recreational programs; and

(9) Any other term, condition, or privilege of employment.

* * * * *

12. Paragraphs (a), (b), (c) and (d) of § 60-741.5 are revised to read as follows:

§ 60-741.5 Affirmative action policy, practices and procedures.

(a) *General requirements.* Under the affirmative action obligation imposed by section 503 of the Act, contractors are required to take affirmative action to employ and advance in employment qualified handicapped individuals at all levels of employment, including the executive level. Such action shall apply to all employment practices including but not limited to those practices specified in paragraph (a) of the affirmative action clause set forth in § 60-741.3.

(b) *Proper consideration of qualifications.* Contractors shall review their personnel processes to determine whether their present procedures assure careful, thorough and systematic consideration of the job qualifications of known handicapped applicants and employees for job vacancies filled either by hiring or promotion, and for all training opportunities offered or available. To the extent that it is necessary to modify their personnel procedures, contractors shall include the development of new procedures for this purpose in their affirmative action program required under this part. These procedures must be designed so as to facilitate a review of the implementation of this requirement by the contractor or the government. (Appendix B attached is an example of an appropriate set of procedures. The procedures in Appendix B are not required and contractors may develop other procedures which are appropriate to their circumstances.)

(c) *Job qualifications.* (1) The contractor shall provide in its affirmative action program, and shall adhere to, a schedule for the review of the appropriateness of all job qualification requirements to ensure that, to the extent job qualifications tend to exclude handicapped individuals because of their handicap they are related to the performance of the job and are consistent with business necessity and safe performance.

(2) Whenever a contractor applies job qualifications in the selection of applicants or employees for employment or other change in employment status such as promotion, demotion or training, which would tend to exclude handicapped individuals because of their handicap, the qualifications shall be related to the specific job or jobs for which the individual is being considered and shall be consistent with business necessity and safe performance. The contractor shall have the burden to demonstrate that it has complied with the requirements of this paragraph.

(3) Except as provided in this section, a contractor may not conduct pre-employment medical examinations or make pre-employment inquiry of an applicant as to whether the applicant is a handicapped person or as to the nature or the severity of a handicap. A contractor may, however, make pre-employment inquiry into an applicant's ability to perform job-related functions.

(4) When a contractor is taking remedial action to correct the effects of past discrimination, when a contractor is taking voluntary action to overcome the effects of conditions that resulted in limited employment opportunities for qualified handicapped individuals, or when a contractor is taking affirmative action under section 503 and the regulations in this part, the contractor may invite employees and applicants for employment to indicate whether and to what extent they are handicapped if:

(i) The contractor states clearly on any written questionnaire used for this purpose or makes clear orally, if no written questionnaire is used, that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary or affirmative action efforts;

(ii) The contractor states clearly that the information is being requested on a voluntary basis, that it will be kept confidential as provided in paragraph (c)(6) of section, that refusal to provide it will not subject the applicant or employee to any adverse treatment, and that it will be used only in accordance with this part.

(5) A contractor who routinely requires medical examinations as part of the employment selection process must demonstrate that each of the requirements of this subsection are met:

(i) The medical examination shall be performed by a physician qualified to make functional assessments of individuals in a form which will express residual capacity for work or training. Such an assessment does not require clinical determinations of disease or disability, but shall provide selecting or referring officials sufficient information regarding any functional limitations relevant to proper job placement. Factors which may be assessed may include, for example, use of limbs and extremities, mobility and posture, endurance and energy expenditure, ability to withstand various working conditions and environments, use of senses and mental capacity.

(ii) The results of the medical examination shall be specific and objective so as to be susceptible to review by independent medical evaluators and shall be transmitted to the applicant or employee at the same time as the employing official;

(iii) The results of the medical examination shall not be used to screen out qualified applicants and employees but to determine proper placement and reasonable accommodation. The employing official using physical or mental information obtained pursuant to this section should be familiar with physical or mental activities involved in performing the job, and the working conditions and environment in which it is carried out. If applicant is being considered for a variety of jobs having different requirements or skills, the employing official should make a functional assessment of the physical or mental demands of the jobs in order to match the applicant with the most suitable vacancy;

(iv) All potential employees for the job shall be subjected to the medical examination;

(v) The procedures for using medical examinations or the medical information shall be constructed in such a manner that:

(A) A conditional job offer was made or the individual was conditionally placed in a job pool or conditionally placed on an eligibility list prior to the medical examination being performed; or

(B) The results of the medical examination were considered by the employing official only after a conditional decision to make job offer or the individual had been placed conditionally in a job pool or conditionally placed on an eligibility list; that is, the medical results were the last factor evaluated by the employing official before a final decision to make an offer of employment was made.

(vi) Unless a conditional job offer is made prior to the medical examination, all potential employees for the job shall be informed at the time of the medical examination that:

(A) The results of the medical examination are the last factor evaluated by the employing official before a final decision to make an offer of employment is made, and

(B) The medical examination results shall be transmitted to the employing official and to the applicant only after a conditional decision to make a job offer has been made.

(6) Information obtained in accordance with this section as to the medical condition or history of the applicant shall be collected and maintained on separate forms that shall be accorded confidentiality as medical records, except that:

(i) Employing officials may obtain the information after making a conditional decision to make a job offer to the applicant or the applicant was placed conditionally in a job pool or placed conditionally on an eligibility list.

(ii) Supervisors and managers may be informed regarding restrictions on the work or duties of qualified handicapped persons and regarding necessary accommodations;

(iii) First aid and safety personnel may be informed, where appropriate, if the condition might require emergency treatment; and

(iv) Government officials investigating compliance with the Act shall be provided information upon request.

(d) *Reasonable accommodation.* (1) A contractor shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the contractor demonstrates that the accommodation would impose an undue hardship on the conduct of the contractor's business.

(2) In determining pursuant to paragraph (d)(1) of this section whether an accommodation would impose an undue hardship on the conduct of a contractor's business, factors which may be considered include:

(i) The overall size of the contractor's operation with respect to the number of employees, number and type of facilities, and financial resources;

(ii) The type of the contractor's operation, including the composition and structure of the contractor's workforce; and

(iii) The nature and cost of the accommodation needed.

(3) A contractor may not deny any employment opportunity to a qualified handicapped employee or applicant if the basis for the denial is the need to make reasonable accommodation to the physical or mental limitations of the employee or applicant.

Note.—For further explanation and examples of accommodations, see Appendix C.

* * * * *

13. Section 60–741.30(a) is revised to read as follows:

§ 60–741.30 Recordkeeping.

(a) Each contractor shall maintain for a period not less than three years records regarding complaints and actions taken thereunder and such employment or other records as required by the Director or agency or by this part and shall furnish such information in the form required by the Director or agency or as the Director deems necessary for the administration of the Act and regulations issued under this part.

* * * * *

Appendix A [Removed]; Appendices B and C [Redesignated as Appendices A and B]

14. Appendix A is removed and Appendices B and C are designated as A and B and a new Appendix C is added as follows:

Appendix C

Accommodations may take many forms based on the type of handicap and the needs of the individual. In developing appropriate accommodations, the individual should be consulted as to particular needs.

The following is a list of possible types of accommodations provided for guidance and technical assistance.

Accommodations for Employees

(a) Job restructuring means the procedure which includes:

(1) Identifying the separate tasks that comprise a job or group of jobs;

(2) Developing new position descriptions which retain some of the tasks of the original job; and

(3) Developing a career ladder which builds upward from the new positions which contain the lesser skilled tasks to regular jobs. A restructured job can be clearly different from the original one in terms of skills, knowledge, abilities, and work experience needed to perform the work. Job restructuring is intended to maximize the abilities of the particular handicapped person and is not intended to permit a contractor to under-employ or job-stereotype that person. A restructured job, for example, could be one in which the more highly skilled but physically less demanding duties are retained, e.g. operating controls and switches in a steel mill, and less skilled, physically taxing duties, e.g. lifting, pulling, are reassigned to non-handicapped employees.

(b) Modify job schedules, for example, by allowing for a flexible schedule a few days a week so that an employee may undergo medical treatment or therapy. Worktimes may also be altered to permit handicapped individuals to travel to and from work during non-rush hours. For employees who become unable to perform the duties of their positions because of a physical or mental condition, contractors may be required to grant liberal time off or leave without pay when paid sick leave is exhausted and when the disability is of a nature that is likely to respond to treatment or hospitalization. See, e.g. 339 Federal Personnel Manual–1–3(b)(1).

(c) Modify work procedures and training time.

(d) Relocate particular offices or jobs so that they are in facilities accessible to and usable by handicapped persons. For example, an employee with a respiratory ailment can be placed in a "nonsmoking" and/or well-ventilated office.

(e) Acquire or modify equipment or devices. For hearing-impaired employees, this may include placing amplifiers on telephone receivers, making telephone equipment compatible with hearing aids, providing flashing lights to supplement telephone rings or installing telecommunications devices (TTD's or TTY's). For blind employees, this may include providing tape recorders or dictating machines for those who cannot type. For wheelchair-users, this may include raising on blocks a desk that is otherwise too low for the employee, rather than purchasing a specially-made desk. A contractor is not obligated to acquire or modify equipment that enables an employee to perform a particular job until after an employee with a need for these modifications is hired.

(f) Provide readers, interpreters, and similar assistance as needed for deaf, blind and other handicapped employees. In most instances, this would not require a full-time assistant.

(g) Decrease reliance solely on one form of communication. For example, for deaf employees this may include supplementing job orientation sessions with written manuals and other visual materials. If appropriate, a visual warning system should be installed. It may also include providing flashing lights to supplement auditory signals such as sirens and alarm bells. For blind employees, this may include making some communications available in braille, enlarged print or cassette recordings. A contractor should tailor the accommodations listed above to the needs of the individual employees who have been hired for a particular job.

Accommodation for Applicants

(a) Announce job vacancies in a form readily understandable by mentally handicapped persons and by persons with impaired vision or hearing, for example, by making the announcement available in braille or on cassette tapes. Contractors shall undertake to explain, as appropriate, job announcements to mentally disabled veterans. For example, this might entail notifying known mentally handicapped employees of openings for positions that they might be able to perform and taking specific steps to explain clearly the nature of the job and its benefits to that individual.

(b) Provide readers, interpreters, and other similar assistance during the application, testing and interview process.

(c) Appropriately adjust or modify examinations so that the test results accurately reflect the applicant's skills, aptitudes or whatever other factor that test purports to measure, rather than reflecting the applicant's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure). This may require the extension of traditional time deadlines or allowing, for example, a blind person to answer an examination orally.

(d) If necessary, waive traditional tests and permit the applicant to demonstrate his or her skills through alternate techniques and utilization of adapted tools, aids, and devices.

Architectural Access

(a) Reasonable accommodation includes the duty to make the employment office, worksite and common areas accessible to handicapped applicants and employees. To the extent possible, employment offices, testing areas, waiting rooms and rest rooms serving the employment office should be accessible. A contractor whose only employment office is inaccessible and cannot reasonably be made accessible must develop an alternative method or sites for obtaining applications, conducting interviews and, where applicable, giving tests to handicapped applicants.

(b) When a handicapped individual qualifies for employment, the contractor must make the worksite and other common areas which the employee will use accessible unless such alterations would be unreasonable under the standards of these regulations. Common areas may include hallways, rest rooms, cafeterias, lounges, auditoriums, libraries, parking lots, credit-unions and other facilities generally available for employee use.

(c) If there are no present handicapped employees or applicants, a contractor is not required to retrofit facilities in the absence of need. However, contractors have an affirmative action duty to ensure that any facilities constructed, acquired by purchase or lease or renovated after the effective date of its affirmative action program must be barrier-free, unless the contractor can establish that no mobility-impaired individual could work in the affected worksite for reasons of business necessity. However, the business necessity reason which may relieve, for example, a coalmine, shipyard, logging camp or similar facility from the duty to be barrier free will not apply to the contractor's office jobs or other parts of the worksite where mobility-impaired workers may be qualified for jobs.

(d) For purposes of this appendix, newly built, acquired or renovated facilities will be deemed in compliance if they meet the standard for physical accessibility prescribed by the General Services Administration under the Architectural Barriers Act at 41 CFR 101–19.6. For specific employees, the contractor shall make whatever reasonable architectural modifications necessary which will enable the handicapped individual to work.

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Part VI

Department of Labor

Office of Federal Contract Compliance Programs

Government Contractors; Affirmative Action Requirements; Final Rule

DEPARTMENT OF LABOR

Office of Federal Contract Compliance Programs

41 CFR Parts 60-1, 60-2, 60-4, 60-20, 60-30, 60-50, 60-60, 60-250, and 60-741

Government Contractors; Affirmative Action Requirements

AGENCY: Office of Federal Contract Compliance Programs, Labor.

ACTION: Final rule.

SUMMARY: The regulations published today amend a limited number of the regulatory provisions under Executive Order 11246, as amended, and under sections 402 and 503 of the Vietnam Era Veterans' Readjustment Assistant Act of 1974, as amended, and the Rehabilitation Act of 1973, as amended, respectively. This final rule also consolidates and integrates certain portions of the regulations pertaining to sections 402 and 503 into 41 CFR Part 60-1 which, heretofore, has been devoted solely to regulations implementing Executive Order 11246.

EFFECTIVE DATE: These regulations, except new reporting and recordkeeping requirements established by this final rule (see discussion following item 49 below), shall take effect January 29, 1981.

FOR FURTHER INFORMATION CONTACT: James W. Cisco, Acting Director, Division of Program Policy, Office of Federal Contract Compliance Programs, Room C-3324, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210, Telephone (202) 523-9426.

SUPPLEMENTARY INFORMATION: On December 28, 1979, the Office of Federal Contract Compliance Programs (OFCCP), U.S. Department of Labor, published in the **Federal Register** (44 FR 77006) a proposed rule to amend, consolidate, and integrate certain regulatory provisions pertaining to the three programs administered by OFCCP: Executive Order 11246, as amended; section 402 of the Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended; and section 503 of the Rehabiliation Act of 1973, as amended. The December 28 publication stated that comments would be received until February 26, 1980. However, the comment deadline was extended until March 24, 1980, by a notice published in the **Federal Register** on February 22, 1980 (45 FR 11856), which also proposed that a new paragraph (g) be added to proposed § 60-1.29, originally published on December 28, 1979. The December 28, 1979, proposal also stated that nonsubstantive editorial changes would be made on final rulemaking, and that consideration would be given to republishing 41 CFR Chapter 60 in its entirety so that users of the OFCCP regulations would have all parts intact until they could be codified in the Code of Federal Regulations. Some editorial changes have been made in the final rule published today. No changes have been made in Part 60-3, the Uniform Guidelines on Employee Selection Procedures (1978), and Part 60-3 is not being republished today. Three clarifying amendments to Part 60-4, pertaining to construction contractors, were published on October 3, 1980, (45 FR 65976), and became effective on November 3, 1980. Part 60-4, including the November 3, 1980, amendments thereto, is republished in its entirety today so that users of Part 60-4 will have a single document which contains all the construction regulations under Executive Order 11246 until they have been published in codified form. Part 60-40, pertaining to disclosure of documents, presently is being considered for revision as a result of the Supreme Court's opinion in *Chrysler Corporation v. Brown*, 441 U.S. 281, and is not being republished today. Part 60-60 is being deleted from the regulations today. However, some parts of 60-60 have been transferred to Parts 60-1 and 60-2. See discussion of Part 60-60 below. Except as indicated above, 41 CFR Chapter 60 is being republished today. Those parts of Chapter 60 which are not being republished today may be found in the latest edition of 41 CFR Chapter 60. It is not expected that the regulations published today will be codified into 41 CFR Chapter 60 until July 1981, and that revised Title should be available to the public early in 1982.

Since consolidation of the Executive Order program into the Department of Labor, it has been OFCCP's practice to review simultaneously a contractor's compliance with each of the three laws administered by OFCCP. To reflect this unified approach of administering and enforcing the three laws, an effort has been made to consolidate and integrate the regulations of each of the three programs to the extent clarity permits. The regulations published today, therefore, incorporate into Part 60-1 important elements which are common to each of the three laws. Some of these provisions previously appeared in Parts 60-250 (veterans) and 60-741 (handicap). Some rearrangement of specific sections also has been made. In addition, published as the Part V of this **Federal Register** are proposed amendments to Parts 60-250 and 60-741 which are designed to conform these two parts to the Department of Labor's regulations implementing section 504 of the Rehabilitation Act of 1973. The latter regulations were published on October 7, 1980 (45 FR 66706), and the preamble to those regulations stated that such conforming amendments would be proposed.

A total of 602 comments were received on the December 28, 1979, and February 22, 1980, proposals. Comments also were received after the comment period closed. This latter group of comments were reviewed, analyzed and considered but are in addition to the 602 comments.

Section-by-Section Analysis

1. *Section 60-1.1.* This section describes the purpose and application of the regulations contained in Part 60-1. Presently, Part 60-1 applies only to Executive Order 11246. However, the proposal would amend Part 60-1 by transferring some of the regulations in Part 60-250 (pertaining to section 402 of the Vietnam Era Veterans' Readjustment Assistance Act) and in Part 60-741 (pertaining to section 503 of the Rehabilitation Act of 1973) to Part 60-1. Also, the proposal would amend Part 60-1 to make certain procedures (e.g., show cause notice and preaward reviews), heretofore applicable only to the Executive Order, applicable to sections 402 and 503. In view of these proposed amendments, it was necessary to expand the scope of § 60-1.1 to reflect that Part 60-1, in addition to implementing requirements of the Executive Order, implements requirements of sections 402 and 503.

The comments received on § 60-1.1 assumed that all requirements under the Executive Order program would be applicable to sections 402 and 503 if the proposed amendment were adopted. Specifically, they were concerned that contractors would be required to develop affirmative action programs (AAPs) for Vietnam Era and disabled veterans and handicapped workers pursuant to Executive Order 11246 procedures. One comment also raised questions as to whether sections 402 and 503 were being extended to cover federally assisted construction contracts. Other comments suggested that the proposed amendment was an attempt to evade the Contracts Disputes Act of 1978 (92 Stat. 2383).

The proposed amendment was intended merely to reflect that some of the regulations applicable to the sections 402 and 503 programs were being transferred to Part 60-1 of the

regulations and that some of the regulations already contained in Part 60–1 would be applicable to the Veterans and handicapped programs. The amendment is adopted as proposed.

The Part 60–1 regulations which have been transferred from Parts 60–250 and 60–741 are specifically identified as being applicable only to the veterans and handicapped programs. Regulations already contained in Part 60–1, for the most part, now state whether they are applicable to sections 402 and 503. An expressed statement is not made if the application of the regulation is clear from the context. The definition of "Vietnam era veteran" in § 60–1.3, for example, is not specifically limited to section 402, but that definition has no meaning for Executive Order purposes.

Regulations regarding the development of AAPs for the veterans and handicapped programs are still published in Parts 60–250 and 60–741, respectively. The regulations do not require contractors to follow Executive Order procedures in Part 60–2 in developing AAP's under sections 402 and 503. Neither do sections 402 and 503 apply to federally assisted construction contracts.

Presumably, the sentence in the proposed amendment to § 60–1.1(b) which stated that the regulations in Chapter 60, Title 41 of the Code of Federal Regulations govern a contractor's compliance obligations under the Executive Order and sections 402 and 503, led some persons submitting comments to conclude that the regulations attempt to evade the Contract Disputes Act. The thrust of the statement in § 60–1.1(b) is that with regard to matters of equal employment opportunity, the OFCCP regulations, not the disputes clause in the contract, determine whether the contractor is in compliance. This provision has been in § 60–1.1 since at least 1968 (see 33 FR 7804). The Contract Disputes Act is not in issue. The Department of Labor view of the Contract Disputes Act, however, is that it does not change the obligations of contractors with regard to the programs administered by OFCCP.

2. *Section 60–1.3.* Presently, each of the three OFCCP programs has separate regulations. Each set of regulations contains a definitions section. Because of the similarities among the three programs, certain words and phrases are common to each, and the definitions of such words and phrases are identical. Thus, words like contract, contractor, contracting agency, complaint, and Government, to list a few, are common to each program. Of course, there also are definitions which are peculiar or unique to only one of the three programs. No useful purpose is served by maintaining separate sections in three different and separate parts of the regulations for definitions. This view makes particular sense because the regulations of all three contract compliance programs have been consolidated into 41 CFR Chapter 60. Prior to 1976, the section 402 regulations appeared in Title 29 of the CFR and the section 503 regulations appeared in Title 20 of the CFR. Accordingly, the December 28, 1979, proposal would amend 41 CFR Chapter 60 by consolidating the definitions relating to the three contract compliance programs into 41 CFR 60–1.3. The major amendment proposed to § 60–1.3 last December related to consolidating the definitions. Modifications of four definitions and the addition of a small number of new definitions also were proposed.

Some definitions were proposed to avoid repetitions throughout the regulations. Where the regulations prohibit certain conduct or describe activities which may result in a violation, for example, the practice has been to state in the regulations that the act or omission is a violation of the Order, the Equal Opportunity clause and the regulations implementing the Order. Similar clauses are used in the sections 402 and 503 regulations. The definition of "Order" therefore was proposed to include Executive Order 11246 and its predecessor executive orders, the equal opportunity clause and the rules, regulations or orders issued pursuant to the Executive Order. Sections 402 and 503 also were defined to make it clear that references to the regulations, for example, were not necessary to bind contractors to their 402 and 503 obligations.

Similarly, the word "contractor" was proposed to be amended to include the word "subcontractor," to avoid the present practice of repeating subcontractor each time contractor is used in the regulations in order to demonstrate that the particular regulation applies to both contractors and subcontractors. The same is true with regard to the words "contract" and "subcontract."

The amendment to the definition section is adopted essentially as proposed. Some changes in the definitions have been made based on the comments, however. We now consider the definitions about which the comments raised specific problems.

Applicant. The proposal recognized that this word relates to one who is seeking employment, and in the context of federally assisted construction, one who is seeking financial assistance from the Government. But the major problem raised by the comments relates to the definition in its employment context. The basic problem perceived by the comments is the breadth of the definition of "applicant for employment." The comments were concerned more about what they characterized as informal applications for employment and related problems which would result in attempting to maintain applicant flow data on telephone inquiries, for example.

In attempting to define an applicant for employment, an effort has been made to provide a workable definition. The Department of Labor's view is that the definition must be sufficiently broad to protect from discrimination all persons who apply for work. It would be easy to limit the term applicant to one who has filed a written application for employment with a contractor. Such a definition, however, would permit a contractor to prescreen too easily those persons who would be given an opportunity to file the formal application. On the other hand, a contractor is certainly in a position to gather more data on a person who submits a formal application and is granted some type of an interview than it is on a person who makes only a casual inquiry about employment. But it is unlikely that any definition of applicant can be constructed with such precision that reasonable people would not disagree about specific factual circumstances fitting within the definition. On balance, the definition provides adequate protection and gives a contractor a fair standard to follow. In the event that disagreements develop with regard to specific factual circumstances, they can be resolved through conciliation and enforcement procedures.

Complaint. Except for the addition of the phrase, "former employee," the definition of complaint is adopted as proposed. The addition of this new phrase is technical in nature and is made simply to avoid disputes as to whether a former employee may file complaints. Several comments were submitted on the proposed definition, but they relate more to proposed § 60–1.23 and therefore have been treated in the discussion on that section.

Establishment. The proposal attempted to balance the obligation of all contractors subject to 41 CFR 60–1.40 and Part 60–2 to cover all employees with an affirmative action plan with the fact that some establishments are so small that it would not be unreasonable to combine them for affirmative action program purposes. Individuals

submitting comments were primarily concerned with the fact that the term "small locations" was not defined and that almost all physical locations have someone who exercises a degree of personnel authority, even though most decisions are made at some other location. In order to meet those concerns, a revision has been made in the definition adopted today. "Small" has been defined as less than 50 employees, and such locations may be combined regardless of whether some personnel functions are exercised there. However, in order to prevent against possible misuse of the ability of contractors to consolidate establishments, the definition clarifies the fact that they must be in the same SMSA or labor area. In addition, § 60–2.2 has been clarified so that there can be no doubt regarding each covered contractor's obligation to include all its employees in an AAP.

Handicapped individual. A change was proposed in this definition. However, no major revisions in the section 503 program were proposed because efforts are underway to conform as much as possible the section 503 and the Department of Labor's section 504 regulations. Therefore any amendment to the 503 regulations will be deferred to that effort.

Minority group. No amendment was proposed to this definition; however, it is being deleted from the regulations because it no longer serves a useful purpose. It was added initially to require construction contractors to include at least minority women in their goals efforts. Since May 1978 female utilization goals have been required of construction contractors.

Prime contractor. A number of comments objected to this definition and to the definition of "contractor" because they include persons holding, and for purposes of enforcement, persons who have held a contract. The comments expressed the view that whenever the procured goods or services have been delivered in accordance with the contract, the contractor's obligation is terminated. The provisions objected to, however, have been in the regulations since 1968 (see 33 FR 7805), and were not proposed to be amended. The rationale of the provision is that, for example, a contractor which has delivered the goods under the contract may nevertheless be sanctioned if it has not performed the equal employment opportunity obligations of the contract.

3. *Section 60–1.4.* Paragraphs (d), (e) and (f) of this section relating to incorporation by reference, incorporation by operation of the Order and adaptation of language have been transferred to §§ 60–1.45, 60–1.46 and 60–1.47, respectively. In addition, as part of the consolidation of the regulations, these sections have been amended to include sections 402 and 503 within their ambit, and comparable sections in Parts 60–250 and 60–741 have been deleted.

4. *Section 60–1.5(a).* Generally, contracts for $10,000 or less are exempt from the requirements of the Order. This exemption has not been applied to financial institutions which are covered by the Order if they act as depositories of Federal funds in any amount or as issuing or paying agents for U.S. savings bonds or savings notes in any amount.

OFCCP believes that Federal deposit and share insurance are contracts within the meaning of the Order and of sections 402 and 503. Such contracts are excluded from the generally applicable $10,000 and under exemption of the Order. (The jurisdictional amount under section 402 is $10,000 and must exceed $2,500 under section 503.) OFCCP's opinion that deposit and share insurance are contracts within the meaning of the Order and sections 402 and 503 is contested by the Federal Deposit Insurance Corporation (FDIC), the National Credit Union Administration (NCUA), the Board of Governors of the Federal Reserve System (FRB) and the Comptroller of the Currency (Comptroller). These financial institutions regulatory agencies believe that deposit and share insurance are not contracts within the meaning of the Order and of sections 402 and 503. These agencies and the Federal Home Loan Bank Board (FHLBB) contend that only the financial institutions regulatory agencies themselves have the authority to debar, deny, suspend or terminate deposit or share insurance.

On February 22, 1980, OFCCP published a clarification, at 45 FR 11856, of its proposal of December 28, 1979. In the clarification, OFCCP indicated that it did not intend to debar financial institutions from deposit or share insurance. Rather, in a proposed addition to § 60–1.29 (Enforcement Proceedings), OFCCP indicated that, where a financial institution which has Federal deposit or share insurance is alleged to have violated the Order, section 402 or section 503, the Department of Labor would pursue one of two options with respect to the insurance relationship—either refer the matter to the appropriate Federal financial institutions regulatory agency for action under that agency's procedures or to the Department of Justice.

While the clarification should relieve public concern that OFCCP would not endanger the accounts of innocent depositors, the questions remain of whether deposit or share insurance are contracts within the meaning of Executive Order 11246, sections 402 and 503 and whether the financial institutions regulatory agencies have exclusive jurisdiction to deny or terminate deposit or share insurance. All agencies will be free to argue their respective legal positions, if necessary, in any subsequent legal proceedings that may arise.

Under the regulations published today, where financial institutions have contractual relationships with the Federal Government (other than deposit or share insurance), OFCCP may enforce any suspected violations of the Order or of sections 402 or 503 in any manner described in § 60–1.29, including referral of the matter to the appropriate financial institution regulatory agency for enforcement action. See § 60–1.29(i).

In those few instances in which the only nexus between a financial institution and the Federal Government is deposit or share insurance, OFCCP will refer the matter to the Department of Justice under section 209(a)(2) of Executive Order 11246 and § 60–1.29(f) of the regulations for injunctive relief or, if appropriate, exercise its discretion pursuant to section 209(a)(3) of Executive Order 11246 § 60–1.29(h) of these regulations to recommend to the EEOC that proceedings be instituted under Title VII of the Civil Rights Act of 1964. In addition, OFCCP also may refer such matters to financial institutions regulatory agencies.

Regulations for the FHLBB explicitly prohibit employment discrimination. See 12 CFR 528.7 (1979). OFCCP and EEOC encourage the FDIC and NCUA to publish similar regulations.

The proposed amendment to add utilities which comprise part of a State or local government to the list of agencies of such governments which must develop and maintain written affirmative action programs has been adopted.

5. *Section 60–1.7.* This section requires contractors with 50 employees and a contract of $50,000 to file the EEO–1 report. It also requires contractors to make certain certifications in their bids with regard to AAPs and other aspects of compliance. In addition, prime contractors are required to obtain the same certifications from their subcontractors. The certification requirement has resulted in a major paperwork requirement. Contractors, not knowing precisely when they may be required to make such certifications or require them of their subcontractors, have adopted the practice of requiring on an annual basis such certifications

from their vendors and others which may have or develop a contractual relationship with them.

The proposed amendment, consistent with the proposed amendments to § 60–1.40 and § 60–2.1, would require a contractor with 50 employees and contracts which total $50,000 to file the EEO–1 report. No amendments were proposed regarding the certification requirements. Nevertheless, the comments raised the paperwork burden argument both with respect to EEO–1 reports and the certification requirements.

The proposed amendment to § 60–1.40 and to § 60–2.1 which would require contractors to accumulate contracts to $50,000 for purposes of coverage under Revised Order 4 is adopted (see discussion under § 60–1.40 below). Similary, the proposed amendment to § 60–1.7 to require such contractors to submit EEO–1 reports is adopted.

The certification of the prime contractor to the contracting agency is retained. However, the obligation of prime contractors to obtain certifications from subcontractors is discontinued. In other words, prime contractors will make the certification only to the contracting agency and only with respect to their own practices. They no longer will be required to obtain certifications from their subcontractors.

Finally, paragraph (c) of this section which states that data obtained under § 60–1.7 will be used only in connection with administering the Executive Order and the Civil Rights Act of 1964 was not proposed to be amended. Paragraph (c), however, is viewed as a potential obstacle to sharing information for purposes of enforcing other EEO laws. It is very likely, for example, that OFCCP will share information with Federal agencies which have EEO responsibilities under statutes other than the Civil Rights Act. Therefore, in the regulation adopted today, paragraph (c) has been deleted from § 60–1.7. See discussion of § 60–1.43 below.

6. *Section 60–1.8.* This section requires a certification that the contractor's facilities are not segregated. The proposal would delete the certification but contractors would continue to have an obligation not to maintain facilities on a segregated basis. Contractors also would be required to assure privacy between the sexes in toilet, changing and similar facilities. The regulation is adopted as proposed.

7. *Section 60–1.9.* The regulatory policy of providing for limited union participation in the compliance process under the Executive Order dates back to the days of the President's Committee on Equal Employment Opportunity. The present regulations continue that policy and provide for hearings and other efforts with regard to employee representatives, to assist in implementing the purposes of the Order. They also provide that collective bargaining representatives shall be given an opportunity to present their views to OFCCP when compliance with the Order necessitates a revision of the labor agreement. In addition, the Director of OFCCP may notify Federal, state and local agencies when unions are violating equal employment laws.

The proposal would restructure § 60–1.9. The proposal also would transfer comparable provisions from the veterans (Part 60–250) and the handicapped (Part 60–741) regulations as part of the general consolidation of the regulations, and delete the corresponding provisions in Parts 60–250 and 60–741. The thrust of the comments was that the proposal would allow union participation in activities which essentially are matters between the Government and contractors, and that such participation should not occur without concomitant duties on the unions.

As pointed out above, the concepts embodied in this regulation have remained consistent since the early 1960s and revisions of those concepts were not proposed. Moreover, this section and the corresponding sections in Parts 60–250 and 60–741 have not generated substantial activity. It also is considered to be essential that unions be allowed to present their views, particularly when a bargaining agreement may require revision, in order to achieve compliance under the three laws administered by OFCCP. This approach is consistent with the concept of conciliation which is a touchstone of all Federal equal employment opportunity laws. Accordingly, this section has been amended to require notification to the union of on site reviews and an invitation to participate in conciliation discussions to the extent those discussions involve proposed changes in the collective bargaining agreement.

Contractors are obligated to advise labor unions and other workers' representative of the contractors' contractual obligations under the Executive Order. The OFCCP also expects contractors to inform unions and other workers' representatives of items disclosed in the compliance review which require changes in a collective bargaining agreement, and initially seek a resolution with the union.

Accordingly, the proposed amendment to § 60–1.9 is adopted as modified. (See discussion of § 60–1.25 relating to show cause notices.)

8. *Section 60–1.20.* This section outlines in broad form the basic procedures for conducting compliance reviews. The proposal would amend § 60–1.20 by consolidating therein all the general procedures relating to compliance reviews except for preaward reviews. The proposal also would transfer certain items relating to compliance reviews to this section from Revised Order 14 (Part 60–60) which today is being deleted from the regulations. Finally, the proposal would amend § 60–1.20 to state that compliance reviews under sections 402 and 503 would be governed by this section also.

Some comments objected to the references to sections 402 and 503 on the grounds that compliance reviews are not authorized under those two statutes. These statutes, of course, provide for broad rulemaking authority. They emphasize complaint processing but nothing in the statutes indicates that compliance is to be achieved only through investigations of complaints. Indeed, if Congress had intended that compliance activity should depend upon receipt of a complaint it could have so provided explicitly. The only reasonable conclusion is that Congress intended that a full complement of enforcement mechanisms be available to achieve compliance with sections 402 and 503.

Some of the comments raised objections to the provision which states that contractors will be notified that commitments in a conciliation agreement do not preclude future determinations of noncompliance based either on a finding that the commitments are inadequate to achieve compliance or on a violation not previously revealed. This concept has been in the regulations since 1968 (see 33 FR 7808). Moreover, it is not unusual for conciliation agreements or even court orders to be modified in order to achieve full compliance. If circumstances do occur where further corrective action is required, it is appropriate to attempt other resolutions to achieve full compliance. In such event, the rule adopted today requires that the contractor be given notice by show cause rather than by the 15-day notice of violations. See § 60–1.25. The comments also raised questions about delegations of authority to conduct compliance reviews. The practice is, as reflected in the proposal, that compliance reviews are conducted under the general supervision of the OFCCP Assistant

Regional Administrators. However, from time-to-time, national office officials also conduct compliance reviews, and the purpose of the delegation is to continue to allow for that possibility.

The section is adopted as proposed. However, small technical word changes have been incorporated into the final rule such as substituting the word "action" for "commitment" in § 60–1.20(c).

9. *Section 60–1.21.* The proposal would add a new section to the regulations which would modify the existing preaward concept. Preawards would also be applied to the veterans and handicapped workers programs. Forty-five days notice from contracting agencies to OFCCP would be required for formally advertised competitive contracts, and 120-days notice would be required for negotiated contracts, in place of the present 30-days notice for all contracts subject to the preaward requirement. Preaward reviews would be mandated only where the proposed contact exceeds $1 million, and the proposed contract is to be performed at an establishment with 250 or more employees where a compliance review has not been conducted in the previous 24 months. Currently, there is no employee number threshold. The present monetary threshold is "exceeding $1 million" and the previous compliance review period is 12 months. A new provision would give the Director, OFCCP, discretionary authority to conduct preaward compliance reviews of any contractor even though the establishment has less than 250 employees and a compliance review has been conducted within the last 24 months. If the compliance review is not completed or if the contractor/bidder's alleged noncompliance is not resolved prior to the award date of the contract, the proposal would also permit the Director to request the contracting agency to delay the award of the contract until such time as the contractor is found eligible or ineligible for the contract in accordance with the hearing procedures proposed in § 60–30.38. If the Director requested a delay, the contracting agency would be required to delay award unless it determined that a delay would be contrary to the national security. In all other cases where the preaward review is not completed, clearance would be granted.

Civil rights groups were about evenly split on the proposal with half favoring retention of present thresholds and the remainder favoring the "freed-up resources" to concentrate on target reviews. Contractors favored the increases in the preaward threshold, but urged extension of the thresholds to $10 million and 36 months.

Contractors and Federal agencies opposed the provisions requiring 45 days advance notice for competitive contracts and 120 days for negotiated contracts (paragraph c). Both groups stated that the time delay would increase costs and, in many instances, would hamper Federal agencies in their procurement efforts. Most of these comments recommended that the present 30-days notice be retained.

Contractors objected to the delay of award (paragraph (f)) because they viewed such a procedure as a debarment without a hearing, and Federal agencies viewed it as an interference with the procurement process. One comment recommended adding a provision that the contracting agency would be obligated to delay the award only where it was feasible.

Several comments stated that the subsection is not clear, especially the provision which provides that unless a preliminary hearing has been commenced, or would be invoked shortly, the award of the contract shall not be withheld. They said the word "shortly" is indefinite. One contractor recommended that a specific number of days be set.

Some contractors and a Federal agency opposed paragraph (i) which would authorize the Director to direct a preaward review on the basis of a contractor's prior statement that it would no longer contract with the Government. The Federal agency questioned how the Government would know when a contractor has made such a statement. Contractors commented that the paragraph would constitute retaliation against contractors for exercising their freedom of speech.

This section and the entire proposal, consistent with Executive Order 12044, were subject to intensive participation by the public prior to publication in the **Federal Register.** Persons thought to have an interest were directly contacted and a series of open conferences was held. As a result of this public participation, this section went through a number of revisions prior to publication for comment. The suggestions for change made by the various groups in the formal comments reflect the fact that the proposal represents a balancing of interests. While the increase in the thresholds for preawards was not popular with some civil rights groups, others recognized the benefits which will result from the use of "freed-up" resources to concentrate on reviews which may produce greater results. Contractors and contractor associations agreed with the increased preaward thresholds and recommended even higher thresholds. Neither contractors nor Federal agencies favored the increased timeframes for advance notice for preaward reviews or authority for the Director to request delay of award. Both groups complained of the increased costs and delays that would result from delay of award. Most contractors objected to paragraph (i), which would give the Director discretion to order a preaward review where a contractor has stated that it will not contract with the Government.

The rule adopted today has been modified further to take into account some of the objections raised in the comments. The prime concerns of the Department of Labor are that the interest of groups protected under the three programs be assured and that procedures be designed which accomplish that goal in a fair and uniform way with consideration being given to the resources available to perform the job. The proposal was designed to achieve these goals. The timeframes proposed with regard to notice from contracting agencies, the Department believes, give OFCCP just a bit more flexibility to process preaward requests. However, the 120-day notice proposed for negotiated contracts has been dropped and a flat 45-day preaward notice has been adopted for both advertised and negotiated contracts. The extension of the review threshold to 24 months also assists in that same connection. (For a discussion of the types of problems the present preaward procedures are causing see 44 FR 77006.)

Although the number of reviews mandated under the present preaward procedure will be reduced because of the increased thresholds, discretionary preaward reviews are being authorized so that even if such reviews are not mandated, they will be conducted where warranted.

Paragraph (i) as proposed has not been adopted. The sole idea behind proposed paragraph (i) was that where a contractor discontinues contracting with the Government because of what the contractor perceives as burdens of the contract compliance programs, it was considered to be a fair requirement to determine whether the contractor is complying with equal employment obligations before it resumes a contractual relationship with the Government. After considering all factors, however, paragraph (i), as proposed, is not necessary to achieve this goal. For example, there have been instances where contractors have

accepted debarments rather than comply. Such contractors must come into compliance with the Order and sections 402 and 503 before they may resume Government contracting. Moreover, a noncomplying contractor may be debarred even though it has performed the goods or services aspects of its contract (see discussion above regarding the definition of prime contractor). Also, paragraph (e) of this section as adopted today provides adequate authority to conduct preaward reviews in such situations.

Finally, with regard to requests that awards be delayed so that the preliminary enforcement proceeding be instituted, the word "shortly" has been deleted and the phrase, "15 working days," has been substituted. The concept is that a decision to pursue the hearing route has been made at least preliminarily before the request to the contracting agency is made. Such delays would allow the necessary paperwork and filing procedures to be completed.

A clarification has been added to show that the request applies to all other pending contracts at the establishment which triggered the preaward review. The request would not apply to establishments which are not part of the preaward review.

10. *Section 60–1.22.* No substantive changes were proposed in this section. It would combine present §§ 60–1.21 and 60–1.22. The proposal is adopted.

11. *Section 60–1.23.* The proposed amendment to this section relates to complaints filed by third parties.

All contractors and contractor associations opposed the addition of third party complaints which do not identify the complainant. The female and minority groups which commented upon this section favored the addition of third party complaints.

All contractors which submitted detailed statements on the third party complaint issue were of the opinion that permitting complaints by unidentified third parties would be a denial of due process. Most said the procedure would be unfair and that contractors have the right to know their accusers. Others commented that unidentified third party complaints would lead to contractor harassment; that third party complaints would frequently be frivolous; that such a process constituted an unwarranted fishing expedition; that it would lead to forum shopping; that the process is not needed because persons are protected from intimidation and interference; that unions would be able to file against contractors under this provision which would permit OFCCP to interfere in the collective bargaining process; and that it is not needed as it would apply only to the small number of persons who would not file themselves or authorize another to file on their behalf. The contractors recommended that the section be deleted or that the complainant be identified. It was also recommended that the contractor receive a copy of the complaint before any investigation. Educational institutions, as a whole, were opposed to inclusion of third party complaints.

The wording of proposed § 60–1.23(a) which states that, "Signed third party complaints will be accepted which do not identify the complainant * * *" is confusing. Obviously, if a complaint is signed, the complainant is identified. The confusion was compounded because the proposal would delete a provision in the existing regulations at § 60–1.23(a) which permits class type complaints that do not identify the discriminatees. The intent was and is to permit a complaint alleging class type discrimination to be filed by third parties regardless of whether the discriminatees are identified. Individual complaints may be filed by the discriminatee or the discriminatee's authorized representative. Third parties would be able to file class type complaints without authorization from the discriminatees.

The drafting problems discussed above have been corrected and the proposal as modified is adopted. Comparable changes have been made in the complaint provisions of the veterans and handicapped regulations (41 CFR 60–250.23 and 41 CFR 60–741.23). The comments regarding due process, etc., are not well founded. A complaint simply precipitates the investigatory process. If the allegations in the complaint are verified by the investigation, then the Department of Labor becomes the accuser and attempts resolution through conciliation. Moreover, it is essential that information regarding employment discrimination be available to the Department. This avenue to employment discrimination information should not be closed because a victim of discrimination is reluctant to make direct contact on his/her own behalf. Indeed, other enforcement programs administered by the Department for many years have observed the practice of accepting anonymous complaints.

12. *Section 60–1.24.* The proposal would permit OFCCP the discretion to "defer," rather than "refer," complaints to EEOC. Deferral would mean that OFCCP would retain jurisdiction over the complaints and could later investigate the complaints if OFCCP chose to do so. The proposal states that the complainant would be notified of any deferral. Complaints deferred to EEOC and unresolved at the time of a later OFCCP compliance review, as well as those retained at OFCCP, would be investigated and resolved during that compliance review of the contractor against which the complaints are filed.

Nearly all comments were opposed to deferral. Contractors and contractor associations thought the OFCCP should not process complaints, except for broadly based systemic complaints, and should refer all other complaints to EEOC. Others objected that retaining complaints to be resolved during compliance reviews was impractical; that complicated complaints take more time to resolve than is permitted during the compliance review process; that merging complaint resolution with compliance reviews gives OFCCP disproportionate leverage to force settlement; that concentrating on complaints will give a few persons attention at the expense of women and minorities in general; and that deferral was contrary to President Carter's Reorganization Plan. Contractors also recommended that OFCCP notify them of deferrals in the interest of fairness. Most contractors and contractor associations expressed fear that deferral would lead to multiple investigations of the same complaint.

As proposed, § 60–1.24 undoubtedly would expand the number of complaints processed by OFCCP. OFCCP, as a matter of policy and procedure, traditionally has referred most individual complaints to EEOC for investigation and normally retained only class type complaints for investigation. Under proposed paragraph (b), OFCCP would be required to investigate all complaints which it elected to retain and not defer to EEOC. In addition, all class type complaints would be deemed to be retained by OFCCP, even though a copy may have been sent to EEOC. The class or systemic complaints would be required to be investigated and resolved in the next compliance review of the contractor.

In the final regulation, paragraph (b) has been modified to make it clear, consistent with OFCCP past practice, that all systemic and class complaints will be retained, investigated and resolved by OFCCP. However, EEOC, under the final rule adopted today, could request that such class complaints be referred to it in order to avoid duplication and to assure effective law enforcement. In resolving the class complaints referred to EEOC at its request, the two agencies will consult and coordinate with each other to

ensure that the resolution of such complaints comports with the requirements of the two agencies. As modified, the proposal is adopted. In addition, this section has been amended on final rulemaking to state that OFCCP will also investigate and resolve individual complaints, on file with OFCCP at the commencement of a compliance review, against the contractor establishment if resolution of such individual complaints does not unduly delay completion of the compliance review. Also, on final rule making the word "refer" has been substituted for "defer."

With regard to OFFCCP investigating complaints, the Executive Order specifically authorizes complaint investigations. Moreover, all Federal EEO agencies are making every effort to ensure that duplication (in this instance separate investigations by EEOC and OFCCP on the same issue) is eliminated.

Paragraph (c)(5), regarding the authority of the Director to reconsider matters pending in OFCCP has been transferred to 41 CFR 60–1.27 because paragraph (c)(5) has application and implications beyond complaints.

13. *Section 60–1.25.* This amendment was proposed as a new section dealing with show cause notices and notices of violation. Paragraph (a) would set forth the circumstances under which a show cause notice or a notice of violation would be served on the contractor. Paragraph (b) delineates the contents of a show cause notice and when it would be used.

Paragraph (c) would provide the circumstances under which a notice of violation would be used. A notice of violation would be permitted where circumstances do not permit 30 days to resolve the matters under investigation; where there is a serious violation; and where the violation is the subject of a prior conciliation agreement, letter of commitment or consent or other decree.

Paragraph (d) would provide that where a notice to show cause or notice of violation proposes a change in a collective bargaining agreement, the collective bargaining representative would be given notice of the proposed change and invited to participate in conciliation.

Paragraph (a). This paragraph would have provided for a show cause notice in appropriate circumstances if deficiencies revealed in the course of a review or investigation have not been resolved by some form of an agreement. Paragraph (b) would have provided for a show cause notice in appropriate circumstances where the deficiency is not covered by an "existing" agreement. One comment argued that as a result of the word "existing," paragraph (a) is voided. The contractors recommended that paragraph (b) be eliminated.

Paragraph (b). Several contractors and two construction contractor associations recommended deletion of the last sentence which permits finding a previous conciliation agreement inadequate.

Paragraph (c). An association claimed that the paragraph is vague as to when a notice of violation would be used. An association and two educational institutions further stated that 15 days would be insufficient to conciliate and respond. Further, the association believed that a serious violation would require more, not less, time to resolve.

Paragraph (d). One contractor stated that OFCCP should not get involved in union-management disputes unless there is an impasse. A union commented that there is not enough participation by unions.

The rule adopted today follows the concepts contained in the proposal. However, certain changes have been added to conform this section to other regulations and to take into account problems raised by the comments. Some restructuring of this section has been made in this process.

Under present regulations a show cause notice is not required in all instances. Accordingly, § 60–1.25 has been modified to refer to situations in which a show cause notice is not required to be used. With respect to paragraph (b), the intention was to show that in some circumstances a notification other than a show cause notice must be used. However, the phraseology was confusing. This confusion has been eliminated by cross referencing other sections of the regulations which describe the situations when a notification other than a show cause is required.

With regard to the comments concerning inadequate remedies in conciliation agreements and concerning collective bargaining, see the discussions above relating to compliance reviews (§ 60–1.20) and unions participating in the conciliation process (§ 60–1.9).

14. *Section 60–1.26.* This section would consoldiate the regulations dealing with the contents of conciliation agreements. The major amendment proposed was that conciliation agreements would not be entered into after enforcement proceedings have been initiated.

The general tenor of the comments received from contractors is that clarification is needed as to when a letter of commitment would be required. Another comment stated that a complaint is necessary for jurisdiction under section 503. A contractor stated that a conciliation agreement should be accepted when signed rather than 45 days after receipt by the Director.

On the matter of when a conciliation agreement would be used, paragraph (e) states that a letter of commitment, rather than a concilation agreement, is to be used for "minor technical deficiencies." The OFCCP manual provides instruction as to when conciliation agreements as opposed to letters of commitment should be used.

The provision that a conciliation agreement will not be entered into after enforcement proceedings have commenced contemplates that subsequent settlements normally will be in the form of consent decrees rather than conciliation agreements. It was not intended to suggest that settlements would not be made after enforcement proceedings commence.

Contractors recommended that conciliation agreements become effective when signed by the Assistant Regional Administrator because otherwise they are uncertain whether the conciliation agreement has been accepted by the Director. However, the 45-day review period is considered to be important at least for the immediate future in order to ensure uniformity and consistency among the regions.

The amendment is adopted as proposed.

15. *Section 60–1.27.* Subsection (a) of this section which presently is section 60–1.25 permits the Director to assume jurisdiction over matters pending in OFCCP. The only substantive change proposed to this section would be to add a reference to sections 402 and 503. The thrust of the comments was that this section was an unnecessary statement of the obvious and recommended that the section be deleted.

This section was designed at a time when compliance responsibilities were assigned to various compliance agencies and was intended to give OFCCP some control, in appropriate circumstances, over cases being processed by the former compliance agencies or which would normally be within the jurisdiction of a particular compliance agency. The present regulations, however, do make specific delegations in certain instances (see 41 CFR 60–1.20(b)). By stating in the regulations that the Director may assume jurisdiction over matters pending in OFCCP, a number of process questions will be avoided which have arisen from time-to-time even after the Executive Order program was consolidated into the Department of Labor. Subsection (b) of this section as adopted today presently is contained in § 60–1.24(c)(5)

and relates to the authority of the Director to reconsider matters. See discussion under § 60–1.24 herein.

16. *Section 60–1.28.* The present regulation prohibits intimidation or interference because an individual participates in compliance activities (e.g., filing a complaint, assisting in an investigation, etc.). The prohibition applies to such participation under Federal and state and local laws. The proposed amendment would transfer comparable provisions in the section 402 and 503 regulations to this section. The proposed amendment also would add a new provision which would prohibit a contractor from intimidating or interfering with an individual because he/she opposed an employment practice under any Federal or state or local law. The latter provision was added to the regulations at the request of the EEOC in consultations with that agency under Executive Order 12067 prior to publication of the December 28, 1979, proposal.

The comments objected to the references to state and local laws. This reference, of course, has been in the regulations for a number of years albeit not in the specific context of the new provisions. The objective of this section is not, as the comments suggest, to enforce a state or local law but to proscribe activities which interfere with a person's exercise of his/her rights under a state or local law. The amendment is adopted as proposed.

17. *Section 60–1.29.* This section sets forth in general outline form the procedures governing legal proceedings to enforce the Order and sections 402 and 503. The proposal would reorganize the present regulation and transfer it from 41 CFR 60–1.26 to 41 CFR 60–1.29. The major additions to the section would be paragraphs (e), (h) and (i). The latter two paragraphs relate, in part, to the issue of Federal deposit and share insurance, and are discussed under § 60–1.5(a).

Paragraph (e) would establish a preliminary enforcement procedure under 41 CFR 60–30.38. The Preliminary enforcement proceeding would be utilized when: (1) The contractor is engaging in unlawful employment practices; (2) the contractor has refused or failed to develop or submit a current AAP; (3) the contractor has failed or refused to supply requested records; (4) the contractor has failed or refused to permit access to its premises, records, or to its employees or witnesses for interviewing; or (5) the contractor has engaged in intimidation or retaliation.

The comments expressed the view that "unlawful employment practices" is too broad a standard upon which to invoke a preliminary enforcement proceeding suggesting that the procedure will be abused. The prime purpose of a preliminary enforcement proceeding is to obtain results promptly in those circumstance where the issues lend themselves to quick resolution and where a prompt resolution is needed; for example, when there are impediments to completing the review. When such impediments exist, a process should be available to resolve them promptly. Like the expedited hearing procedure, the preliminary enforcement procedure is not to be used for resolution of complex factual issues, including complex issues of affected class relief.

The comments are correct in stating that "unlawful employment practices" is a broad standard on which to invoke the preliminary enforcement procedures. However, the other standards are specific and relatively well defined. It is conceivable that practices could be revealed in an investigation which are not conveniently catalogued under one of the specific standards but which nevertheless could be resolved promptly. The general standard would permit the processing of such practices under the procedure. At the same time, however, it must be acknowledged that the timeframes involved in the preliminary enforcement procedure apply to the Department as well as to the contractor. The timeframes themselves will operate to confine the procedure to circumstances which actually are suitable for prompt resolution. In addition, the word "unlawful" has been deleted and the phrase, "which violate its contractual obligations," has been added to further define "employment practices."

Section 60–1.29 is adopted as proposed with the modifications discussed here and elsewhere in this preamble.

18. *Section 60–1.30.* The present regulation states that no contractor will be debarred without being afforded an opportunity for a hearing. A similar requirement is contained in the section 402 and 503 regulations. The proposal would consolidate the requirements for each program into this section. In addition, the proposal would add the requirement that prime contractors would be notified when contractors are ineligible for subcontracts.

A small number of comments were received on the proposal which focused on the notification of prime contractors requirement. The comments objected to the notification requirement, but also suggested that if there were to be notification of debarments, fair play dictated that comparable notification be provided when reinstatement is ordered. The amendment is adopted as proposed. In addition, a requirement has been added to § 60–1.31 that notification be provided to prime contractors when reinstatement of a debarred contractor is ordered.

19. *Section 60–1.31.* This section and comparable sections in Parts 60–250 and 60–741 presently provide that a debarred contractor may petition for reinstatement in a letter to the Director, and that the burden will be on the contractor to show that it has established and will carry out policies and practices in compliance with the Order, section 402 and section 503, as appropriate.

The proposal would establish a single reinstatement procedure for each of the OFCCP programs. The contractor would have the burden to demonstrate that it is entitled to reinstatement. The Director could require a compliance review before reinstating the contractor or remand the matter to the Administrative Law Judge before making a final determination on the petition for reinstatement. Also, any party or person who participated in the debarment proceeding would have a right to participate in the reinstatement procedure.

A relatively small number of comments were received on this proposed amendment. The thrust of the comments was that a petition for reinstatement should be granted promptly, and that reinstatement should not be impeded by complex procedures.

The amendment is adopted. However, a requirement has been added that the petition for reinstatement be served on the parties to the original debarment proceeding. If parties to the proceeding are going to be able to participate meaningfully in the reinstatement procedure as they will have a right to do under 41 CFR 60–1.31(e), a copy of the petition is necessary.

In addition, clarifications have been made on final rulemaking with regard to procedures to be followed when the Director remands a matter subsequent to a petition for reinstatement.

The procedures which have been added are based on experience with petitions for reinstatement and the need for a process to gather facts so that the Department may determine whether the contractor will implement and carry out employment practices and policies which are in compliance with the Order and sections 402 and 503, as appropriate. In some instances, a compliance review may be necessary to make that determination and in others a hearing before the Administrative Law Judge may be appropriate. In either situation, the objective is to determine

what the facts are and to provide fair procedures in making these determinations.

20. *Section 60–1.40.* This section presently establishes the dollar volume and employee thresholds for requiring written affirmative action programs under the Executive Order. The proposal would add two new requirements to this section. Contractors with 50 or more employees would be required to aggregate their contracts and would be subject to the written AAP requirement if the total dollar value of the contracts is $50,000 or more. Also, a construction contractor with 50 noncraft employees and a $50,000 or more contract or contracts totaling $50,000 or more would be required to develop and implement a written AAP.

The majority of the comments expressed objection either to the aggregation of the dollar value of contracts or to the expansion of § 60–1.40 to encompass the noncraft workforce of construction contractors.

Some technical language modifications in the proposal have been made. Also paragraph (b) of the section has been amended to clarify that when a contractor becomes subject to § 60–1.40, it must develop and implement a written AAP at each of its establishments within 120 days from the date it is first covered. With these changes, the proposed amendment has been adopted.

A loophole always has existed under the Executive Order program's written AAP requirements with regard to noncraft employees of construction contractors who are not included in the construction affirmative action plans. Section 60–1.40 does not expressly exclude construction contractors in imposing the written AAP requirement. However, § 60–2.1 of Revised Order 4, which provides the guidelines for developing an AAP, specifically limits the application of Revised Order 4 to nonconstruction contractors. Because of the inconsistencies in the language of the two sections, no concerted effort has ever been made to require construction contractors to develop AAPs for their noncraft employees. The noncraft employees include categories such as estimators, project managers, financial personnel, clerks, secretaries and typists. Some nonconstruction contractors also employ the same types of employees and are required to include such job categories in their AAPs. There is no reasonable basis for allowing the loophole to continue to exist with regard to noncraft employees of construction contractors, and the final rule adopted today requires that construction contractors subject to § 60–1.40 adopt AAPs which include the noncraft positions.

The basic concept behind the aggregation of contracts to reach the $50,000 volume is that consideration should be given to the total amount of Government business the contractor has in addition to the size of a particular contract.

21. *Section 60–1.43.* This section presently requires access to the contractor's records for inspection and copying. Comparable provisions are contained in the sections 402 and 503 regulations. The proposal would amend the regulations by incorporating the sections 402 and 503 requirements into this section. The proposal also would include the present practice of interviewing employees as part of the compliance review and would add computer tapes and print-outs to the list of specific types of data contractors would be required to produce in the investigation or compliance review.

The comments basically were concerned about data gathered in the investigation, taken off-site and subsequently disclosed pursuant to a request under the Freedom of Information Act. Some comments also were opposed to allowing employee interviews.

The issues raised by the proposal and the comments go to the ability of the Government to conduct its investigation. If the data are not needed for the investigation it should not be gathered in the investigation, and procedures are incorporated into the regulations to allow contractors to obtain rulings with regard to data they believe are not relevant to the investigation. See, e.g., 41 CFR 60–2.4. If they are needed, on the other hand, obtaining copies and making them part of the investigation file should not depend upon whether the Freedom of Information Act may require disclosure if a request is received. Indeed, the provision that information obtained under this section will be used only in connection with the Order and the Civil Rights Act of 1964 was not included in the proposal but is being deleted from this section by the regulation adopted today because, *inter alia*, a representation that the use of the information will be so limited may conflict with the Freedom of Information Act. Nevertheless, the Department of Labor is sensitive to contractor concerns regarding the possible confidentiality of data gathered in compliance reviews and has taken steps to ensure that confidential data is not routinely released. See e.g., the Decision and Administrative Order of the Secretary of Labor *In the matter of U.S. Department of Labor, Office of Federal Contract Compliance and University of California, Berkeley*, Case No. 78–OFCCP–7.

It frequently is necessary to include source documents in the investigation file because of the need for review by supervisory and other personnel, such as lawyers, in the event enforcement procedures are required.

Interviews of employees also are critical to the investigation process, and it is more convenient and saves time and money for interviews to be conducted at the time of the on-site review. This is standard operating procedure in law enforcement programs. Accordingly, the amendment is adopted as proposed and with the deletion mentioned above.

22. *Sections 60–1.44, 60–1.45, 60–1.46 and 60–1.47.* These sections relate to rulings and interpretations; adaptation of language in the equal opportunity clause in the Order and the affirmative action clauses of sections 402 and 503; incorporation by reference; and incorporation by operation of law, respectively. The proposal would simply provide for a single regulation, applicable to each program, on each issue, and would delete the corresponding sections in Parts 60–250 and 60–741. See discussion of § 60–1.4. These sections are adopted as proposed.

23. *Section 60–1.48.* This section presently appears at § 60–1.24(c)(4). The present regulation allows a contractor to comply with the demands of OFCCP and then request a hearing. The proposal requested comments as to whether it should be deleted or retained. The comments supported retaining the regulation. However, because of the way the regulations have been reorganized, it no longer fits properly in § 60–1.24 and has been transferred to § 60–1.48. In addition, a provision has been added to reflect the practice under this provision that hearings normally will be on the record before the Director.

24. *Section 60–2.1.* This section sets forth the purpose and scope of Revised Order 4 (Part 60–2). The purpose of the proposed amendment was to conform § 60–2.1 to the amendment proposed to § 60–1.40 regarding accumulation of contracts for the purpose of meeting the $50,000 contract volume requirement for written AAPs, the proposed amendments regarding Federal deposit or share insurance and the obligation of construction contractors to develop written AAPs for their noncraft employees. The amendment is adopted as proposed. See the discussion herein of § 60–1.5(a) for a treatment of the deposit or share insurance issue and § 60–1.40 for a treatment of the accumulation of contracts issue.

25. *Section 60–2.2.* This section provided for contractor "pass overs," in certain instances, without a hearing, based on a finding of nonresponsibility. It also provided for determinations of substantial issues of law or fact with regard to the contractor's responsibility. A determination that the contractor's responsibility raised substantial issues of law or fact had the effect of clearing the contractor for award pending a hearing on the issue. The proposal would delete these procedures thereby making the opportunity for a hearing a requirement before a responsive bidder could be denied a contract.

The comments were largely favorable to this proposal and the amendment is adopted as proposed with a few clarifying modifications.

26. *Section 60–2.3.* The proposal would add a new section providing procedures for submitting the AAP and support data. Most of the procedures contained in the section previously appeared in Part 60–60. A new time frame of 15 days, in lieu of the 30 days in the present regulations, would be established for submitting the AAP and support data.

Most of the comments on this section were received from contractors and contractor associations, and these comments primarily focused on issues of confidentiality of data and the 15-day time frame. The confidentiality and disclosure of data issue already has been treated to some degree in the discussion on § 60–1.7 and § 60–1.43, and is further treated in § 60–2.4. With regard to the 15-day time frame, there are strong indications that the current 30-day period is being used routinely to require that the AAP be updated on an annual basis and the 30-day time frame was not designed to allow time for the annual update. The 15 days should be adequate for the ministerial function of forwarding the AAP and also should provide an incentive for contractors to update the AAP in a timely fashion rather than to wait for a request for the AAP before beginning that process. Moreover, it is essential that the AAP be current in the event that a preaward review of the contractor is conducted, and, more importantly, to ensure its implementation.

The section is adopted as proposed with a few clarifying modifications.

26–A. *Section 60–2.4.* This section was not proposed. However, because of the number of concerns raised by contractors regarding the confidentiality of data gathered in compliance reviews, this section has been added. This section continues the procedure presently contained in 41 CFR 60–60.4 for coding data and making determinations of relevancy of data. The requirement that the confidentiality of data be maintained prior to determination of relevancy also has been retained. As mentioned earlier in this preamble, Part 60–40, pertaining to disclosure of documents, presently is being revised.

26–B. *Part 60–4.* Amendments to the construction regulations were published in the **Federal Register** on October 3, 1980. Part 60–4 is republished today incorporating those amendments. In addition, conforming changes have been made to Part 60–4 to reflect other changes in Part 60–1. See, e.g., § 60–4.7.

27. *Section 60–20.2.* Only minor language changes were proposed for this section. No comments were received on § 60–20.2 and it is adopted as proposed.

27–A. *Section 60–2.3.* No amendment to this section was proposed in the December 28, 1979, notice. Previously, however, an amendment to this section had been proposed and that proposal is still under consideration. On final rulemaking, paragraph (c) has been amended to reflect the dictates of the Supreme Court's opinion in *Los Angeles Department of Water and Power* v. *Manhart*, 435 U.S. 702 (1978), regarding the equal benefits, equal contributions rule. In addition, a subparagraph (ii) has been reserved to indicate an additional amendment to the fringe benefit regulation.

28. *Section 60–20.4.* As proposed, the section would read: "Where they exist, seniority lines and lists must not be based upon sex. Where such a separation has existed, the contractor must eliminate this distinction *and provide appropriate relief.*" The portion emphasized is the proposed amendment.

The comments focused upon the restrospective aspects of the proposed amendments and argued that the Executive Order was limited to prospective relief. The Department of Labor has required retroactive relief under the contract compliance program since at least 1961 and has outlined its position on the issue in the **Federal Register** and other publications. See, e.g., 41 FR 77000. The section is adopted as proposed.

29. *Section 60–20.5.* As proposed, § 60–20.5(a) would read: "The contractor's wage schedules must not be related to or based on the sex of the employees.

"While the more obvious cases of discrimination exist where employees of different sexes are paid different wages on jobs which require substantially equal skill, effort and responsibility and are performed under similar working conditions, *compensation practices with respect to any job where males or females are substantially underutilized will be scrutinized closely to assure that sex has played no role in the setting of levels of pay.*" The portion emphasized is the proposed amendment.

The contractor comments stated that the proposal was an attempt to assert jurisdiction over the comparable worth issue, some stating that the proposal was a violation of the Equal Pay Act and Title VII of the Civil Rights Act. All contractor groups were opposed to the proposal. The Congress, courts, and EEOC were variously thought to be the proper authorities to promulgate this doctrine. Other comments suggested that OFCCP should defer its regulations on this issue until it has been accepted by the courts. Women's groups viewed the proposal as an attempt to clarify Executive Order jurisdiction over the comparable worth issue and approved of the proposal.

The Executive Order prohibits discrimination based on sex. The prohibition is broad and does not depend upon characterizations such as comparable worth. OFCCP has conducted investigations which involve the wage discrimination issue. The Department also is involved presently in litigation where wage discrimination is an issue. The proposed amendment simply codifies policies and practices the Department already is following.

30. *Section 60–20.6.* The proposed amendment would not make substantive changes. Rather the paragraphs have been rearranged and small language changes have been made on final rulemaking. This section is adopted.

31. *Section 60–20.7.* The proposed amendment would add a new section to incorporate some of the features of the Pregnancy Discrimination Act of 1978.

A total of nine comments were received on this proposal. The Women's groups were generally supportive of this change but objected to the exclusion of abortion from coverage.

Some very detailed comments from contractor groups stated that the proposal goes beyond the Pregancy Discrimination Act.

As proposed, this section essentially would have adopted EEOC's Guidelines (29 CFR 1604.10) on the subject, which implement the Pregnancy Discrimination Act (PDA) (see 44 FR 23804, April 20, 1979). The PDA provides, *inter alia*, that the prohibition against sex discrimination contained in Section 701 of the Civil Rights Act of 1964, as amended, includes discrimination "because of or on the basis of pregnancy, childbirth, or related medical conditions." However, under the PDA am employer is not required to provide health insurance benefits for abortion, "except where the life of the mother would be endangered if the fetus were

carried to term, or except where medical complications have arisen from an abortion." Although OFCCP believes that the PDA, including the abortion exemption, applies only to the Civil Rights Act and not to the Executive Order program, the rule adopted today follows the EEOC's Guidelines and the PDA, including the provision relating to benefits for abortion. In addition, the present regulations require a reasonable period of time away from work for childbearing purposes and reinstatement after a reasonable period of time to a similar job without loss of service credits. In adopting the EEOC Guidelines, the final rule eliminates the present regulation. However, as with abortion, OFCCP believes that the PDA applies only to the Civil Rights Act and does not require the change in the Executive Order regulations.

32. *Section 60–20.8.* This is a new proposal designed to protect employees from the sexual advances of persons who are in a position to affect their employment opportunities as well as to prohibit employment decisions based upon sexual favors.

Twenty-eight comments were received on this section from female groups and contractor groups.

Female groups were supportive of the proposed amendment as a recognition of a very serious problem in the workplace. The female groups thought the regulation did not go far enough and should specifically make reference to harassment by coworkers, clients and customers and that a specific reference on the subject should be required in a contractor's policy statement.

Contractors primarily were opposed to the language that liability attaches if the contractor "knows or should have known" of the prohibited activities. Questions were also raised as to the meaning of "official authority." Some thought that OFCCP should not get into this area at all. Finally, it was suggested that the standards enunciated in some court cases should be used.

The rule adopted today has been redrafted and is consistent with EEOC's Guidelines on the subject. A contractor is liable under the rule adopted today for the acts of its officials, managers and supervisors when they engage in sexual advances or favors regardless of whether their specific acts were authorized by the contractor and whether the constractor knew or should have known of their occurence. Althought the rule adopted today also refers to the liability of the contractor for the acts of a contractor's customers and clients as do the EEOC Guidelines.

The rule adopted today also holds a contractor responsible for the sexual advances and favors of nonsupervisory employees, if the contractor or its agents or supervisory employees should have known of the conduct. This element was not contained in the proposal but is already an Executive Order violation.

33. *Section 60–30.1.* The rule adopted today simply adds references to sections 402 and 503 to reflect that the rules of practice also govern hearings before Administrative Law Judges under these two programs.

34. *Section 60–30.3.* The rule adopted today excludes intermediate Saturdays, Sundays and legal holidays observed by the Federal Government when the time for responding to a matter is less than seven days.

35. *Section 60–30.4.* No substantive changes have been made from the existing regulations.

36. *Section 60–30.5.* The amendment adopted today emphasizes that notice rather than fact pleading obtains under the rules of practice. However, fact pleading is required for preliminary enforcement proceedings under § 60–30.38. Also, the requirement that an amended answer be responded to has been deleted.

37. *Section 60–30.7.* Because contractors have a right to an opportunity for a hearing initiated by an administrative complaint, the requirement that the Administrative Law Judge respond to the request for a hearing has been deleted in the rule adopted today. Also, a requirement has been added that the Administrative Law Judge conduct a final pretrial conference.

38. *Section 60–30.8.* The rule adopted today amends § 60–30.8(b) to require every reasonable effort by the Administrative Law Judge to dispose of all outstanding motions prior to the hearing. A new paragraph (c) has been added requiring counsel to attempt resolution of discovery issues prior to filing motions to compel discovery.

39. *Section 60–30.9.* This section is amended by deleting the references to filing times in order to conform the timeframes to the changes adopted today at 41 CFR 60–30.12(c)(3). Finally, § 60–30.9 is amended to require that discovery documents be filed with the Administrative Law Judge.

40. *Section 60–30.11.* Subsection (c) of this section is adopted to bring the rules for objecting to questions at depositions more closely into conformity with the Federal Rules of Civil Procedure.

41. *Section 60–30.12.* This section is amended by adding a new paragraph (c) which contains mandatory requirements for a final prehearing conference and the exchange of witness lists and hearing exhibits by the parties. In addition, it provides for concluding discovery at least 30 days prior to the hearing or at such other times as ordered by the Administrative Law Judge.

42. *Section 60–30.15.* This section is amended to add to the Administrative Law Judge's powers the authority (1) to invoke a presumption that answers or actions ordered, if made, would be unfavorable or adverse to the party ordered to answer or act and (2) to issue interlocutory decisions pursuant to the preliminary enforcement proceedings under 41 CFR 60–30.38.

43. *Section 60–30.18.* This section is amended by placing limitations on the introduction of deposition testimony into evidence in lieu of testimony given at the hearing.

44. *Section 60–30.19.* This section is amended by adding a new requirement at the end of paragraph (c) to the effect that an "offer of proof" made during a hearing contain a specific statement regarding the significance of the excluded evidence.

45. *Section 60–30.30.* This section has been amended to provide for final Administrative Orders by the Under Secretary of Labor in the absence of the Secretary or when the Secretary disqualifies himself/herself for some reason. It also mandates compliance with the consultation requirements of Section 209(a)(5) of Executive Order 11246 before an order terminating, suspending, or cancelling contracts becomes effective.

46. *Section 60–30.38.* The amendment adopted today adds a new section containing a new preliminary enforcement procedure. The preliminary enforcement procedure already has been treated in the discussion of § 60–1.29. However, when the procedure was proposed, the preamble stated that the preliminary enforcement procedure would replace the expedited hearing procedure adopted on December 28, 1979. Upon reflection, the two types of hearings serve different purposes and a decision has been made to retain both. However, some timeframes have been changed in the expedited hearing procedure.

47. *Section 60–50.1.* The proposal stated that OFCCP would defer any amendments on religious accommodation until the EEOC Guidelines on the same subject are made final. EEOC has published final Guidelines which are being reviewed by the Department of Labor to determine whether they may be adopted as a final rule without the necessity to publish them as a proposal.

With regard to § 60–50.1(b), the two comments which were received on the proposed amendment raised no

objection to it, and it is adopted as proposed. In addition, some editorial changes such as substituting the word "contractor" for the word "employer" have been made throughout Part 60–50.

48. *Part 60–60.* The proposal would delete this part from the regulations. However, as already discussed herein, some of the sections in Part 60–60 which are regulatory in nature have been transferred to Parts 60–1 and 60–2. Most of Part 60–60 is properly characterized as internal operating procedures. Such procedures should be in the OFCCP contract compliance manual rather than in the regulations. The comments on this part focused primarily on the provisions in § 60–60.4 which provide some degree of confidentiality with regard to data furnished to OFCCP by contractors. The key elements of § 60–60.4 have been adopted in a new § 60–2.4 in response to some of the concerns raised by contractors. Accordingly, Part 60–60 is deleted.

49. *Parts 60–250 and 60–741.* The basic changes in these parts adopted today were made to conform these two parts to the general consolidation of a number of regulations relating to sections 402 and 503 into Part 60–1. Consequently, a number of sections have been transferred from Parts 60–250 and 60–741 and the remaining sections have been renumbered.

The regulations adopted today impose new reporting and recordkeeping requirements. These new requirements have not been cleared by the Office of Management and Budget under the Federal Reports Act, however. The Office of Federal Contract Compliance Programs is in the process of preparing the necessary clearances required under the Federal Reports Act for all its recordkeeping and reporting requirements. Accordingly, the new reporting and recordkeeping requirements adopted in the regulations published today will be held in abeyance until OMB has granted the necessary clearances under the Federal Reports Act. This means that contractors will not be required to keep records or report on items which are adopted for the first time today.

After the new recordkeeping and reporting requirements have been cleared by OMB, appropriate notice of the effective dates of the new reporting and recordkeeping requirements will be published in the **Federal Register**. The new reporting and recordkeeping requirements which will be held in abeyance include those which increase and decrease recordkeeping and reporting requirements.

The new recordkeeping and reporting requirements which will be held in abeyance are:

1. *Section 60–1.7* (a). This section presently requires contractors with 50 employees and a contract of at least $50,000 to file the EEO–1 report. The new requirements would expand this reporting requirement to include contractors which have 50 employees and contracts which total $50,000 in a 12-month period. The new requirement is held in abeyance until OMB clearance and further notice in the **Federal Register.**

(b) The present regulations also require construction contractors performing work at the site of construction to file the EEO–1 report if they have 50 employees and a contract of at least $50,000. The regulations adopted today would delete this requirement and such contractors would file only the CC–257. However, until the deletion of this requirement is cleared by OMB such contractors must continue to report.

2. *Section 60–1.8.* This section presently requires contractors to maintain nonsegregated facilities and to so certify "in the form approved by the Director" of OFCCP. The quoted language makes the certification subject to the Federal Reports Act. This requirement is deleted from the regulations adopted today. However, it must be continued until approved by OMB.

3. *Section 60–1.40.* (a) This section requires contractors with 50 employees and a contract of at least $50,000 or Government bills of lading which total $50,000 in a 12-month period to develop and implement an affirmative action program. Certain recordkeeping and reporting requirements are associated with developing and implementing an AAP. The regulation adopted today would expand the written AAP requirement to those contractors with 50 employees and contracts which total $50,000. This new requirement, as it relates to reports and recordkeeping, will be held in abeyance until OMB has cleared the new requirement and notice has been published in the **Federal Register**. However, contractors with Government bills of lading which total $50,000 will continue to keep records and report as in the past. In addition, contractors covered for the first time by the AAP requirement will also be obligated to prepare and implement the AAP although they will not be required to keep any new records or make any new reports.

(b) the written AAP also is being required for the first time of construction contractors with regard to their noncraft employees if they have 50 such employees and a $50,000 contract or contracts which total $50,000 in a 12-month period. The reporting and recordkeeping requirements but not the requirement to develop and implement the AAP is held in abeyance until OMB has cleared the reporting and recordkeeping requirements and until further notice in the **Federal Register.**

4. *Section 60–2.1.* This section repeats the requirements of § 60–1.40. See item 3 above.

5. *Section 60–2.3.* This section requires contractors to submit their AAPs and supporting documentation within 15 days of receipt of a request from OFCCP. The present requirement is 30 days. The 30-day requirement will remain in effect until the new time frame has been cleared by OMB.

It has been determined that this document does not contain a major proposal requiring the preparation of a regulatory analysis under Executive Order 12044 (43 FR 12661) or under the Department of Labor's guidelines implementing Executive Order 12044.

This document was prepared under the direction and control of Weldon J. Rougeau, Director, Office of Federal Contract Compliance Programs.

Accordingly, 41 CFR Chapter 60 is amended by removing Part 60–60 and by revising Parts 60–1, 60–2, 60–4, 60–20, 60–30, 60–50, 60–250 and 60–741 as set forth below.

December 22, 1980.

Ray Marshall,

Secretary of Labor.

CHAPTER 60—OFFICE OF FEDERAL CONTRACT COMPLIANCE PROGRAMS, EQUAL EMPLOYMENT OPPORTUNITY, DEPARTMENT OF LABOR

Part

60–1 Obligations of contractors and subcontractors.
60–2 Affirmative action programs.
60–3 Guidelines on employee selection procedures.
60–4 Construction contractors—affirmative action requirements.
60–20 Sex discrimination guidelines.
60–30 Rules of practice for administrative proceedings to enforce equal opportunity under Executive Order 11246, Section 402 and Section 503.
60–40 Examination and copying of OFCCP documents.
60–50 Guidelines on discrimination because of religion or national origin.
60–250 Affirmative action obligations of contractors and subcontractors for disabled veterans and veterans of the Vietnam era.
60–741 Affirmative action obligations of contractors and subcontractors for handicapped workers.

PART 60-1—OBLIGATIONS OF CONTRACTORS AND SUBCONTRACTORS

Subpart A—Preliminary Matters; Equal Opportunity Clause; Compliance Reports

Subpart B—General Enforcement; Compliance review and Complaint Procedure

Subpart C—Ancillary Matters

Authority: Sec. 201, 202, 205, 211, 301, 302, 303, 401, E.O. 11246 (30 FR 12319), as amended by E.O. 12086; Sec. 402 of the Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended (38 U.S.C. 2012); Sec. 503 of the Rehabilitation Act of 1973, (29 U.S.C. 793), as amended by Sec. 111(a), Pub. L. 93-516, 88 Stat. 1619 (29 U.S.C. 706) and by Sections 119 and 122 of the Rehabilitation Comprehensive Services and Development Disabilities Amendment of 1978, Pub. L. 95-602, 92 Stat. 2955 and Executive Order 11758.

Subpart A—Preliminary Matters Equal Opportunity Clause: Compliance Reports

§ 60-1.1 Purpose and application.

(a) The purpose of the regulations in this part is to set forth the general obligations of Government contractors and subcontractors (hereinafter referred to simply as contractor; see definition of contractor in § 60-1.3) and of contractors performing on federally assisted construction contracts and subcontracts (hereinafter referred to simply as contract; see definition of contract in § 60-1.3) under Executive Order 11246, and to promote and ensure equal opportunity for all persons, without regard to race, color, religion, sex, or national origin, employed or seeking employment with Government contractors or with contractors performing under federally assisted construction contracts. The regulations in this part also set forth some general obligations which are equally applicable to contractors covered by section 503 of the Rehabilitation Act of 1973, as amended, and section 402 of the Vietnam Era Veterans Readjustment Assistance Act of 1974. When the regulations in this part implement sections 402 and 503 the regulations expressly indicate that fact. Specific obligations of contractors covered under the three laws are set forth in other parts of the regulations in this chapter.

(b) The regulations in this part apply to all contracting agencies of the Government and to contractors which perform under Government contracts. The regulations in this part also apply to all agencies of the Government administering programs involving Federal financial assistance which results in a construction contract, to applicants seeking or receiving such assistance and to all contractors performing under construction contracts which are related to any such programs. The procedures set forth in the regulations in this chapter govern all disputes relative to a contractor's compliance with its obligations under the three laws regardless of whether its contract contains a "Disputes" clause. Failure of a contractor or applicant to comply with any provision of the regulations in this part shall be grounds for the imposition of any or all the sanctions authorized by the Order or by the regulations implementing sections 402 and 503. The regulations in this chapter do not apply in any action taken to effect compliance with respect to employment practices subject to Title VI of the Civil Rights Act of 1964. The rights and remedies of the Government hereunder are not exclusive and do not affect rights and remedies provided elsewhere by law, regulation, or contract. Neither do the regulations limit the exercise by the Secretary of powers not herein specifically set forth but granted to him/her by the Order or by sections 402 and 503.

§ 60-1.2 Administrative responsibility.

The Director has been delegated authority and assigned responsibility for carrying out the responsibilities assigned to the Secretary under the Executive Order. All correspondence regarding the Order should be directed to the Director, Office of Federal Contract Compliance Programs, Employment Standards Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

§ 60-1.3 Definitions.

As used in this chapter, "Act" means the Vietnam Era Veterans Readjustment Assistance Act, as amended, (38 U.S.C. 2012), and the Rehabilitation Act, as amended, (29 U.S.C. 793), as applicable.

"Administering agency" means any department, agency or establishment in the executive branch of the Government, including any wholly owned Government corporation, which administers a program involving federally assisted construction contracts.

"Administrative complaint" means the pleading which commences an administrative enforcement proceeding under the Order, section 402 or section 503.

"Administrative law judge" means an administrative law judge appointed as provided in 5 U.S.C. 3105 and subpart B of part 930 of title 5 of the Code of Federal Regulations (see 37 FR 16787) and qualified to preside at hearings under 5 U.S.C. 557.

"Affirmative action clause" means the contract clause set forth at 41 CFR 60-250.3 or at 41 CFR 60-741.3, as applicable.

"Agency" means any contracting or any administering agency of the Government.

"Applicant" means a person applying for Federal assistance involving, or which results in, a construction contract or a person who has received such assistance. "Applicant" also means a person who is seeking employment or who has sought employment with a contractor.

"Assistance Secretary" means the Assistant Secretary of Labor for Employment Standards or his/her designee.

"Complaint" means a charge filed with OFCCP by an employee, former

employee, applicant for employment or by a third party alleging discriminatory employment practices under the Order, or under section 402 or section 503.

"Construction work" means the construction, rehabilitation, alteration, conversion, extension, demolition or repair of buildings, highways, or other changes or improvements to real property, including facilities providing utility services. The term also includes the supervision, inspection, and other onsite functions incidental to the actual construction.

"Contract" means any Government contract or subcontract, and with respect to the Order, any federally-assisted construction contract or subcontract. The regulations in this chapter frequently refer only to contract. The word subcontract is subsumed under the word contract.

"Contracting agency" means any department, agency, establishment, or instrumentality in the executive branch of the Government, including any wholly owned Government corporation, which enters into contracts.

"Contractor" means a Government contractor or subcontractor, and with respect to the Order, a federally-assisted construction contractor or subcontractor. For the purpose of Subpart B of this part and part 60–30 of this chapter the term also includes any person who has held a contract. The regulations in this chapter frequently refer only to contractor. The word subcontractor is subsumed under the word contractor.

"Director" means the Director of the Office of Federal Contract Compliance Programs of the United States Department of Labor or his/her designee.

"Disabled veteran" means a person entitled to disability compensation under laws administered by the Veterans Administration for disability rated at 30 per centum or more, or a person whose discharge or release from active duty was for a disability incurred or aggravated in the line of duty.

"Establishment," except as used in the definition of "administering agency" and "contracting agency" contained in this section, means the location of a contractor's business or operations generally having some component which exercises personnel authority and responsibilities. Small locations (i.e., those having fewer than 50 employees) may be considered to be part of an establishment in a different location if such locations are in the same Standard Metropolitan Statistical Area or labor area and are within the same chain of command.

"Equal opportunity clause" means the contract provisions set forth in section 202 of the Order, and in § 60–1.4(a) or (b), as appropriate.

"Facilities" means buildings, structures, equipment, roads, walks, parking lots or other real or personal property.

"Federally assisted construction contract" means any agreement or modification thereof between any applicant and a person for construction work which is paid for in whole or in part with funds obtained from the Government or borrowed on the credit of the Government pursuant to any Federal program involving a grant, contract, loan, insurance, or guarantee, or undertaken pursuant to any Federal program involving such grant contract, loan, insurance, or guarantee, or any application or modification thereof approved by the Government for a grant, contract, loan insurance, or guarantee under which the applicant itself participates in the construction work.

"Government" means the Government of the United States of America.

"Government contract" means any agreement or modification thereof between any contracting agency and any person for the furnishing of supplies or services or for the use of real or personal property, including lease arrangements. But sections 402 and 503 do not apply to contracts for the use of real property. The term "services", as used in this section includes, but is not limited to the following services: Utility, construction, transportation, research, insurance, and fund depository, irrespective of whether the Government is the pruchaser or seller. The term "Government contract" does not include (1) agreements in which the parties stand in the relationship of employer and employee and (2) federally assisted construction contracts.

"Handicapped individual" means any person who (a) has a physical or mental impairment which substantially limits one or more of the person's major life activities; (b) has a record of such impairment; or (c) is regarded as having such an impairment. A handicapped individual is "substantially limited" if he or she is likely to experience difficulty in securing, retaining, or advancing in employment because of a real or perceived handicap. For purposes of this chapter, "major life activities" includes employment or training. "Regarded as" means the employer perceives the individual as having an impairment whether or not there is an impairment.

"Modification" means any alteration in the terms and conditions of a contract, including supplemental agreements, amendments, and extensions.

"Order," "Executive Order," or "Executive Order 11246" means parts II, III, and IV of Executive Order 11246 dated September 24, 1965 (30 FR 12319), any Executive Order amending such Order, and any other Executive Order superseding such Order. Order specifically includes the equal opportunity clause and the rules, regulations and orders issued pursuant to the Order. The short form reference of Order is used simply to avoid needless repetition of the above phrases.

"Person" means any natural person, corporation, partnership, unincorporated association, state or local government, and any agency, instrumentality, or subdivision of such a government.

"Prime contractor" means any person holding a contract and, for the purposes of Subpart B of this part and 41 CFR Part 60–30, any person who has held a contract subject to the Order or to sections 402 and 503.

"Qualified disabled veteran" means a disabled veteran as defined in this section 60–1.3 who is capable of performing a particular job, with reasonable accommodation to his or her handicap or disability.

"Qualified handicapped individual means a handicapped individual capable of performing a particular job with reasonable accommodation to his or her handicap or disability.

"Recruiting and training agency", means any person who refers workers to any contractor or who provides for employment by any contractor.

"Rules, regulations, and relevant orders of the Secretary of Labor" used in paragraph (4) of the equal opportunity clause means rules, regulations, and relevant orders of the Secretary of Labor or his/her designee issued pursuant to the Order.

"Secretary" means the Secretary of Labor, U.S. Department of Labor.

"Section 503" means section 503 of the Rehabilitation Act, as amended. The reference, section 503, specifically includes rules and regulations promulgated pursuant to the Act.

"Section 402" means section 402 of the Vietnam Era Veterans' Readjustment Assistant Act, as amended. The reference, section 402, specifically includes rules and regulations promulgated pursuant to the Act.

"Site of construction" means the general physical location of any building, highway, or other change or improvement to real property which is undergoing construction, rehabilitation, alteration, conversion, extension, demolition, or repair and any temporary location or facility at which a contractor

or other participating party meets a demand or performs a function relating to the contract.

"Subcontract" means any agreement or arrangement between a contractor and any person (in which the parties do not stand in the relationship of an employer and an employee):

(1) For the furnishing of supplies or services or for the use of real or personal property, including lease arrangements, which, in whole or in part, is necessary to the performance of any one or more contracts; or

(2) Under which any portion of the contractor's obligation under any one or more contracts is performed, undertaken, or assumed: *Provided,* That sections 402 and 503 do not apply to contracts relating to real property.

"Subcontractor" means any person holding a subcontract and, for the purposes of Subpart B of this part, any person who has held a subcontract subject to the Order. The term "First-tier subcontractor" refers to a subcontractor holding a subcontract with a prime contractor.

"United States" means the several States, the District of Columbia, the Virgin Islands, the Commonwealth of Puerto Rico, Guam, the Panama Canal Zone, American Samoa and the Trust Territory of the Pacific Islands.

"Veteran of the Vietnam Era" means a person (a) who (1) served on active duty for a period of more than 180 days, any part of which occurred between August 5, 1964, and May 7, 1975, and was discharged or released therefrom with other than a dishonorable discharge, or (2) was discharged or released from active duty for a service-connected disability if any part of such active duty was performed between August 5, 1964, and May 7, 1975, and (b) who was so discharged or released within 48 months preceding the alleged violation of the Act.

§ 60–1.4 Equal opportunity clause.

(a) *Government contracts.* Except as otherwise provided, each contracting agency shall include the following equal opportunity clause contained in section 202 of the Order in each of its Government contracts (and modifications thereof if not included in the original contract):

During the performance of this contract, the contractor agrees as follows:

(1) The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin. The contractors will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, or national origin. Such action shall include, but not be limited to the following: Employment, upgrading, demotion, or transfer, recruitment or recruitment advertising, layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided by the contracting officer setting forth the provisions of this nondiscrimination clause.

(2) The contractor will in all solicitations or advertisements for employees placed by or on behalf of the contractor, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, or national origin.

(3) the contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice to be provided by the agency contracting officer, advising the labor union or workers' representative of the contractor's commitments under section 202 of Executive Order 11246 of September 24, 1965, and shall post copies of the notice in conspicuous places available to employees and applications for employment.

(4) The contractor will comply with all provisions of Executive Order 11246 of September 24, 1965, and of the rules, regulations, and relevant orders of the Secretary of Labor.

(5) The contractor will furnish all information and reports required by Executive Order 11246 of September 24, 1965, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the contracting agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations and orders.

(6) In the event of the contractor's noncompliance with the nondiscrimination clauses of this contract or with any of such rules, regulations, or orders, this contract may be canceled, terminated or suspended in whole or in part and the contractor may be declared ineligible for further Government contracts in accordance with procedures authorized in Executive Order 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(7) the contractor will include the provisions of paragraphs (1) thorugh (7) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as may be directed by the Secretary of Labor as a means of enforcing such provisions including sanctions for noncompliance: *Provided, however,* that in the event the contractor becomes involved in, or is threatened with litigation with a subcontractor or vendor as a result of such direction, the contractor may request the United States to enter into such litigation to protect the interests of the United States.

(b) *Federally assisted construction contracts.* (1) Except as otherwise provided, each administering agency shall require the inclusion of the following language as a condition of any grant, contract, loan, insurance, or guarantee involving federally assisted construction which is not exempt from the requirements of the equal opportunity clause:

The applicant hereby agrees that it will incorporate or cause to be incorporated into any contract for construction work, or modification thereof, as defined in the regulations of the Secretary of Labor at 41 CFR Chapter 60, which is paid for in whole or in part with funds obtained from the Federal Government or borrowed on the credit of the Federal Government pursuant to a grant, contract, loan insurance, or guarantee, or undertaken pursuant to any Federal program involving such grant, contract, loan, insurance, or guarantee, the following equal opportunity clause:

During the performance of this contract, the contractor agrees as follows:

(1) The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex; or national origin. The contractor will take affirmative action ensure that applicants are employed, and that employees are treated during employment without regard to their race, color, religion, sex, or national origin, such action shall include, but not be limited to the following: Employment, upgrading demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices to be provided setting forth the provisions of this nondiscrimination clause.

(2) The contract will, in all solicitations or advertisements for employees placed by or on behalf of the contractor, state that all qualified applicants will receive considerations for employment without regard to races, color, religion, sex, or national origin.

(3) The contractor will send to each labor union or representative of workers with which he has a collective bargaining agreement or other contract or understanding, a notice to be provided advising the said labor union or workers' representative of the contractor's commitments under this section, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(4) The contractor will comply with all provisions of Executive Order 11246 of September 24, 1965, and of the rules, regulations, and relevant orders of the Secretary of Labor.

(5) The contractor will furnish all information and reports required by

Executive Order 11246 of September 24, 1965, and by rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to his books, records, and accounts by the administering agency and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(6) In the event of the contractor's noncompliance with the nondiscrimination clauses of this contract or with any of the said rules, regulations, or orders, this contract may be canceled, terminated, or suspended in whole or in part and the contractor may be declared ineligible for further Government contracts or federally assisted construction contracts in accordance with procedures authorized in Executive Order 11246 of September 24, 1965, and such other sanctions may be imposed and remedies invoked as provided in Executive Order 11246 of September 24, 1965, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(7) The contractor will include the portion of the sentence immediately preceding paragraph (1) and the provisions of paragraphs (1) through (7) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to section 204 of Executive Order 11246 of September 24, 1965, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the administering agency may direct as a means of enforcing such provisions, including sanctions for noncompliance: *Provided, however,* That in the event a contractor becomes involved in or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the administering agency the contractor may request the United States to enter into such litigation to protect the interests of the United States.

The applicant further agrees that it will be bound by the above equal opportunity clause with respect to its own employment practices when it participates in federally assisted construction work: *Provided,* That if the applicant so participating is a State or local government, the above equal opportunity clause is not applicable to any agency, instrumentality or subdivision of such government which does not participate in work on or under the contract.

The applicant agrees that it will assist and cooperate actively with the administering agency and the Secretary of Labor in obtaining the compliance of contractors and subcontractors with the equal opportunity clause and the rules, regulations, and relevant orders of the Secretary of Labor, that it will furnish the administering agency and the Secretary of Labor such information as they may require for the supervision of such compliance, and that it will otherwise assist the administering agency in the discharge of the agency's primary responsibility for securing compliance.

The applicant further agrees that it will refrain from entering into any contract or contract modification subject to Executive Order 11246 of September 24, 1965, with a contractor debarred from, or who has not demonstrated eligibility for Government contracts and federally assisted construction contracts pursuant to the Executive order and will carry out such sanctions and penalties for violation of the equal opportunity clause as may be imposed upon contractors and subcontractors by the administering agency or the Secretary of Labor pursuant to Part II, Subpart D of the Executive order. In addition, the applicant agrees that if it fails or refuses to comply with these undertakings, the administering agency may take any or all of the following actions: Cancel, terminate, or suspend in whole or in part this grant (contract, loan, insurance, guarantee), refrain from extending any further assistance to the applicant under the program with respect to which the failure or refund occurred until satisfactory assurance of future compliance has been received from such applicant; and refer the case to the Department of Justice for appropriate legal proceedings.

(c) Subcontracts.

Each nonexempt contractor or subcontractor shall include the equal opportunity clause in each of its nonexempt subcontracts.

Note.—See, also, § 60–1.46 and § 60–1.47 regarding incorporation by reference and incorporation by operation of law, respectively.

§ 60–1.5 Exemptions.

(a) *General.*—(1) *Transactions of $10,000 or under.* Contracts not exceeding $10,000, other than (i) Government bills of lading and (ii) contracts with financial institutions which serve as depositories of Government funds in any amount, or which serve as issuing or redeeming agents for U.S. savings bonds and savings notes or which subscribe to Federal deposit or share insurance, are exempt from the requirements of the Order. In determining the applicability of this exemption to any federally assisted construction contract, the amount of such contract rather than the amount of the Federal financial assistance shall govern. No agency or contractor shall procure supplies or services in a manner so as to avoid applicability of the order: *Provided,* That where a contractor has contracts with the Government in any 12-month period which have an aggregate total value (or can reasonably be expected to have an aggregate total value) exceeding $10,000, the $10,000 or under exemption does not apply, and the contracts are subject to the order regardless of whether any single contract exceeds $10,000.

(2) *Contrtacts for indefinite quantities.* With respect to contracts for indefinite quantities (including, but not limited to, open end contracts, requirement-type contracts, Federal Supply Schedule contracts, "call-type" contracts, and purchase notice agreements), the equal opportunity clause shall be included unless the purchaser has reason to believe that the amount to be ordered in any year under such contract will not exceed $10,000. The applicability of the equal opportunity clause shall be determined by the purchaser at the time of award for the first year, and annually thereafter for succeeding years, if any. Notwithstanding the above, the equal opportunity clause shall be applied to such contract whenever the amount of a single order exceeds $10,000. Once the equal opportunity clause is determined to be applicable, the contract shall continue to be subject to such clause for its duration, regardless of the amounts ordered, or reasonably expected to be ordered in any year.

(3) *Work outside the United States.* Contracts are exempt from the requirements of the equal opportunity clause with regard to work performed outside of the United States by employees who were not recruited within the United States.

(4) *Contracts with state or local governments.* The Order, and sections 402and 503, with respect to a contract with a state or local government (or any agency thereof) shall apply only to the agency or agencies of such government which perform on the contract. Agencies, instrumentalities or subdivisions of state or local governments, except educational institutions, utilities, and medical facilities, are exempt from filing the annual compliance report required by § 60–1.7(a)(1) of this part and from maintaining a written affirmative action program prescribed by § 60–1.40 of this part and Part 60–2 of this chapter.

(5) *Contracts with certain educational institutions.* It shall not be a violation of the equal opportunity clause for a school, college, university, or other educational institution or institution of learning to hire and employ employees of a particular religion if such school, college, university, or other educational institution or institution of learning is, in whole or in substantial part, owned, supported, controlled, or managed by a particular religion or by a particular religious corporation, association, or society, or if the curriculum of such school, college, university, or other educational institution or institution of learning is directed toward the propagation of a particular religion. The primary thrust of this provision is directed at religiously oriented church-related colleges and universities and should be so interpreted.

(6) *Work on or near Indian reservations.* It shall not be a violation of the equal opportunity clause for a contractor to extend a publicly announced preference in employment to

Indians living on or near an Indian reservation in connection with employment opportunities on or near an Indian reservation. The use of the word "near" would include all that area where a person seeking employment could reasonably be expected to commute to and from in the course of a work day. Contractors extending such a preference shall not, however, discriminate among Indians on the basis of religion, sex, or tribal affiliation, and the use of such a preference shall not excuse a contractor from complying with the other requirements contained in this chapter.

(b) *Specific contracts and facilities*—(1) *Specific contracts.* The Director may exempt an agency or any person from requiring the inclusion of any or all of the equal opportunity clause in any specific contract or subcontract when he/she deems that special circumstances in the national interest so require. The Director may also exempt groups or categories of contracts or subcontracts of the same type where he/she finds it impracticable to act upon each request individually or where group exemptions will contribute to convenience in the administration of the Order.

(2) *Facilities not connected with contracts.* The Director may exempt from the requirements of the equal opportunity clause any of a contractor's facilities which he/she finds to be in all respects separate and distinct from activities of the contractor related to the performance of the contract, provided that he/she also finds that such an exemption will not interfere with or impede the effectuation of the Order.

(c) *National security.* Any requirement set forth in the regulations in this part shall not apply to any contract whenever the head of an agency determines that such contract is essential to the national security and that its award without complying with such requirement is necessary to the national security. Upon making such a determination, the head of the agency will notify the Director in writing within 30 days.

(d) *Withdrawal of exemption.* When any contract is of a class exempted under this section, the Director may withdraw the exemption for a specific contract or group of contracts when in his/her judgment such action is necessary or appropriate to achieve the purposes of the Order. Such withdrawal shall not apply to contracts awarded prior to the withdrawal, except that in procurements entered into by formal advertising, or the various forms of restricted formal advertising, such withdrawal shall not apply unless the withdrawal is made more than 10 calendar days before the date set for the opening of the bids.

§ 60–1.6 [Reserved]

§ 60–1.7 Reports and other required information.

(a) *Requirements for contractors.* (1) Each contractor shall file annually, on or before the 31st day of March, complete and accurate reports on Standard Form 100 (EEO–1) promulgated jointly by the Office of Federal Contract Compliance Programs and the Equal Employment Opportunity Commission or such form as may hereafter be promulgated in its place if such contractor (i) has 50 or more employees; and has a contract of $50,000 or more; or (ii) has contracts which total $50,000 or more, or which reasonably may be expected to total $50,000 or more, in any 12-month period; or (iii) is a financial institution which serves as a depository for Government funds in any amount, acts as an issuing or redeeming agent for U.S. savings bonds and notes in any amount, or subscribes to federal deposit or share insurance.

(2) Each contractor required by § 60–1.7(a)(1) to submit reports shall file such report within 30 days after the award to it of a contract unless such contractor has submitted such a report within 12 months preceding the date of the award. Subsequent reports shall be submitted annually in accordance with § 60–1.7(a)(1), or at such other intervals as the Director may require. The Director may extend the time for filing any report.

(3) The Director or the applicant, on their own motions, may require a contractor to keep employment or other records and to furnish, in the form requested, within reasonable limits, such information as the Director or the applicant deems necessary for obtaining compliance under the Order.

(4) Failure to file timely, complete and accurate reports as required constitutes noncompliance with the contractor's obligations under the Order and is ground for the imposition of any sanction authorized by the Order.

(b) *Requirements for bidders or prospective prime contractors* (1) *Certification of compliance with Part 60–2; Affirmative Action Programs.* Each contracting agency shall require each bidder or prospective prime contractor to state in the bid or in writing at the outset of negotiations for the contract: (i) Whether it has developed and has on file at each establishment affirmative action programs pursuant to Part 60–2 of this chapter; (ii) whether it has participated in any previous contract or subcontract subject to the Order; and (iii) whether it has filed with the Joint Reporting Committee, the Director or the Equal Employment Opportunity Commission all reports due under the applicable filing requirements.

(2) *Additional information.* A bidder or prospective prime comtractor shall be required to submit such information as the Director requests prior to the award of the contract. When a determination has been made to award the contract to a specific contractor, such contractor shall be required, prior to award, or after the award, or both, to furnish such other information as the applicant or the Director requests.

§ 60–1.8 Segregated facilities.

To comply with its obligations under the Order, a contractor must ensure that facilities provided for employees are provided in such a manner that segregation on the basis of race, color, religion, sex or national origin cannot result. The contractor may neither require such segregated use by written or oral policies nor tolerate such use by employee custom. This obligation extends to all contracts regardless of the amount of the contract. The term "facilities" as used in this section means waiting rooms, work areas, restaurants, and other eating areas, time clocks, restrooms, wash rooms, locker rooms, and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees: *Provided,* That separate or single-user toilet and necessary changing facilities shall be provided to assure privacy between the sexes.

§ 60–1.9 Compliance by labor unions and by recruiting and training agencies.

(a) The policy of OFCCP is to use its best efforts, directly and through agencies, contractors, applicants, state and local officials, public and private agencies, and all other available instrumentalities, to cause any labor union, recruiting and training agency or other representative of workers who are or may be engaged in work under contracts to cooperate with, and to comply in the implementation of, the purposes of the Order and of sections 402 and 503.

(b) To effectuate the purposes of paragraph (a) of this section, the Director may hold hearings, public or private, with respect to the practices and policies of any such labor union or recruiting and training agency.

(c)(1) The collective bargaining representatives shall be given written notice of the commencement of any on site investigation of compliance with the

Executive Order or with section 402 or 503 at the same time the contractor is notified.

(2) Whenever compliance with the Order or with section 402 or 503 effects the terms or conditions of employment which are governed by the provisions of a collective bargaining agreement, the collective bargaining representatives shall be given notice and an opportunity to present their positions and supporting evidence to OFCCP and shall be invited to participate in conciliation discussions to the extent those discussions relate to any proposed changes, prior to any resolution or agreement between OFCCP and the contractor relating to such matters. (See 41 CFR 60–1.25(e).)

(d) The Director may notify any Federal, state or local agency of his/her conclusions and recommendations with respect to any such labor organization or recruiting and training agency which in his/her judgment has failed to cooperate with OFCCP, agencies, contractors or applicants in carrying out the purposes of the Order or of sections 402 and 503. The Director also may notify the Equal Employment Opportunity Commission, the Department of Justice, or other appropriate Federal agencies when there is reason to believe that the practices of any such labor organization or agency violate Title VII of the Civil Rights Act of 1964 or other provisions of Federal law.

§ 60–1.10 Foreign government practices.

Contractors shall not discriminate on the basis of race, color, religion, sex, or national origin when hiring or making employee assignments for work to be performed in the United States or abroad. Contractors are exempted from this obligation only when hiring persons outside of the United States for work to be performed outside of the United States (see 41 CFR 60–1.5(a)(3)). Therefore, a contractor hiring workers in the United States for either Federal or nonfederally connected work shall be in violation of Executive Order 11246, as amended, by refusing to employ or assign any person because of race, color, religion, sex, or national origin regardless of the policies of the country where the work is to be performed or for whom the work will be performed. Should any contractor be unable to acquire a visa of entry for any employee or potential employee to a country in which or with which it is doing business, and which refusal it believes is due to the race, color, religion, sex, or national origin of the employee or potential employee, the contractor must immediately notify the Department of State and the Director of such refusal.

Subpart B—General Enforcement; Review and Complaint Procedure

§ 60–1.20 Compliance reviews.

(a) The purpose of a compliance review is to determine if the contractor maintains nondiscriminatory hiring and employment practices and is taking affirmative action to ensure that applicants are employed and that employees are placed, trained, upgraded, promoted, terminated, and otherwise treated during employment without regard to race, color, religion, sex, national origin, veteran status or handicap. It shall consist of a comprehensive analysis and evaluation of each aspect of the aforementioned practices and policies and conditions resulting therefrom. Compliance reviews normally are conducted in three stages (desk audit, on-site review and off-site analysis). The desk audit may be shortened or omitted, however, when an immediate on-site review (e.g., where a preaward compliance review is involved, where intimidation is alleged or other circumstances do not permit a desk audit) is required. (See, 41 CFR 60–1.24(b).)

(b) Compliance reviews generally are conducted under the direction of an OFCCP Assistant Regional Administrator, but the Director is authorized to designate other OFCCP officials for this purpose.

(c) Where deficiencies or violations are found, reasonable efforts shall be made to secure compliance through conciliation and persuassion. Before the contractor can be found to be in compliance with the Order, section 402 or section 503, it must make a specific commitment, in a written conciliation agreement or a letter of commitment, as appropriate, to correct any such deficiencies or violations. Minor technical deficiencies usually may be resolved in a letter of commitment from the contractor. The agreement or letter must include the precise actions to be taken and dates for completion. The time period allotted shall be no longer than the minimum period necessary to effect such changes. Upon approval by OFCCP, the contractor may be considered in compliance, on condition that the actions are faithfully taken. The contractor shall be notified, however, that taking such actions does not preclude future determinations of noncompliance based either on a finding that the actions are not sufficient to achieve compliance or on violations not previously revealed in a compliance review or complaint investigation.

§ 60–1.21 Preaward reviews.

(a) The purpose of a preaward compliance review is to determine whether a responsive contractor or bidder will be able to comply with the requirements of the Order and with sections 402 and 503.

(b) Each contracting agency shall include in the invitation for bids for each formally advertised nonconstruction contract or state at the outset of negotiations for each negotiated nonconstruction contract, that if the award, when let, should exceed $1 million, the prospective contractor and known first-tier subcontractors with subcontracts in excess of $1 million will be subject to a compliance review before the award of the contract.

(c) Prior to the award of any nonconstruction contract in excess of $1 million, the contracting agency shall give written notice of the proposed award to the OFCCP Assistant Regional Administrator of the Region in which the contract is to be performed as far in advance of the award date as possible. In any event, the notice shall be given no less than 45 days in advance of the award date. The notice shall identify the projected prime contractor and all known first-tier subcontractors or prospective subcontractors projected to receive subcontracts in excess of $1 million.

(d) If the establishment where the contract or subcontract is to be performed has 250 or more employees and no compliance review of that establishment has been conducted in the 24 months prior to the notification, a compliance review of the establishment shall be commenced on a priority basis.

(e) OFCCP is authorized to conduct preaward compliance reviews of any contractor receiving a contract in excess of $1 million even though the establishment has less than 250 employees and a compliance review has been conducted within the last 24 months. In determining whether to conduct a preaward review under this paragraph (e), OFCCP may consider, for example, (1) the past EEO performance of the contractor, including its current EEO profile and indications of underutilization; (2) the volume and nature of complaints filed by employees or applicants against the contractor; (3) whether the contractor is in a growth industry; (4) the level of employment or promotional opportunities resulting from the expansion of or turnover in the contractor's work force; (5) the employment opportunities likely to result from the contract in issue; and (6)

whether resources are available to conduct the review.

(f) If, prior to the award date of the contract or subcontract, the contracting agency has not provided the notice required by paragraph (c) of this section, the preaward compliance review has not been completed or the contractor-bidder's alleged noncompliance has not been resolved, the Director may request the contracting agency to delay the award of the contract, until such time as the contractor is found eligible or ineligible for the contract in accordance with the preliminary hearing procedures in 41 CFR 60–30.38 of this chapter. The request shall also be applicable to all other contracts which are then (or become) pending at the establishment where the preaward review which triggered the request was conducted. The request shall not be applicable to contracts pending at other establishments which are not part of the preaward review. If such a request is made, the award of the contract(s) shall be delayed, unless the contracting agency determines that a delay is contrary to the national security of the United States. Written notification of such determination shall be given to the Director within 30 days of the determination (see 41 CFR 60–1.5(c)): *Provided,* That unless the preliminary hearing procedures in 41 CFR 60–30.38 have been invoked or will be invoked within 15 working days, Executive Order, and sections 402 and 503 clearance for award of the contract shall not be withheld.

(g) The preaward review authorized by this section shall be conducted in accordance with the procedures of § 60–1.20 of this part to the extent that those procedures are not inconsistent with the provisions of this section.

(h) If by the award date, the preaward compliance review has not been completed or a decision to invoke the preliminary hearing procedure in 41 CFR 60–30.38 of this chapter has not been made, Executive Order, and sections 402 and 503 clearance for the contract shall be granted, except as provided in paragraph (f) of this section, and the review shall be completed on an expedited basis.

§ 60–1.22 Filing complaints.

Complaints shall be filed within 180 days of the alleged violation unless the time for filing is extended by the Director for good cause shown. Complaints may be filed with the OFCCP, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210, or with any OFCCP regional or area office.

§ 60–1.23 Contents of complaint.

(a) The complaint shall include the name, address, and telephone number of the complainant, the name and address of the contractor committing the alleged discrimination, a description of the acts considered to be discriminatory, and any other pertinent information which will assist in the investigation and resolution of the complaint. The complaint shall be signed by the complainant or his/her authorized representative. Signed third party complaints which allege class-type discrimination and which do not identify the alleged discriminatees will be accepted, whether or not the third party signing the complaint is an authorized representative, provided that the other information required by this paragraph is included.

(b) If a complaint contains incomplete information, OFCCP shall seek the needed information from the person filing the complaint. In the event such information is not furnished within 60 days of the date of such request, the case may be closed.

§ 60–1.24 Processing complaints.

(a) *Complaints.* OFCCP may refer individual complaints to the Equal Employment Opportunity Commission (EEOC) for processing under Title VII of the Civil Rights Act of 1964, as amended, in lieu of processing them under the Order. Upon referring a complaint to the EEOC, OFCCP shall promptly notify the complainant. OFCCP also may transmit a copy of any complaint to EEOC and to any state or local agency with jurisdiction over the subject of the complaint.

(b) *Complaint investigations under the Order.* (1) OFCCP will retain and investigate class or systemic complaints. However, where EEOC is about to initiate or is in the process of an investigation of any contractor against which OFCCP has received a class complaint, OFCCP may, at the request of EEOC, refer the complaint to EEOC for processing in order to avoid duplication and to assure effective law enforcement. In resolving such class complaints, the agencies will consult and coordinate with each other to ensure that the resolution of the complaints comports with the law enforcement requirements of each agency.

(2) During a compliance review, OFCCP will investigate and resolve individual complaints on file with OFCCP and unresolved at the commencement of the compliance review: *Provided,* That resolution of such individual complaints does not unduly delay the completion of the compliance review. With regard to unresolved individual complaints which have been referred to EEOC, OFCCP will consult with EEOC at the commencement of the compliance review to determine whether EEOC or OFCCP will investigate and resolve such complaints.

(c) *Resolution of matters.* (1) If any complaint investigation indicates a violation of the Order, reasonable efforts shall be made to secure compliance through conciliation and persuasion. (2) Where any complaint investigation indicates a violation of the Order and the matter has not been resolved by informal means, the matter may be recommended to the Office of the Solicitor for consideration of legal enforcement proceedings.

§ 60–1.25 Show cause notices and notices of violation.

(a) *General Rule.* At the conclusion of a compliance review or complaint investigation conducted pursuant to the Order or sections 402 and 503, a notice to show cause or a notice of violation shall be served on the contractor if the deficiencies which were disclosed in the review or investigation have not been corrected through a conciliation agreement, letter of commitment or consent decree. Where appropriate, show cause notices may be used at any other stage of the review.

(b) *Show cause notices—exceptions to the general rule.* A notice to show cause why enforcement proceedings should not be initiated shall be used when an uncorrected deficiency is disclosed in a compliance review or complaint investigation, except when: (1) A notice of violation under paragraph (d) of this section is appropriate; (2) a violation of a conciliation agreement under paragraph (f) of this section is alleged; (3) one or more special violations as discussed in § 60–1.29(d) of this part is alleged; or (4) OFCCP contemplates judicial enforcement under § 60–1.29(f) of this part.

(c) *Show cause notices—contents and timeframes.* (1) A notice to show cause should contain:

(i) An itemization of the sections of the Order, sections 402 and 503, and of the regulations with which the contractor has been found in violation, with a description of the conditions, practices, facts, or circumstances which give rise to each violation;

(ii) A statement of the corrective actions proposed by OFCCP to achieve compliance;

(iii) A request for a written response to the findings, including commitments to corrective actions or the presentation of opposing facts and evidence; and

(iv) A suggested date for the conciliation conference.

(2) The contractor shall be accorded 30 days, or such longer period as may be authorized by the Director or his/her designee, to establish that it is not covered by or is in compliance with the Order and sections 402 and 503, or to enter into a conciliation agreement or letter of commitment.

(d) *Notice of Violation.* (1) A notice of violation may be used where circumstances do not permit 30 days to resolve the matters (e.g. pre-award compliance reviews), and may be used at any time during the compliance review or complaint investigation (e.g. where serious violations such as intimidation, or interference with the orderly process of the review or investigation are alleged). A notice of violation shall contain a short and plain statement of the deficiency adequate to put the contractor on notice of the violation with which it is charged. The notice shall accord the contractor a reasonable period of time (not to exceed 15 days) in which to respond and for conciliation.

(2) A notice of violation also may be used when the compliance review or complaint investigation discloses a violation of a matter which is the subject of a conciliation agreement, letter of commitment or consent or other decree between the contractor and the Department of Labor, the Attorney General acting on behalf of OFCCP, or a former compliance agency (see 41 CFR 60–1.25(b)).

(e) *Participation by collective bargaining representatives.* When a notice to show cause or a notice of violation proposes a change in the terms or conditions of employment which are governed by the provisions of a collective bargaining agreement the collective bargaining representatives shall be given notice of the proposed change and an opportunity to present their positions and supporting evidence to OFCCP and shall be invited to participate in conciliation discussions to the extent those discussions relate to such changes, prior to any resolution or agreement between OFCCP and the contractor relating to such matters.

(f) *Procedure when a conciliation agreement is violated.* When a conciliation agreement has been violated, the following procedures are applicable: (1) A written notice shall be sent to the contractor setting forth the violations alleged and summarizing the supporting evidence. The contractor shall have 15 days from receipt of the notice to respond, except in those cases in which such a delay would result in irreparable injury to the employment rights of affected employees or applicants.

(2) During the 15-day period the contractor may demonstrate in writing that it has not violated its commitments.

(3) If the contractor is unable to demonstrate that it has not violated its commitments, or if the notice alleges irreparable injury, enforcement proceedings may be initiated immediately without issuing a show cause notice or proceeding through any other requirement contained in this chapter.

§ 80–1.26 Conciliation agreements.

(a) A conciliation agreement is a written agreement between OFCCP and a contractor by which the contractor undertakes specific obligations to correct or remedy noncompliance with the Order or with sections 402 and 503. A conciliation agreement normally is required where a compliance review, complaint investigation or some other review discloses violations of the Order or of sections 402 and 503, and (1) the contractor is willing to correct the violations or deficiencies and (2) OFCCP determines that a settlement (rather than formal enforcement) is appropriate. The agreement shall provide for the remedial relief necessary to correct the violations or deficiencies, which may include priority rights to hire or promotion, training, back pay, front pay and retroactive seniority, etc., for an affected class or for individuals, as appropriate.

(b) A conciliation agreement shall include (1) A statement of each deficiency or violation; (2) the corresponding precise remedial action to be taken and a timetable for implementation; (3) a requirement for periodic reporting to OFCCP as to implementation of the agreement, if appropriate; and (4) a copy of the notice to show cause or notice of violation when such has been previously issued.

(c) A conciliation agreement is effective when it has been signed by the contractor and the proper Assistant Regional Administrator, OFCCP, unless within 45 days of receipt from the Assistant Regional Administrator, the Director rejects the agreement.

(d) Conciliation agreements shall not be entered into after enforcement proceedings have been initiated. Settlements of enforcement proceedings by the Office of the Solicitor normally will be by consent decree.

(e) Letters of commitment, in lieu of conciliation agreements, are appropriate for resolving minor technical deficiencies.

60–1.27 Assumption of jurisdiction by the Director.

(a) The Director may inquire into the status of any pending matter. Where the Director considers it necessary or appropriate to the achievement of the purposes of the Order or of sections 402 and 503, he/she may assume jurisdiction over the matter and proceed as provided in this chapter. Whenever the Director assumes jurisdiction over any matter, he/she may conduct, or have conducted, such investigation, hold such hearings, including record hearings, and hearings under § 60–1.9(b) of this part, make such findings, issue such recommendations and directives and take such other action as may be necessary or appropriate to achieve the purposes of the Order or of sections 402 and 503.

(b) For reasonable cause shown, the Director may, on his/her own motion or pursuant to a request, reconsider or cause to be reconsidered a matter arising under the Order or under sections 402 and 503 which presently is pending in OFCCP.

§ 60–1.28 Intimidation and interference.

The sanctions and penalties contained in Subpart D of the Order, and in Parts 60–250 and 60–741 of this chapter may be exercised against any contractor or applicant which fails to take all necessary steps to ensure that no person intimidates, threatens, coerces, or discriminates against any individual for the purpose of interfering with the filing of a complaint, furnishing information, or assisting or participating in any manner in an investigation, compliance review, hearing, or any other activity related to the administration of the Order, sections 402 and 503 or any other Federal, state or local laws requiring equal employment opportunity. Such sanctions and penalties also apply to contractors or applicants which discriminate against a person because he or she has opposed any employment practice unlawful under the Order, sections 402 and 503, Title VII of the Civil Rights Act of 1964, as amended, or any other Federal, state or local laws.

§ 60–1.29 Enforcement proceedings.

(a) *General.* If, as a result of a compliance review, complaint investigation or some other review, OFCCP believes that the Order or that sections 402 and 503 have been violated, the matter may be referred to the Office of the Solicitor for consideration of legal enforcement proceedings.

(b) *Violations.* Violations may be found based upon, *inter alia*, any of the following: (1) the results of a compliance review or complaint investigation; (2) analysis of an affirmative action

program; (3) the results of an on-site review of the contractor's compliance with the Order or of sections 402 and 503; (4) a contractor's refusal or failure to submit an affirmative action program; (5) a contractor's refusal or failure to permit an on-site compliance review or complaint investigation to be conducted; (6) a contractor's refusal or failure to maintain records and other information, or to supply copies of such records or information required to be maintained or supplied by the Order or by sections 402 and 503; and (7) any substantial or material violation of the contractual provisions of the Order or of the regulations implementing sections 402 and 503.

(c) *Administrative enforcement proceedings.* Administrative enforcement proceedings are brought by the Office of the Solicitor and shall be conducted under the Rules of Practice for Administrative Proceedings to Enforce Equal Opportunity under Executive Order 11246, Section 402 and Section 503 contained in Part 60–30 of this chapter. Administrative enforcement proceedings may be commenced to enjoin violations of the Order or of sections 402 and 503, to seek appropriate relief (which may include back pay, front pay, retroactive seniority, training, priority rights to hire or promotion, etc., for an affected class or for individuals) or to impose sanctions.

(d) *Special violations.* If the contractor refuses or fails to (1) submit an affirmative action program; (2) supply copies of relevant records or other requested information; (3) allow OFCCP access to its premises for an on-site review or investigation; or if the contractor is being charged with intimidation or interference under § 60–1.28 of the part, and if conciliation efforts under this part are unsuccessful, administrative enforcement proceedings may be commenced without serving the contractor with a show cause notice or a notice of violation.

(e) *Preliminary administrative enforcement proceedings.* Preliminary or summary enforcement proceedings under 41 CFR 60–30.38 may be appropriate when the evidence indicates one or more of the following violations of the Order, section 402 or section 503: (1) The contractor is engaging in employment practices which violate its contractual obligations so as to made the contractor not responsible to perform its contractual EEO obligations (such as, where a preaward or other compliance review discloses evidence that the contractor is engaging in prohibited employment practices and the contractor has failed to change the practices); (2) the contractor has refused or failed to develop or submit a current affirmative action program; (3) the contractor has failed or refused to supply requested records or other information it is required to supply; (4) the contractor has failed or refused to permit access to its premises, to its records for reviewing or copying or to its employees or witnesses for interviewing or questioning during an on-site review or investigation; (5) the contractor has engaged in intimidation or retaliation in violation of § 60–1.28 of this part. Preliminary enforcement proceedings involving one or more such violations may be commenced by the office of the Solicitor, and shall be conducted pursuant to the rules of practice for such proceedings under Part 60–30 of this chapter.

(f) *Judicial enforcement—referrals to the Department of Justice.* (1) Violations of the Order or section 402 or 503 or the threat of violations of the Order or section 402 or 503 may be referred to the Department of Justice for judicial enforcement. There are no procedural prerequisites to a referral to the Department of Justice.

(2) Whenever a matter has been referred to the Department of Justice for consideration of judicial proceedings, the Attorney General may bring a civil action against the contractor or any other person in the appropriate district court of the United States requesting a temporary restraining order, preliminary or permanent injunction, and an order for such additional equitable relief, including back pay, deemed necessary or appropriate to ensure the full enjoyment of the rights secured by the Order or section 402 or 503, or any of the above.

(3) The Attorney General is authorized to conduct such investigation of the facts as he/she may deem necessary or appropriate to carry out his/her responsibilities under these regulations.

(4) Prior to the institution of any judicial proceedings, the Attorney General, on behalf of the Director, is authorized to make reasonable efforts to secure compliance with the contract provisions of the Order. He/she may do so by providing the contractor and any other person with reasonable notice of findings, his/her intent to file suit, and the actions he/she believes necessary to obtain compliance with the contract provisions of the Order without contested litigation, and by offering the contractor and any other person a reasonable opportunity for conference and conciliation, in an effort to obtain such compliance without contested litigation.

(5) As used in this part, the Attorney General shall mean the Attorney General, the Assistant Attorney General for Civil Rights, or any other person authorized by regulations or practice to act for the Attorney General with respect to the enforcement of equal employment opportunity laws, orders and regulations generally, or in a particular matter or case.

(g) *Recommendations to the Attorney General for investigation and possible suit.* In addition to recommending that suit be instituted upon referral under 41 CFR 60–1.29(f) above, the Department of Labor may recommend that the Attorney General conduct further investigation of a contractor to determine whether there are substantial violations of the Order, section 402, section 503 or other contractural obligations assumed by the contractor that warrant the initiation of a lawsuit. Upon doing so the Department of Labor shall promptly notify the contractor of that recommendation. Upon receipt of such a recommendation the Attorney General is authorized to take any action, with respect to a contractor, which is authorized by a referral under 41 CFR 60–1.29(f) above.

(h) *Referrals to the Equal Employment Opportunity Commission.* The Department of Labor may recommend that the Equal Employment Opportunity Commission institute appropriate proceedings under Title VII of the Civil Rights Act of 1964. In addition, and where appropriate, the Department of Labor will make such recommendations to the EEOC in connection with alleged violations by financial institutions whose only nexus to the Federal Government is Federal deposit or share insurance.

(i) *Referrals to financial institution regulatory agencies.* Where appropriate, the Department of Labor may refer alleged violation of the Order, section 402 or section 503 by financial institutions to the appropriate Federal financial institutions regulatory agency for actions under that agency's procedures. Whenever the Department of Labor refers a violations by a financial institution to the appropriate regulatory agency, the agency, after consultation with the Department of Labor, may take such action, in its sole discretion, as it deems appropriate. These agencies are: (1) Federal Home Loan Bank Board; (2) Federal Deposit Insurance Corporation; (3) Comptroller of the Currency; (4) the Board of Governors of the Federal Reserve System; and (5) the National Credit Union Administration

(j) *Enforcement policy regarding Federal deposit and share insurance.* The Department of Labor will not debar financial institutions (e.g., banks, savings and loan associations and credit unions) from future Federal deposit or share insurance, or cancel, terminate or suspend existing Federal deposit or share insurance. In the event that a financial institution which has Federal deposit or share insurance is alleged to be in violation of its contractual commitments under the Executive Order, section 402 or section 503, the Department of Labor will pursue one of the options mentioned in paragraphs (f), (h) and (i) of this section with respect to the deposit or share insurance relationship. Such recommendations or referrals as described in paragraphs (f), (h) and (i) of this section may take place without or after an administrative hearing in the Department of Labor.

§60-1.30 Debarment and contract ineligibility list.

No order for debarment from further Government contracts or subcontracts pursuant to section 209(a)(6) of the Order or pursuant to the regulations implementing sections 402 and 503 shall be made without affording the contractor an opportunity for a hearing, either administrative or judicial. The Director periodically shall distribute a list to all executive departments and agencies giving the names of contractors which have been declared ineligible under the Order or under sections 402 and 503 for further Government contracts and subcontracts. The Director shall promptly notify the Comptroller General of the United States when contracts have been cancelled or terminated or when a contractor has been debarred from further Government contracts under the Order or under sections 402 and 503. The Director shall take appropriate steps to notify prime contractors of the debarred contractor's ineligibility for subcontracts.

§ 60-1.31 Petition for reinstatement for debarred contractors.

(a) Any contractor declared ineligible under the Order or under section 402 or 503 for further contracts may petition the Director for reinstatement. A copy of the petition for reinstatement shall be served on the parties to the original proceeding which led to the debarment. The petition for reinstatement shall set forth what actions the contractor has taken to comply, as applicable, with the Order, section 402 or section 503 and in what way the contractor will comply with requirements which may involve future performance. The burden shall be on the contractor to demonstrate that it is entitled to reinstatement.

(b) Rescission of the debarment order and reinstatement of the contractor's eligiblity for further contracts may be conditioned on the contractor satisfying the Director that it has established and will implement personnel and employment policies in compliance with the provisions of the Order or of section 402 or 503. In carrying out his/her responsibilities under this section, the Director may require that compliance reviews be conducted of the contractor's establishments, and that the contractor supply copies of any information relevant to determining its compliance with the Order or with sections 402 or 503. Reinstatement also may be conditioned on a program of compliance which may include meeting requirements not specifically mentioned in the debarment order where meeting these requirements is necessary to achieve compliance under the Order or under section 402 or 503. Where the debarment was based on a determination of the contractor's liability but the extent of the relief or the number or identity of persons entitled to relief has not been determined or where there are other issues appropriate for hearing, the Director may remand the matter to the Administrative Law Judge for a recommended determination of such issues prior to reinstatement. On remand from the Director, the Administrative Law Judge shall follow the procedures in Part 60–30 of this chapter in making his/her recommended determination of the number of identity of the individuals entitled to relief and the amount of relief. Reasonable discovery shall be allowed on those issues. The matter shall then proceed in accordance with §§ 60–30.25 through 60–30.30 of this chapter. Reinstatement by the Director or Secretary, as applicable, may be conditioned on the contractor's satisfying any relief finally determined by the Secretary or Director, as applicable, to be owed.

(c) Any conditions upon which the recission of the debarment order and reinstatement of the contractor are based shall be set forth by the Director or the Secretary, as appropriate, in an order which shall be filed with the Administrative Law Judge and made a part of the record in the original proceeding from which the debarment resulted. The Administrative Law Judge shall retain jurisdiction, and any subsequent violations involving the same issues which gave rise to the debarment order or which are included in the reinstatement order may be raised by motion in the original proceeding.

(d) The Director's or Secretary's decision on the petition for reinstatement shall constitute a final administrative order.

(e) Any party or person who participated (pursuant to 41 CFR 60–30.24) in the proceeding which gave rise to the debarment order may make submissions opposing or supporting the contractor's petition for reinstatement.

(f) When a debarred contractor is reinstated, the Director shall take prompt action to notify the contractors, Comptroller General and the agencies which received notice of the debarment.

Subpart C—Ancillary Matters

§ 60-1.40 Affirmative action programs.

(a) *Requirements of programs.* Each nonconstruction contractor which has 50 or more employees and (1) has a contract of $50,000 or more; or (2) has contracts (including Government bills of lading) which, in any 12-month period total $50,000 or more, or reasonably may be expected to total $50,000 or more; or (3) is a financial institution which serves as a depository for Government funds in any amount, acts as an issuing or redeeming agent for U.S. savings bonds and savings notes in any amount, or subscribes to Federal deposit or share insurance, shall develop a written affirmative action program for each of its establishments. Each nonconstruction contractor shall require each subcontractor which has 50 or more employees and (i) has a subcontract of $50,000 or more; or (ii) has subcontracts (including Government bills of lading) which, in any 12-month period total $50,000 or more, or reasonably may be expected to total $50,000 or more; or (iii) is a financial institution which serves as a depository for Government funds in any amount, acts as an issuing or redeeming agent for U.S. savings bonds and savings notes in any amount, or subscribes to Federal deposit or share insurance, to develop a written affirmative action program for each of its establishments. A necessary prerequisite to the development of a satisfactory affirmative action program is the identification and analysis of problem areas inherent in minority and female employment and an evaluation of opportunities for utilization of minority group and female personnel. The contractor's program shall provide in detail for specific steps to guarantee equal employment opportunity keyed to the problems and needs of members of minority groups and women, including, when there is underutilization or other deficiencies, the development of specific goals and timetables for the prompt

achievement of full and equal employment opportunity.

(b) *Maintenance of programs.* Contractors currently subject to this section and Part 60–2 of this chapter must have an affirmative action program in place at each establishment. If a contractor is not currently subject to this section and Part 60–2 it must, within 120 days from the commencement of the contract, develop, implement, and maintain separate affirmative action programs for each of its establishments. A copy of the appropriate affirmative action program shall be maintained at each of the contractor's locations. An affirmative action program shall be part of the staffing and training plans for each new establishment and shall be developed and made available prior to the staffing of such establishment. A report of the results of such program shall be compiled annually and the program shall be updated at that time. This information shall be made available to OFCCP upon request and the contractor's affirmative action program and the results it produces shall be evaluated as part of compliance review activities.

(c) *Application to construction contractors.* The provisions of this section 60–1.40 shall be applicable to the nonconstruction employees of a construction contractor which has 50 or more nonconstruction employees and which has (1) a contract of $50,000 or more; or (2) contracts (including Government bills of lading) which, in any 12-month period total $50,000 or more, or reasonably may be expected to total $50,000 or more.

§ 60–1.41 Solicitations or advertisements for employees.

In solicitations or advertisements for employees placed by or on behalf of a contractor, the requirements of paragraph (2) of the equal opportunity clause shall be satisfied whenever the contractor complies with any of the following:

(a) States expressly in the solicitations or advertising that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, or national origin;

(b) Uses display or other advertising, and the advertising includes an appropriate insignia prescribed by the Director. The use of the insignia is considered subject to the provisions of 18 U.S.C. 701;

(c) Uses a single advertisement, and the advertisement is grouped with other advertisements under a caption which clearly states that all employers in the group assure all qualified applicants equal consideration for employment without regard to race, color, religion, sex, or national origin;

(d) Uses a single advertisement in which appears in clearly distinguishable type the phrase "an equal opportunity employer."

§ 60–1.42 Notices to be posted.

(a) Unless alternative notices are prescribed by the Director, the notices which contractors are required to post by paragraphs (1) and (3) of the equal opportunity clause will contain the following language in English and Spanish and will be provided by the contracting or administering agencies:

Equal Employment Opportunity Is the Law—Discrimination Is Prohibited by the Civil Rights Act of 1964 and by Executive Order No. 11246

Private Industry, State, and Local Government

Title VII of the Civil Rights Act of 1964, as amended, prohibits job discrimination because of race, color, religion, sex or national origin.

Applicants to and employees of private employers, state/local governments, and public/private educational institutions are protected. Also covered are employment agencies, labor unions and apprenticeship programs. Any person who believes he or she has been discriminated against should contact immediately:

The U.S. Equal Employment Opportunity Commission (EEOC), 2401 E St. N.W., Washington, D.C. 20506.

Federal Contract Employment

Executive Order 11246, as amended, prohibits job discrimination because of race, color, religion, sex or national origin and requires affirmative action to ensure equality of opportunity in all aspects of employment.

Section 503 of the Rehabilitation Act of 1973 prohibits job discrimination because of handicap and requires affirmative action to employ and advance in employment qualified handicapped workers.

Section 402 of the Vietnam Era Veterans' Readjustment Assistance Act of 1974 prohibits job discrimination and requires affirmative action to employ and advance in employment (1) qualified Vietnam era veterans during the first four years after their discharge and (2) qualified disabled veterans throughout their working life if they have a 30 percent or more disability.

Applicants to and employees of any company with a Federal Government contract or subcontract are protected. Any person who believes a contractor has violated its affirmative action obligations, including nondiscrimination under Executive Order 11246, as amended or under Section 503 of the Rehabilitation Act, or under Section 402 of the Vietnam Era Veterans' Readjustment Assistance Act of 1974 should contact immediately:

The Employment Standards Administration, Office of Federal Contract Compliance Programs (OFCCP), Third and Constitution Avenue, N.W., Washington, D.C. 20210 or an OFCCP regional office, listed in most telephone directories under U.S. Government, Department of Labor. Complaints specifically under the veterans' law may also be filed directly with the Veterans' Employment Service through local offices of the state employment service.

All complaints must be filed within 180 days from the date of the alleged violation.

(b) The requirements of paragraph (3) of the equal opportunity clause will be satisfied whenever the contractor posts copies of the notification prescribed by or pursuant to paragraph (a) of this section in conspicuous places available to employees, applicants for employment, and representatives of each labor union or other organization representing its employees with which it has a collective-bargaining agreement or other contract or understanding.

§ 60–1.43 Access to records and site of employment.

Each contractor shall permit access during normal business hours to its premises for the purpose of conducting on-site compliance reviews which include interviewing employees, inspecting, copying and removing off-site copies of such books, records, accounts, and other material such as computer tapes and printouts as may be relevant to the matter under investigation and pertinent to compliance with the Order or with sections 402 and 503.

§ 60–1.44 Rulings and interpretations.

Rulings under or interpretations of the Order and of sections 402 and 503 shall be made by the Director.

§ 60–1.45 Adaptation of language.

Such necessary changes in language may be made in the equal opportunity clause of the Order and in the affirmative action clauses of sections 402 and 503 as shall be appropriate to identify properly the parties and their undertakings.

§ 60–1.46 Incorporation by reference.

The equal opportunity clause and the affirmative action clauses may be incorporated by reference in all Government contracts and subcontracts, including Government bills of lading, transportation requests, contracts for deposit of Government funds, and contracts for issuing and paying U.S. savings bonds and notes, and such other contracts as the Director may designate.

§ 60–1.47 Incorporation by operation of law.

By operation of the Order and sections 402 and 503, the equal opportunity clause of the Order and the

affirmative action clauses of sections 402 and 503 shall be considered to be a part of every contract and subcontract required by the Order and sections 402 and 503 to include such clauses regardless of whether the clauses are physically incorporated into such contracts and regardless of whether the contract is written.

§ 60-1.48 Request for hearing after compliance.

When a contractor, without a hearing, shall have complied with the recommendations or orders of the OFCCP and believes such recommendations or orders to be erroneous, it shall, upon filing a request therefore within 10 days of such compliance, be afforded an opportunity for a hearing and review of the alleged erroneous action. Such hearings normally will be record hearings before the Director.

§ 60-1.49 Existing contracts.

All contracts in effect prior to October 24, 1965, which are not subsequently modified shall be administered in accordance with the nondiscrimination provisions of any prior applicable Executive Orders. Any contract or subcontract modified on or after October 24, 1965, shall be subject to Executive Order 11246. Complaints received by and violations coming to the attention of OFCCP regarding contracts and subcontracts which were subject to Executive Orders 10925 and 11114 shall be processed as if they were complaints regarding violations of Executive Order 11246.

§ 60-1.50 Delegation of authority by the Director.

The Director is authorized to redelegate the authority given to him/her by the regulations in this chapter. The authority redelegated by the Director pursuant to the regulations in this chapter shall be exercised under his/her general direction and control.

PART 60-2—AFFIRMATIVE ACTION PROGRAMS

Subpart A—General

Subpart B—Required Contents of Affirmative Action Programs

Subpart C—Methods of Implementing the Requirements of Subpart B

Subpart D—Miscellaneous

Authority: 5 U.S.C. 553(a)(3)(B); 29 CFR 2.7; section 201, E.O. 11246, 30 FR 12319, and E.O. 11375, 32 FR 14303, as amended by E.O. 12086.

Subpart A—General

§ 60-2.1 Title, purpose and scope.

(a) The regulations in this part implement provisions of Executive Order 11246 only. This part shall also be known as "Revised Order No. 4" and shall cover nonconstruction contractors. The provisions of this part also shall apply to the nonconstruction employees of a construction contractor with 50 or more nonconstruction employees and one or more contracts which meet the criteria set forth in section 60-1.40 of this chapter. Section 60-1.40 of this chapter, requires that within 120 days from the commencement of a contract each contractor which has 50 or more employees and (1) has a contract of $50,000 or more; or (2) has contracts (including Government bills of lading) which, in any 12-month period, total or can reasonably be expected to total $50,000 or more; or (3) which is a financial institution which (i) serves as a depository of Government funds in any amount; (ii) acts as an issuing or redeeming agent for U.S. savings bonds and savings notes in any amount; or (iii) subscribes to Federal deposit or share insurance, shall develop, implement and maintain a written affirmative action program for each of its establishments. This part sets forth guidelines to be used by contractors and the OFCCP in developing and judging written affirmative action programs as well as the good faith effort required to transform these programs from paper commitments to equal employment opportunity.

(b) Relief, including back pay, where appropriate, for members of an affected class or individuals who by virtue of past discrimination continue to suffer the present effects of that discrimination, shall be provided in the conciliation agreement entered into pursuant to 41 CFR 60-1.26 of this chapter. An affected class problem must be remedied before a contractor may be considered in compliance. Section 60-2.2 of this part, pertaining to an acceptable affirmative action program, also is applicable to a contractor's failure to remedy discrimination against members of an affected class.

§ 60-2.2 Requirements for contractors.

Any contractor required by 41 CFR 60-1.40 of this chapter to develop an affirmative action program at each of its establishments which has not complied fully with that section is not in compliance with the Order. Until such programs are developed and found to be acceptable in accordance with the standards and guidelines set forth in §§ 60-2.10 through 60-2.32 of this part, the contractor is unable to comply fully with the Order. An affirmative action program shall be deemed to have been accepted by OFCCP at the time the appropriate OFCCP area, regional or national office has accepted such program unless within 45 days thereafter the Director has disapproved such program. The intention of 41 CFR 60-1.40 and this part is that each contractor establishment will be covered by a written affirmative action program and that all the contractor's employees will be included in an affirmative action program regardless of where they work. Contractors may reach agreements with OFCCP on nationwide AAP formats or methodology.

§ 60-2.3 Submission of affirmative action programs and support data.

(a) The contractor shall submit the affirmative action program and supporting documentation within 15 days of receipt of a request from OFCCP. The terms "affirmative action program" and "supporting documentation" refer to the required contents of Affirmative Action Programs, as set forth in Subpart B of this part, and Methods of Implementing the Requirements of Subpart B, set forth in Subpart C of this part.

(b) The contractor also shall submit the affirmative action program and supporting documentation upon OFCCP's request when a complaint is being investigated or a preaward compliance review is being conducted.

(c) The contractor in accordance with 41 CFR 60–1.43, shall provide full access to and copies of all additional, relevant information and data for the on-site phase of the review.

(d) The contractor shall provide, for off-site review, all data or information determined by the compliance officer to be necessary to analyze more fully alleged deficiencies or violations before a determination of compliance is made.

(e) If a contractor fails or refuses to submit its affirmative action program and supporting documentation or other information as required by paragraphs (a), (b), (c) and (d) of this section, enforcement proceedings authorized by this chapter may be initiated against the contractor after appropriate conciliation efforts have been attempted, without issuing a show cause notice or notice of violations.

§ 60–2.4 Confidentiality and relevancy of information.

(a) *Desk audit data.* If the contractor is concerned with the confidentiality of such information as lists of employees, employee names, reasons for termination and pay data, then alphabetic or numeric coding or the use of an index of pay and pay ranges are acceptable for desk audit purposes.

(b) *Data required for off-site analysis.* The contractor must provide all data determined by the compliance officer to be necessary for off-site analysis pursuant to § 60–2.3(d) of this part. Such data may only be coded if the contractor makes the code available to the compliance officer. If the contractor believes that particular information which is to be taken off-site is not relevant to compliance with the Executive Order, the contractor may request a ruling by the OFCCP Area Director. The OFCCP Area Director shall issue a ruling promptly. The contractor may appeal that ruling to the OFCCP Assistant Regional Administrator within 10 days of receipt. The Assistant Regional Administrator shall issue a final ruling promptly. Pending a final ruling, the information in question must be made available to the compliance officer off-site, but OFCCP shall take all necessary precautions to safeguard the confidentiality of such information until a final determination is made. Such information may not be copied and access to the information shall be limited to the compliance officer and personnel involved in the determination of relevancy. Data determined to be not relevant to the investigation will be returned to the contractor immediately.

(c) *Public access to information.* Information obtained from contractors under this chapter may be subject to public inspection under the Freedom of Information Act, 5 U.S.C. 552. If a contractor believes that information should be withheld from public inspection, it shall, at the time of submission of the information to the agency, clearly mark the materials "subject to a claim of confidentiality." If the agency receives a request from the public for such materials under the Freedom of Information Act, it will notify the contractor of the request and solicit a statement of reasons why the information should be withheld. As to any claim that the information contains trade secrets, or commercial or financial information which is privileged or confidential, the contractor shall set forth, with respect to each reasonably segregable portion of the materials, the manner in which it is claimed that release of the material would cause harm to the competitive position of the contractor. If information to which the contractor has filed an objection to disclosure is determined by OFCCP to be disclosable under 5 U.S.C. 552, the contractor shall be notified of such determination at least ten days prior to disclosure of the information.

Subpart B—Required Contents of Affirmative Action Programs

§ 60–2.10 Purpose of affirmative action program.

An affirmative action program is a set of specific and result-oriented procedures to which a contractor commits itself to apply every good faith effort. The objective of those procedures plus such efforts is equal employment opportunity. Procedures without effort to make them work are meaningless; and effort, undirected by specific and meaningful procedures, is inadequate. An acceptable affirmative action program must include an analysis of areas within which the contractor is deficient in the utilization of minority groups and women, and further, goals and timetables to which the contractor's good faith efforts must be directed to correct the deficiencies and, thus to achieve prompt and full utilization of minorities and women, at all levels and in all segments of its work force where deficiencies exist.

§ 60–2.11 Required utilization analysis.

Based upon the Government's experience with compliance reviews under the Executive Order program and the contractor reporting system, minority groups are most likely to be underutilized in departments and jobs within departments that fall within the following Employer's Information Report (EEO–1) designations: Officials and managers, professionals, technicians, sales workers, office and clerical and craftsmen (skilled). As categorized by the EEO–1 designations, women are likely to be underutilized in departments and jobs within departments as follows: Officials and managers, professionals, technicians, sales workers (except over-the-counter sales in certain retail establishments), craftsmen (skilled and semi-skilled). Therefore, the contractor shall direct special attention to such jobs in its analysis and goal setting for minorities and women. Affirmative action programs must contain the following information:

(a) Workforce analysis which is defined as a listing of each job title as it appears in applicable collective bargaining agreements or payroll records (not job group) ranked from the lowest paid to the highest paid within each department or other similar organizational unit, including departmental or unit supervision. If there are separate work units or lines of progression within a department, a separate list must be provided for each such work unit, or line, including unit supervisors. For lines of progression there must be indicated the order of jobs in the line through which an employee could move to the top of the line. Where there are no formal progression lines or usual promotional sequences, job titles should be listed by department, job families, or disciplines, in order of wage rates or salary ranges. For each job title, the total number of incumbents, the total number of male and female incumbents, and the total number of male and female incumbents in each of the following groups must be given: Blacks, Spanish-surnamed Americans, American Indians, and Orientals. The wage rate or salary range for each job title must be given. All job titles, including all managerial job titles, must be listed.

(b) An analysis of all major job groups at the facility, with explanation if minorities or women are currently being underutilized in any one or more job groups ("job groups" herein meaning one or a group of jobs having similar content, wage rates and opportunities). "Underutilization" is defined as having fewer minorities or women in a particular job group than would reasonably be expected by their availability. In making the utilization analysis, the contractor shall conduct such analysis separately for minorities and women.

(1) In determining whether minorities are being underutilized in any job group, the contractor will consider at least all of the following factors:

(i) The minority population of the labor area surrounding the facility;

(ii) The size of the minority unemployment force in the labor area surrounding the facility;

(iii) The percentage of the minority work force as compared with the total work force in the immediate labor area;

(iv) The general availability of minorities having requisite skills in the immediate labor area;

(v) The availability of minorities having requisite skills in an area in which the contractor can reasonably recruit;

(vi) The availability of promotable and transferable minorities within the contractor's organization;

(vii) The existence of training institutions capable of training persons in the requisite skills; and

(viii) The degree of training which the contractor is reasonably able to undertake as a means of making all job classes available to minorities.

(2) In determining whether women are being underutilized in any job group, the contractor will consider at least all of the following factors:

(i) The size of the female unemployment force in the labor area surrounding the facility;

(ii) The percentage of the female workforce as compared with the total workforce in the immediate labor area;

(iii) The general availability of women having requisite skills in the immediate labor area;

(iv) The availability of women having requisite skills in an area in which the contractor can reasonably recruit;

(v) The availability of women seeking employment in the labor or recruitment area of the contractor;

(vi) The availability of promotable and transferable female employees within the contractor's organization;

(vii) The existence of training institutions capable of training persons in the requisite skills; and

(viii) The degree of training which the contractor is reasonably able to undertake as a means of making all job classes available to women.

§ 60-2.12 Establishment of goals and timetables.

(a) The goals and timetables developed by the contractor should be attainable in terms of the contractor's analysis of its deficiencies and its entire affirmative action program. Thus, in establishing the size of its goals and the length of its timetables, the contractor should consider the results which could reasonably be expected from its putting forth every good faith effort to make its overall affirmative action program work. In determining levels of goals, the contractor should consider at least the factors listed in § 60-2.11.

(b) Involve personnel relations staff, department and division heads, and local and unit managers in the goal-setting process.

(c) Goals should be significant, measurable, and attainable.

(d) Goals should be specific for planned results, with timetables for completion.

(e) Goals may not be rigid and inflexible quotas which must be met, but must be targets reasonably attainable by means of applying every good faith effort to make all aspects of the entire affirmative action program work.

(f) In establishing timetables to meet goals and commitments, the contractor will consider the anticipated expansion, contraction, and turnover of and in the work force.

(g) Goals, timetables, and affirmative action commitments must be designed to correct any identifiable deficiencies.

(h) Where deficiencies exist and where numbers or percentages are relevant in developing corrective action, the contractor shall establish and set forth specific goals and timetables separately for minorities and women.

(i) Such goals and timetables, with supporting data and the analysis thereof, shall be a part of the contractor's written affirmative action program and shall be maintained at each establishment of the contractor.

(j) A contractor or subcontractor extending a publicly announced preference for Indians as authorized in 41 CFR 60-1.5(a)(6) may reflect in its goals and timetables the permissive employment preference for Indians living on or near an Indian reservation.

(k) Where the contractor has not established a goal, its written affirmative action program must specifically analyze each of the factors listed in § 60-2.11 and must detail its reason for a lack of a goal.

(l) In the event it comes to the attention of the Office of Federal Contract Compliance Programs that there is a substantial disparity in the utilization of a particular minority group or men or women of a particular minority group, OFCCP may require separate goals and timetables for such minority group and may further require, where appropriate, such goals and timetables by sex for such group for such job classifications and organizational units specified by the OFCCP.

(m) Support data for the required analysis and program shall be compiled and maintained as part of the contractor's affirmative action program. This data will include but not be limited to progression line charts, seniority rosters, applicant flow data, and applicant rejection ratios indicating minority and sex status.

(n) Copies of affirmative action programs and/or copies of support data shall be made available to the Office of Federal Contract Compliance Programs, upon request, for such purposes as may be appropriate to the fulfillment of its responsibilities under Executive Order 11246, as amended.

§ 60-2.13 Additional required ingredients of affirmative action programs.

Effective affirmative action programs shall contain, but not necessarily be limited to, the following ingredients:

(a) Development or reaffirmation of the contractor's equal employment opportunity policy in all personnel actions.

(b) Formal internal and external dissemination of the contractor's policy.

(c) Establishment of responsibilities for implementation of the contractor's affirmative action program.

(d) Identification of problem areas (deficiencies) by organizational units and job group.

(e) Establishment of goals and objectives by organizational units and job groups, including timetables for completion.

(f) Development and execution of action-oriented programs designed to eliminate problems and further designed to attain established goals and objectives.

(g) Design and implementation of internal audit and reporting systems to measure effectiveness of the total program.

(h) Compliance of personnel policies and practices with the Sex Discrimination Guidelines (41 CFR Part 60-20).

(i) Active support of local and national community action programs and community service programs, designed to improve the employment opportunities of minorities and women.

(j) Consideration of minorities and women not currently in the work force having requisite skills who can be recruited through affirmative action measures.

§ 60-2.14 Program summary.

The affirmative action program shall be summarized and updated annually. The program summary shall be prepared in a format which shall be prescribed by the Director and published in the **Federal Register** as a notice before becoming effective. Contractors shall submit the program summary to OFCCP each year on the anniversary date of the affirmative action program.

§ 60-2.15 Compliance status.

No contractor's compliance status shall be judged alone by whether or not it reaches its goals and meets its timetables. Rather, each contractor's compliance posture shall be reviewed and determined by reviewing the contents of its program, the extent of its adherence to this program, and its good faith efforts to make its program work toward the realization of the program's goals within the timetables set for completion. There follows an outline of examples of procedures that contractors and OFCCP should use as a guideline for establishing, implementing, and judging an acceptable affirmative action program.

Subpart C—Methods of Implementing the Requirements of Subpart B

§ 60-2.20 Development or reaffirmation of the equal employment opportunity policy.

(a) The contractor's policy statement should indicate the chief executive officer's attitude on the subject matter, assign overall responsibility and provide for a reporting and monitoring procedure. Specific items to be mentioned should include, but not be limited to:

(1) Recruit, hire, train, and promote persons in all job titles, without regard to race, color, religion, sex, or national origin, except where sex is a bona fide occupational qualification. (The term "bona fide occupational qualification" has been construed very narrowly under the Civil Rights Act of 1964. Under Executive Order 11246, as amended, and this part, this term will be construed in the same manner.)

(2) Base decisions on employment so as to further the principle of equal employment opportunity.

(3) Ensure that promotion decisions are in accord with principles of equal employment opportunity by imposing only valid requirements for promotional opportunities.

(4) Ensure that all personnel actions such as compensation, benefits, transfers, layoffs, return from layoff, company sponsored training, education, tuition assistance, social and recreation programs, will be administered without regard to race, color, religion, sex, or national origin.

§ 60-2.21 Dissemination of the policy.

(a) The contractor should disseminate its policy internally as follows:

(1) Include it in contractor's policy manual.

(2) Publicize it in company newspaper, magazine, annual report, and other media.

(3) Conduct special meetings with executive, management, and supervisory personnel to explain intent of policy and individual responsibility for effective implementation, making clear the chief executive officer's attitude.

(4) Schedule special meetings with all other employees to discuss policy and explain individual employee responsibilities.

(5) Discuss the policy thoroughly in both employee orientation and management training programs.

(6) Meet with union officials to inform them of policy, and request their cooperation.

(7) Include nondiscrimination clauses in all union agreements, and review all contractual provisions to insure they are nondiscriminatory.

(8) Publish articles covering EEO programs, progress reports, promotions, etc., of minority and female employees, in company publications.

(9) Post the policy on company bulletin boards.

(10) When employees are featured in product or consumer advertising, employee handbooks or similar publications both minority and nonminority, men and women should be pictured.

(11) Communicate to employees the existence of the contractor's affirmative action program and make available such elements of its program as will enable such employees to know of and avail themselves of its benefits.

(b) The contractor should disseminate its policy externally as follows:

(1) Inform all recruiting sources verbally and in writing of company policy, stipulating that these sources actively recruit and refer minorities and women for all positions listed.

(2) Incorporate the equal opportunity clause in all purchase orders, leases, contracts, etc., covered by Executive Order 11246, as amended, and its implementing regulations.

(3) Notify minority and women's organizations, community agencies, community leaders, secondary schools, and colleges, of company policy, preferably in writing.

(4) Communicate to prospective employees the existence of the contractor's affirmative action program and make available such elements of its program as will enable such prospective employees to know of and avail themselves of its benefits.

(5) When employees are pictured in consumer or help wanted advertising, both minority and nonminority men and women should be shown.

(6) Send written notification of company policy to all subcontractors, vendors, and suppliers requesting appropriate action on their part.

§ 60-2.22 Responsibility for implementation.

(a) An executive of the contractor should be appointed as director or manager of company equal opportunity programs. Depending upon the size and geographical alignment of the company, this may be his or her sole responsibility. He or she should be given the necessary top management support and staffing to execute the assignment. His or her identity should appear on all internal and external communications on the company's equal opportunity programs. His or her responsibilities should include, but not necessarily be limited to:

(1) Developing policy statements, affirmative action programs, internal and external communication techniques.

(2) Assisting in the identification of problem areas.

(3) Assisting line management in arriving at solutions to problems.

(4) Designing and implementing audit and reporting systems that will:

(i) Measure effectiveness of the contractor's programs.

(ii) Indicate need for remedial action.

(iii) Determine the degree to which the contractor's goals and objectives have been attained.

(5) Serve as liaison between the contractor and enforcement agencies.

(6) Serve as liaison between the contractor and minority organizations, women's organizations and community action groups concerned with employment opportunities of minorities and women.

(7) Keep management informed of latest developments in the entire equal opportunity area.

(b) Line responsibilities should include, but not be limited to the following:

(1) Assistance in the identification of problem areas and establishment of local and unit goals and objectives.

(2) Active involvement with local minority organizations, women's organizations, community action groups and community service programs.

(3) Periodic audit of training programs, hiring and promotion patterns to remove impediments to the attainment of goals and objectives.

(4) Regular discussions with local managers, supervisors, and employees to be certain the contractor's policies are being followed.

(5) Review of the qualifications of all employees to insure that minorities and women are given full opportunities for transfers and promotions.

(6) Career counseling for all employees.

(7) Periodic audit to insure that each location is in compliance in areas such as:

(i) Posters are properly displayed.

(ii) All facilities, including company housing, which the contractor maintains for the use and benefit of its employees, are in fact desegregated, both in policy and use. If the contractor provides facilities such as dormitories, locker rooms and rest rooms, they must be comparable for both sexes.

(iii) Minority and female employees are afforded a full opportunity and are encouraged to participate in all company sponsored educational, training, recreational, and social activities.

(8) Supervisors should be made to understand that their work performance is being evaluated on the basis of their equal employment opportunity efforts and results, as well as other criteria.

(9) It shall be a responsibility of supervisors to take actions to prevent harassment of employees placed through affirmative action efforts.

§ 60-2.23 Identification of problem areas by organizational units and job groups.

(a) An in-depth analysis of the following should be made, paying particular attention to trainees and those categories listed in § 60-2.11(b).

(1) Composition of the work force by minority group status and sex.

(2) Composition of applicant flow by minority group status and sex.

(3) The total selection process including position descriptions, position titles, worker specifications, application forms, interview procedures, test administration, test validity, referral procedures, final selection process, and similar factors.

(4) Transfer and promotion practices.

(5) Facilities, company sponsored recreation and social events, and special programs such as educational assistance.

(6) Seniority practices and seniority provisions of union contracts.

(7) Apprenticeship programs.

(8) All company training programs, formal and informal.

(9) Work force attitude.

(10) Technical phases of compliance, such as poster and notification to labor unions, retention of applications, notification to subcontractors, etc.

(b) If any of the following items are found in the analysis, special corrective action should be appropriate.

(1) An "underutilization" of minorities or women in specific job groups.

(2) Lateral and/or vertical movement of minority or female employees occurring at a lesser rate (compared to work force mix) than that of nonminority or male employees.

(3) The selection process eliminates a significantly higher percentage of minorities or women than nonminorities or men.

(4) Application and related preemployment forms not in compliance with Federal legislation.

(5) Position descriptions inaccurate in relation to actual functions and duties.

(6) Formal or scored selection procedures not validated as required by the OFCCP Uniform Guidelines on Employee Selection Procedures (see 41 CFR Part 60-3).

(7) Test forms not validated by location, work performance and inclusion of minorities and women in sample.

(8) Referral ratio of minorities or women to the hiring supervisor or manager indicates a significantly higher percentage are being rejected as compared to nonminority and male applicants.

(9) Minorities or women are excluded from or are not participating in company sponsored activities or programs.

(10) De facto segregation still exists at some facilities.

(11) Seniority provisions contribute to overt or inadvertent discrimination, i.e., a disparity by minority group status or sex exists between length of service and types of job held.

(12) Nonsupport of company policy by managers, supervisors or employees.

(13) Minorities or women underutilized or significantly underrepresented in training or career improvement programs.

(14) No formal techniques established for evaluating effectiveness of EEO programs.

(15) Lack of access to suitable housing inhibits recruitment efforts and employment of qualified minorities.

(16) Lack of suitable transportation (public or private) to the work place inhibits minority employment.

(17) Labor unions and subcontractors not notified of their responsibilities.

(18) Purchase orders do not contain EEO clause.

(19) Posters not on display.

§ 60-2.24 Development and execution of programs.

(a) The contractor should conduct detailed analyses of position descriptions to insure that they accurately reflect position functions, and are consistent for the same position from one location to another.

(b) The contractor should validate worker specifications by division, department location or other organizational unit and by job title using job performance criteria. Special attention should be given to academic, experience and skill requirements to insure that the requirements in themselves do not constitute inadvertent discrimination. Specifications should be consistent for the same job title in all locations and should be free from bias as regards to race, color, religion, sex (except where sex is a bona fide occupational qualification) or national origin. Where requirements screen out a disproportionate number of minorities or women, such requirements should be professionally validated to job performance.

(c) Approved position descriptions and worker specifications, when used by the contractor, should be made available to all members of management involved in the recruiting, screening, selection, and promotion process. Copies should also be distributed to all recruiting sources.

(d) The contractor should evaluate the total selection process to insure freedom from bias and, thus, aid the attainment of goals and objectives.

(1) All personnel involved in the recruiting, screening, selection, promotion, disciplinary, and related processes should be carefully selected and trained to insure elimination of bias in all personnel actions.

(2) The contractor shall observe the requirements of the OFCCP Uniform Guidelines on Employee Selection Procedures.

(3) Selection techniques other than tests may also be improperly used so as to have the effect of discriminating against minority groups and women. Such techniques include but are not restricted to, unscored interviews, unscored or casual application forms, arrest records, credit checks, considerations of marital status or dependency or minor children. Where there exist data suggesting that such unfair discrimination or exclusion of minorities or women exists, the contractor should analyze its unscored procedures and eliminate them if they are not objectively valid.

(e) Suggested techniques to improve recruitment and increase the flow of minority or female applicants follow:

(1) Certain organizations such as the Urban League, Job Corps, Equal Opportunity Programs, Inc., Concentrated Employment programs, Neighborhood Youth Corps, Secondary Schools, Colleges, and City Colleges with high minority enrollment, the State Employment Service, specialized employment agencies, Aspira, LULAC, SER, the G.I. Forum, the Commonwealth of Puerto Rico are normally prepared to

refer minority applicants. Organizations prepared to refer women with specific skills are: National Organization for Women, Welfare Rights organizations, Women's Equity Action League, Talent Bank from Business and Professional Women (including 26 women's organizations), Professional Women's Caucus, Intercollegiate Association of University Women, Negro Women's sororities and service groups such as Delta Sigma Theta, Alpha Kappa Alpha, and Zera Phi Beta; National Council of Negro Women, American Association of University Women, YWCA, and sectarian groups such as Jewish Women's Groups, Catholic Women's Groups and Protestant Women's Groups, and women's colleges. In addition, community leaders as individuals shall be added to recruiting sources.

(2) Formal briefing sessions should be held, preferably on company premises, with representatives from these recruiting sources. Plant tours, presentations by minority and female employees, clear and concise explanations of current and future job openings, position descriptions, worker specifications, explanations of the company's selection process, and recruiting literature should be an integral part of the briefings. Formal arrangements should be made for referral of applicants, followup with sources, and feedback on disposition of applicants.

(3) Minority and female employees, using procedures similar to subparagraph (2) of this paragraph, should be actively encouraged to refer applicants.

(4) A special effort should be made to include minorities and women on the Personnel Relations staff.

(5) Minority and female employees should be made available for participation in Career Days, Youth Motivation Programs, and related activities in their communities.

(6) Active participation in "Job Fairs" is desirable. Company representatives so participating should be given authority to make on-the-spot commitments.

(7) Active recruiting programs should be carried out at secondary schools, junior colleges, and colleges with predominant minority or female enrollments.

(8) Recruiting efforts at all schools should incorporate special efforts to reach minorities and women.

(9) Special employment programs should be undertaken whenever possible. Some possible programs are:

(i) Technical and nontechnical co-op programs with predominately Negro and women's colleges.

(ii) "After school" and/or work-study jobs for minority youths, male and female.

(iii) Summer jobs for underprivileged youth, male and female.

(iv) Summer work-study programs for male and female faculty members of the predominantly minority schools and colleges.

(v) Motivation, training and employment programs for the hardcore unemployed, male and female.

(10) When recruiting brochures pictorially present work situations, the minority and female members of the work force should be included, especially when such brochures are used in school and career programs.

(11) Help wanted advertising should be expanded to include the minority news media and women's interest media on a regular basis.

(f) The contractor should insure that minority and female employees are given equal opportunity for promotion. Suggestions for achieving this result include:

(1) Post or otherwise announce promotional opportunities.

(2) Make an inventory of current minority and female employees to determine academic, skill and experience level of individual employees.

(3) Initiate necessary remedial, job training and workstudy programs.

(4) Develop and implement formal employee evaluation programs.

(5) Make certain "worker specifications" have been validated on job performance related criteria. (Neither minority nor female employees should be required to possess higher qualifications than those of the lowest qualified incumbent.)

(6) When apparently qualified minority or female employees are passed over for upgrading, require supervisory personnel to submit written justification.

(7) Establish formal career counseling programs to include attitude development, education aid, job rotation, buddy system and similar programs.

(8) Review seniority practices and seniority clauses in union contracts to ensure that such practices or clauses are nondiscriminatory and do not have a discriminatory effect.

(g) Make certain facilities and company-sponsored social and recreation activities are desegregated. Actively encourage all employees to participate.

(h) Encourage child care, housing and tranportation programs appropriately designed to improve the employment opportunities for minorities and women.

§ 60-2.25 Internal audit and reporting systems.

(a) The contractor should monitor records of referrals, placements, transfers, promotions and terminations at all levels to ensure that nondiscriminatory policy is carried out.

(b) The contractor should require formal reports form unit managers on a schedule scheduled basis as to the degree to which corporate or unit goals are attained and timetables met.

(c) The contractor should review report results with all levels of management.

(d) The contractor should advise top management of program effectiveness and submit recommendations to improve unsatisfactory performance.

§ 60-2.26 Support of action programs.

(a) The contractor should appoint key members of management to serve on merit employment councils, community relations boards and similar organizations.

(b) The contractor should encourage minority and female employees to participate actively in National Alliance of Businessmen programs for youth motivation.

(c) The contractor should support vocational guidance institutes, vestibule training programs and similar activities.

(d) The contractor should assist secondary schools and colleges in programs designed to enable minority and female graduates of these institutions to compete in the open employment market on a more equitable basis.

(e) The contractor should publicize achievements of minority and female employees in local and minority news media.

(f) The contractor should support programs developed by such organizations as National Alliance of Businessmen, the Urban Coalition and other organizations concerned with employment opportunities for minorities or women.

Subpart D—Miscellaneous

§ 60-2.30 Use of goals.

The purpose of a contractor's establishment and use of goals is to insure that it meet its affirmative action obligation. It is not intended and should not be used to discriminate against any applicant or employee because of race, color, religion, sex, or national origin.

§ 60-2.31 Preemption.

To the extent that any state or local laws, regulations or ordinances, including those which grant special benefits to persons on account of sex, are in conflict with Executive Order 11246, as amended, or with the requirements of this part, OFCCP will regard them as preempted under the Executive order.

§ 60-2.32 Supersedure.

All orders, instructions, regulations, and memorandums of the Secretary of Labor, other officials of the Department of Labor and contracting agencies are hereby superseded to the extent that they are inconsistent herewith, including a previous "Order No. 4" from this office dated January 30, 1970. Nothing in this part is intended to amend 41 CFR Part 60-3 or 41 CFR Part 60-20.

PART 60-4—CONSTRUCTION CONTRACTORS—AFFIRMATIVE ACTION REQUIREMENTS

Sec.

Authority: Secs. 201, 202, 205, 211, 301, 302, and 303 of E.O. 11246, as amended, 30 FR 12319; 32 FR 14303, as amended by E.O. 12086.

§ 60-4.1 Scope and application.

This part applies to all contractors and subcontractors which hold any Federal or federally assisted construction contract in excess of $10,000. The regulations in this part are applicable to all of a construction contractor's or subcontractor's construction employees who are engaged in on site construction including those construction employees who work on a non-Federal or nonfederally assisted construction site. This part also establishes procedures which all Federal contracting officers and all applicants, as applicable, shall follow in soliciting for and awarding Federal or federally assisted construction contracts. Procedures also are established which administering agencies shall follow in making any grant, contract, loan, insurance, or guarantee involving federally assisted construction which is not exempt from the requirements of Executive Order 11246, as amended.

In addition, this part applies to construction work performed by construction contractors and subcontractors for Federal nonconstruction contractors and subcontractors if the construction work is necessary in whole or in part to the performance of a nonconstruction contract or subcontract.

§ 60-4.2 Solicitations.

(a) All Federal contracting officers and all applicants shall include the notice set forth in paragraph (d) of this section and the Standard Federal Equal Employment Opportunity Construction Contract Specifications set forth in § 60-4.3 of this part in all solicitations for offers and bids on all Federal and federally assisted construction contracts or subcontracts to be performed in geographical areas designated by the Director pursuant to § 60-4.6 of the part. Administering agencies shall require the inclusion of the notice set forth in paragraph (d) of this section and the specifications set forth in § 60-4.3 of this part as a condition of any grant, contract, subcontract, loan, insurance or guarantee involving federally assisted construction covered by this Part 60-4.

(b) All nonconstruction contractors covered by Executive Order 11246 and the implementing regulations shall include the notice in paragraph (d) of this section in all construction agreements which are necessary in whole or in part to the performance of the covered nonconstruction contract.

(c) Contracting officers, applicants and nonconstruction contractors shall give written notice to the Director within 10 working days of award of a contract subject to these provisions. The notification shall include the name, address and telephone number of the contractor; employer identification number; dollar amount of the contract, estimated starting and completion dates of the contract; the contract number; and geographical area in which the contract is to be performed.

(d) The following notice shall be included in, and shall be a part of, all solicitations for offers and bids on all Federal and federally assisted construction contracts or subcontracts in excess of $10,000 to be performed in geographical areas designed by the Director pursuant to § 60-4.6 of this part (see 41 CFR 60-4.2(a)):

Notice of Requirement for Affirmative Action To Ensure Equal Employment Opportunity (Executive Order 11246)

1. The Offeror's or Bidder's attention is called to the "Equal Opportunity Clause" and the "Standard Federal Equal Employment Opportunity Construction Contract Specifications" set forth herein.

2. The goals and timetables for minority and female participation, expressed in percentage terms for the Contractor's aggregate workforce in each trade on all construction work in the covered area, are as follows:

Timetables	Goals for minority participation for each trade	Goals for female participation in each trade
.....	Insert goals for each year.	Insert goals for each year.

These goals are applicable to all the Contractor's construction work (whether or not it is Federal or federally assisted) performed in the covered area. If the contractor performs construction work in a geographical area located outside of the covered area, it shall apply the goals established for such geographical area where the work is actually performed. With regard to this second area, the contractor also is subject to the goals for both its federally involved and nonfederally involved construction.

The Contractor's compliance with the Executive Order and the regulations in 41 CFR Part 60-4 shall be based on its implementation of the Equal Opportunity Clause, specific affirmative action obligations required by the specifications set forth in 41 CFR 60-4.3(a), and its efforts to meet the goals. The hours of minority and female employment and training must be substantially uniform throughout the length of the contract, and in each trade, and the contractor shall make a good faith effort to employ minorities and women evenly on each of its projects. The transfer of minority or female employees or trainees from Contractor to Contractor or from project to project for the sole purpose of meeting the Contractor's goals shall be a violation of the contract, the Executive Order and the regulations in 41 CFR Part 60-4. Compliance with the goals will be measured against the total work hours performed.

3. The Contractor shall provide written notification to the Director of the Office of Federal Contract Compliance Programs within 10 working days of award of any construction subcontract in excess of $10,000 at any tier for construction work under the contract resulting from this solicitation. The notification shall list the name, address and telephone number of the subcontractor, employer identification number of the subcontractor; estimated dollar amount of the subcontract; estimated starting and completion dates of the subcontract; and the geographical

area in which the subcontract is to be performed.

4. As used in this Notice, and in the contract resulting from this solicitation, the "covered area" is (insert description of the geographical areas where the contract is to be performed giving the state, county and city, if any).

§ 60–4.3 Equal opportunity clauses.

(a) The equal opportunity clause published at 41 CFR 60–1.4(a) of this chapter is required to be included in and is part of, all nonexempt Federal contracts and subcontracts, including construction contracts and subcontracts. The equal opportunity clause published at 41 CFR 60–1.4(b) is required to be included in, and is a part of, all nonexempt federally assisted construction contracts and subcontracts. In addition to the clauses described above, all Federal contracting officers, all applicants and all nonconstruction contractors, as applicable, shall include the specifications set forth in this section in all Federal and federally assisted construction contracts in excess of $10,000 to be performed in geographical areas designated by the Director pursuant to § 60–4.6 of this part and in construction subcontracts in excess of $10,000 necessary in whole or in part to the performance of nonconstruction Federal contracts and subcontracts covered under the Executive Order.

Standard Federal Equal Employment Opportunity Construction Contract Specifications (Executive Order 11246)

1. As used in these specifications:

a. "Covered area" means the geographical area described in the solicitation from which this contract resulted;

b. "Director" means Director, Office of Federal Contract Compliance Programs, United States Department of Labor, or any person to whom the Director delegates authority;

c. "Employer identification number" means the Federal Social Security number used on the Employer's Quarterly Federal Tax Return, U.S. Treasury Department Form 941.

d. "Minority" includes:

(i) Black (all persons having origins in any of the Black African racial groups not of Hispanic origin);

(ii) Hispanic (all persons of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish Culture or origin, regardless of race);

(iii) Asian and Pacific Islander (all persons having origins in any of the original peoples of the Far East, Southeast Asia, the Indian Subcontinent, or the Pacific Islands); and

(iv) American Indian or Alaskan Native (all persons having origins in any of the original peoples of North America and maintaining identifiable tribal affiliations through membership and participation or community identification).

2. Whenever the Contractor, or any Subcontractor at any tier, subcontracts a portion of the work involving any construction trade, it shall physically include in each subcontract in excess of $10,000 the provisions of these specifications and the Notice which contains the applicable goals for minority and female participation and which is set forth in the solicitations from which this contract resulted.

3. If the Contractor is participating (pursuant to 41 CFR 60–4.5) in a Hometown Plan approved by the U.S. Department of Labor in the covered area either individually or through an association, its affirmative action obligations on all work in the Plan area (including goals and timetables) shall be in accordance with that Plan for those trades which have unions participating in the Plan. Contractors must be able to demonstrate their participation in and compliance with the provisions of any such Hometown Plan. Each Contractor or Subcontractor participating in an approved Plan is individually required to comply with its obligations under the EEO clause, and to make a good faith effort to achieve each goal under the Plan in each trade in which it has employees. The overall good faith performance by other Contractors or subcontractors toward a goal in an approved Plan does not excuse any covered Contractor's or Subcontractor's failure to take good faith efforts to achieve the Plan goals and timetables.

4. The Contractor shall implement the specific affirmative action standards provided in paragraphs 7 a through p of these specifications. The goals set forth in the solicitation from which this contract resulted are expressed as percentages of the total hours of employment and training of minority and female utilization the Contractor should reasonably be able to achieve in each construction trade in which it has employees in the covered area. Covered construction contractors performing construction work in geographical areas where they do not have a Federal or federally assisted construction contract shall apply the minority and female goals established for the geographical area where the work is being performed. Goals are published periodically in the **Federal Register** in notice form, and such notices may be obtained from any Office of Federal Contract Compliance Programs office or from Federal procurement contracting officers. The Contractor is expected to make substantially uniform progress in meeting its goals in each craft during the period specified.

5. Neither the provisions of any collective bargaining agreement, nor the failure by a union with whom the Contractor has a collective bargaining agreement, to refer either minorities or women shall excuse the Contractor's obligations under these specifications, Executive Order 11246, or the regulations promulgated pursuant thereto.

6. In order for the nonworking training hours of apprentices and trainees to be counted in meeting the goals, such apprentices and trainees must be employed by the Contractor during the training period, and the Contractor must have made a commitment to employ the apprentices and trainees at the completion of their training, subject to the availability of employment opportunities. Trainees must be trained pursuant to training programs approved by the U.S. Department of Labor.

7. The Contractor shall take specific affirmative actions to ensure equal employment opportunity. The evaluation of the Contractor's compliance with these specifications shall be based upon its effort to achieve maximum results from its actions. The Contractor shall document these efforts fully, and shall implement affirmative action steps at least as extensive as the following:

a. Ensure and maintain a working environment free of harassment, intimidation, and coercion at all sites, and in all facilities at which the Contractor's employees are assigned to work. The Contractor, where possible, will assign two or more women to each construction project. The Contractor shall specifically ensure that all foremen, superintendents, and other on-site supervisory personnel are aware of and carry out the Contractor's obligation to maintain such a working environment, with specific attention to minority or female individuals working at such sites or in such facilities.

b. Establish and maintain a current list of minority and female recruitment sources, provide written notification to minority and female recruitment sources and to community organizations when the Contractor or its unions have employment opportunities available, and maintain a record of the organizations' responses.

c. Maintain a current file of the names, addresses and telephone numbers of each minority and female off-the-street applicant and minority or female

referral from a union, a recruitment source or community organization and of what action was taken with respect to each such individual. If such individual was sent to the union hiring hall for referral and was not referred back to the Contractor by the union or, if referred, not employed by the Contractor, this shall be documented in the file with the reason therefor, along with whatever additional actions the Contractor may have taken.

d. Provide immediate written notification to the Director when the union or unions with which the Contractor has a collective bargaining agreement has not referred to the Contractor a minority person or woman sent by the Contractor, or when the Contractor has other information that the union referral process has impeded the Contractor's efforts to meet its obligations.

e. Develop on-the-job training opportunities and/or participate in training programs for the area which expressly include minorities and women, including upgrading programs and apprenticeship and trainee programs relevant to the Contractor's employment needs, especially those programs funded or approved by the Department of Labor. The Contractor shall provide notice of these programs to the sources compiled under 7b above.

f. Disseminate the Contractor's EEO policy by providing notice of the policy to unions and training programs and requesting their cooperation in assisting the Contractor in meeting its EEO obligations; by including it in any policy manual and collective bargaining agreement; by publicizing it in the company newspaper, annual report, etc.; by specific review of the policy with all management personnel and with all minority and female employees at least once a year; and by posting the company EEO policy on bulletin boards accessible to all employees at each location where construction work is performed.

g. Review, at least annually, the company's EEO policy and affirmative action obligations under these specifications with all employees having any responsibility for hiring, assignment, layoff, termination or other employment decisions including specific review of these items with onsite supervisory personnel such as Superintendents, General Foremen, etc., prior to the initiation of construction work at any job site. A written record shall be made and maintained identifying the time and place of these meetings, persons attending, subject matter discussed, and disposition of the subject matter.

h. Disseminate the Contractor's EEO policy externally by including it in any advertising in the news media, specifically including minority and female news media, and providing written notification to and discussing the Contractor's EEO policy with other Contractors and Subcontractors with whom the Contractor does or anticipates doing business.

i. Direct its recruitment efforts, both oral and written, to minority, female and community organizations, to schools with minority and female students and to minority and female recruitment and training organizations serving the Contractor's recruitment area and employment needs. Not later than one month prior to the date for the acceptance of applications for apprenticeship or other training by any recruitment source, the Contractor shall send written notification to organizations such as the above, describing the openings, screening procedures, and tests to be used in the selection process.

j. Encourage present minority and female employees to recruit other minority persons and women and, where reasonable, provide after school, summer and vacation employment to minority and female youth both on the site and in other areas of a Contractor's work force.

k. Validate all tests and other selection requirements where there is an obligation to do so under 41 CFR Part 60–3.

l. Conduct, at least annually, an inventory and evaluation at least of all minority and female personnel for promotional opportunities and encourage these employees to seek or to prepare for, through appropriate training, etc., such opportunities.

m. Ensure that seniority practices, job classifications, work assignments and other personnel practices, do not have a discriminatory effect by continually monitoring all personnel and employment related activities to ensure that the EEO policy and the Contractor's obligations under these specifications are being carried out.

n. Ensure that all facilities and company activities are nonsegregated except that separate or single-user toilet and necessary changing facilities shall be provided to assure privacy between the sexes.

o. Document and maintain a record of all solicitations of offers for subcontracts from minority and female construction contractors and suppliers, including circulation of solicitations to minority and femal contractor associations and other business associations.

p. Conduct a review, at least annually, of all supervisors' adherence to and performance under the Contractor's EEO policies and affirmative action obligations.

8. Contractors are encouraged to participate in voluntary associations which assist in fulfilling one or more of their affirmative action obligations (7a through p). The efforts of a contractor association, joint contractor-union, contractor-community, or other similar group of which the contractor is a member and participant, may be asserted as fulfilling any one or more of its obligations under 7a through p of these Specifications provided that the contractor actively participates in the group, makes every effort to assure that the group has a positive impact on the employment of minorities and women in the industry, ensures that the concrete benefits of the program are reflected in the Contractor's minority and female workforce participation, makes a good faith effort to meet its individual goals and timetables, and can provide access to documentation which demonstrates the effectiveness of actions taken on behalf of the Contractor. The obligation to comply, however, is the Contractor's and failure of such a group to fulfill an obligation shall not be a defense for the Contractor's noncompliance.

9. A single goal for minorities and a separate single goal for women have been established. The Contractor, however, is required to provide equal employment opportunity and to take affirmative action for all minority groups, both male and female, and all women, both minority and non-minority. Consequently, the Contractor may be in violation of the Executive Order if a particular group is employed in a substantially disparate manner (for example, even though the Contractor has achieved its goals for women generally, the Contractor may be in violation of the Executive Order if a specific minority group of women is underutilized).

10. The Contractor shall not use the goals and timetables or affirmative action standards to discriminate against any person because of race, color, religion, sex, or national origin.

11. The Contractor shall not enter into any Subcontract with any person or firm debarred from Government contracts pursuant to Executive Order 11246.

12. The Contractor shall carry out such sanctions and penalties for violation of these specifications and of the Equal Opportunity Clause, including suspension, termination and cancellation of existing subcontracts as may be imposed or ordered pursuant to Executive Order 11246, as amended, and

its implementing regulations, by the Office of Federal Contract Compliance Programs. Any Contractor who fails to carry out such sanctions and penalties shall be in violation of these specifications and Executive Order 11246, as amended.

13. The Contractor, in fulfilling its obligations under these specifications, shall implement specific affirmative action steps, at least as extensive as those standards prescribed in paragraph 7 of these specifications, so as to achieve maximum results from its efforts to ensure equal employment opportunity. If the Contractor fails to comply with the requirements of the Executive Order, the implementing regulations, or these specifications, the Director shall proceed in accordance with 41 CFR 60–4.8.

14. The Contractor shall designate a responsible official to monitor all employment related activity to ensure that the company EEO policy is being carried out, to submit reports relating to the provisions hereof as may be required by the Government and to keep records. Records shall at least include for each employee the name, address, telephone numbers, construction trade, union affiliation if any, employee identification number when assigned, social security number, race, sex, status (e.g., mechanic, apprentice trainee, helper, or laborer), dates of changes in status, hours worked per week in the indicated trade, rate of pay, and locations at which the work was performed. Records shall be maintained in any easily understandable and retrievable form; however, to the degree that existing records satisfy this requirement, contractors shall not be required to maintain separate records.

15. Nothing herein provided shall be construed as a limitation upon the application of other laws which establish different standards of compliance or upon the application of requirements for the hiring of local or other area residents (e.g., those under the Public Works Employment Act of 1977 and the Community Development Block Grant Program).

(b) The notice set forth in 41 CFR 60–4.2 and the specifications set forth in 41 CFR 60–4.3 replace the New Form for Federal Equal Employment Opportunity Bid Conditions for Federal and Federally Assisted Construction published at 41 FR 32482 and commonly known as the Model Federal EEO Bid Conditions, and the New Form shall not be used after the regulations in 41 CFR Part 60–4 become effective.

§ 60–4.4 Affirmative action requirements.

(a) To implement the affirmative action requirements of Executive Order 11246 in the construction industry, the Office of Federal Contract Compliance Programs previously has approved affirmative action programs commonly referred to as "Hometown Plans," has promulgated affirmative action plans referred to as "Imposed Plans" and has approved "Special Bid Conditions" for high impact projects constructed in areas not covered by a Hometown or an Imposed Plan. All solicitations for construction contracts made after the effective date of the regulations in this part shall include the notice specified in § 60–4.2 of this part and the specifications in § 60–4.3 of this part in lieu of the Hometown and Imposed Plans including the Philadelphia Plan and the Special Bid Conditions. Until the Director has issued an order pursuant to § 60–4.6 of this part establishing goals and timetables for minorities in the appropriate geographical areas or for a project covered by Special Bid Conditions, the goals and timetables for minorities to be inserted in the Notice required by 41 CFR 60–4.2 shall be the goals and timetables contained in the Hometown Plan, Imposed Plan or Special Bid Conditions presently covering the respective geographical area or project involved.

(b) Signatories to a Hometown Plan (including heavy highway affirmative action plans) shall have 45 days from the effective day of the regulations in this part to submit under such a Plan (for the director's approval) goals and timetables for women and to include female representation on the Hometown Plan Administrative Committee. Such goals for female representation shall be at least as high as the goals established for female representation in the notice issued pursuant to 41 CFR 60–4.6. Failure of the signatories, within the 45-day period, to include female representation and to submit goals for women or a new plan, as appropriate, shall result in an automatic termination of the Office of Federal Contract Compliance program's approval of the Hometown Plan. At any time the Office of Federal Contract Compliance Programs terminates or withdraws its approval of a Hometown Plan, or when the plan expires and another plan is not approved, the contractors signatory to the plan shall be covered automatically by the specifications set forth in § 60–4.3 of this part and by the goals and timetables established for that geographical area pursuant to § 60–4.6 of this part.

§ 60–4.5 Hometown plans.

(a) A contractor participating, either individually or through an association, in an approved Hometown Plan (including heavy highway affirmative action plans) shall comply with its affirmative action obligations under Executive Order 11246 by complying with its obligations under the plan: *Provided*, That each contractor or subcontractor participating in an approved plan is individually required to comply with the equal opportunity clause set forth in 41 CFR 60–1.4; to make a good faith effort to achieve the goals for each trade participating in the plan in which it has employees; and that the overall good performance by other contractors or subcontractors toward a goal in an approved plan does not excuse any covered contractor's or subcontractor's failure to take good faith efforts to achieve the plan's goals and timetables. If a contractor is not participating in an approved Hometown Plan it shall comply with the specifications set forth in § 60–4.3 of this part and with the goals and timetables for the appropriate area as listed in the notice required by 41 CFR 60–4.2 with regard to that trade. For the purposes of this Part 60–4, a contractor is not participating in a Hometown Plan for a particular trade if it:

(1) Ceases to be signatory to a Hometown Plan covering that trade;

(2) Is signatory to a Hometown Plan for that trade but is not party to a collective bargaining agreement for that trade;

(3) Is signatory to a Hometown Plan for that trade but is party to a collective bargaining agreement with labor organizations which are not or cease to be signatories to the same Hometown Plan for that trade;

(4) Is signatory to a Hometown Plan for that trade but is party to a collective bargaining agreement with a labor organization for that trade but the two have not jointly executed a specific commitment to minority and female goals and timetables and incorporated the commitment in the Hometown Plan for that trade;

(5) Is participating in a Hometown Plan for that trade which is no longer acceptable to the Office of Federal Contract Compliance Programs;

(6) Is signatory to a Hometown Plan for that trade but is party to a collective bargaining agreement with a labor organization for that trade and the labor organization and the contractor have failed to make a good faith effort to comply with their obligations under the Hometown Plan for that trade.

(b) Contractors participating in Hometown Plans must be able to

demonstrate their participation and document their compliance with the provision of the Hometown Plan.

§ 60-4.6 Goals and timetables.

The Director, from time to time, shall issue goals and timetables for minority and female utilization which shall be based on appropriate workforce, demographic or other relevant data and which shall cover construction projects or construction contracts performed in specific geographical areas. The goals, which shall be applicable to each construction trade in a covered contractor's or subcontractor's entire workforce which is working in the area covered by the goals and timetables, shall be published as notices in the Federal Register, and shall be inserted by the contracting officers and applicants, as applicable, in the Notice required by 41 CFR 60-4.2. Covered construction contractors performing construction work in geographical areas where they do not have a Federal or federally assisted construction contract shall apply the minority and female goals established for the geographical area where the work is being performed.

§ 60-4.7 Effect on other regulations.

The regulations in this part are in addition to the regulations contained in this chapter which apply to construction contractors and subcontractors generally. See particularly, 41 CFR 60-1.4 (a), (b), and (c); 60-1.5; 60-1.7; 60-1.8; 60-1.28; 60-1.29; 60-1.30; 60-1.31; 60-1.32; 60-1.41; 60-1.42; 60-1.43; 60-1.46; 60-1.47; 60-1.48; and 41 CFR Part 60-3; Part 60-20; Part 60-30; Part 60-40; and Part 60-50.

§ 60-4.8 Show cause notice.

If an investigation or compliance review reveals that a construction contractor or subcontractor has violated the Executive Order, any contract clause, specifications or the regulations in this chapter and if administrative enforcement is contemplated, the Director shall issue to the contractor or subcontractor a notice to show cause which shall contain the items specified in (i)-(iv) of 41 CFR 60-1.25(c)(1). If the contractor does not show good cause within 30 days, or in the alternative, fails to enter an acceptable conciliation agreement which includes where appropriate, make up goals and timetables, back pay, and seniority relief for affected class members, the OFCCP shall follow the procedure in 41 CFR 60-1.29: *Provided,* That where a conciliation agreement has been violated, no show cause notice is required prior to the initiation of enforcement proceedings.

§ 60-4.9 Incorporation by operation of the order.

By operation of the Order, the equal opportunity clause contained in § 60-1.4, the Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity (Executive Order 11246) contained in § 60-4.2, and the Standard Federal Equal Employment Opportunity Construction Contract Specifications (Executive Order 11246) contained in § 60-4.3 shall be deemed to be a part of every solicitation or of every contract and subcontract, as appropriate, required by the Order and the regulations in this chapter to include such clauses whether or not they are physically incorporated in such solicitation or contract and whether or not the contract is written.

PART 60-20—SEX DISCRIMINATION GUIDELINES

Sec.

Authority: Sec. 201, E. O. 11246, 30 FR 12319, and E. O. 11375, 32 FR 14303, as amended by E. O. 12086.

§ 60-20.1 Title and purpose.

The purpose of the provisions in this part is to set forth the interpretations and guidelines of the Office of Federal Contract Compliance Programs regarding the implementation of Executive Order 11246, as amended, for the promotion and ensuring of equal opportunities for all persons employed or seeking employment with Government contractors or with contractors performing under federally assisted construction contracts, without regard to sex. Experience has indicated that special problems related to the implementation of the Executive Order require a definitive treatment beyond the terms of the Order itself. These interpretations are to be read in connection with existing regulations, set forth in Parts 60-1 and 60-2 of this chapter.

§ 60-20.2 Recruitment and advertisement.

(a) Contractors engaged in recruiting activity shall recruit employees of both sexes for all jobs unless sex is a bona fide occupational qualification.

(b) Advertisements in newspapers and other media for employment sponsored by or on behalf of contractors shall not depict, express a preference, or indicate that a particular sex is sought, desired or better suited for a particular job unless sex is a bona fide occupational qualification for the job. The placement of an advertisement in columns headed "Male" or "Female", or similar wording, will be considered an expression of a preference, limitation, specification, or discrimination based on sex.

§ 60-20.3 Job policies and practices.

(a) Written personnel policies relating to this subject area must expressly indicate that there shall be no discrimination against employees on account of sex. If the contractor deals with a bargaining representative for its employees and there is a written agreement on conditions of employment, such agreement shall not be inconsistent with these guidelines.

(b) Employees of both sexes shall have an equal opportunity to any available job that he or she is qualified to perform, unless sex is a bona fide occupational qualification.

Note.—In most Government contract work there are only limited instances where valid reasons can be expected to exist which would justify the exclusion of all men or all women from any given job.

(c)(1) The contractor must not make any distinction based upon sex in employment opportunities, wages, hours or other conditions of employment, including fringe benefits. As the Supreme Court held in *Los Angeles Department of Water and Power* v. *Manhart,* 435 U.S. 702 (1978), fringe benefits for similarly situated men and women must be equal, notwithstanding that the contractor's contributions for men and women are unequal.

(2) [Reserved.]

(d) Any distinction between married and unmarried persons of one sex that is not made between married and unmarried persons of the opposite sex will be considered to be a distinction made on the basis of sex. Similarly, a contractor must not deny employment to women with young children unless it has the same exclusionary policies for men; or terminate an employee of one sex in a particular job classification upon reaching a certain age unless the same rule is applicable to members of the opposite sex.

(e) The contractor's policies and practices must assure appropriate physical facilities to both sexes. The contractor may not refuse to hire men or women, or deny men or women a particular job because there are no restroom or associated facilities, unless the contractor is able to show that providing the facilities would be

unreasonable for such reasons as excessive expense or lack of space.

(f)(1) A contractor must not deny a female employee the right to any job that she is qualified to perform in reliance upon a state "protective" law. For example, such laws include those which prohibit women from performing in certain types of occupations (e.g., a bartender or a core-maker); from working at jobs requiring more than a certain number of hours; and from working at jobs that require lifting or carrying more than designated weights.

(2) Such legislation was intended to be beneficial, but, instead, has been found to result in restricting employment opportunities for men and/or women. Accordingly, it cannot be used as a basis for denying employment or for establishing sex as a bona fide occupational qualification for the job.

(g) The contractor must not specify any differences for male and female employees on the basis of sex in either mandatory or optional retirement age.

(h) Nothing in these guidelines shall be interpreted to mean that differences in capabilities for job assignments do not exist among individuals and that such distinctions may not be recognized by the contractor in making specific assignments. The purpose of these guidelines is to ensure that such distinctions are not based upon sex.

§ 60-20.4 Seniority systems.

When they exist, seniority lines and lists must not be based upon sex. Where such a separation has existed, the contractor must eliminate this distinction and provide appropriate relief.

§ 60-20.5 Discriminatory wages and placements.

(a) *Wages.* The contractor's wage schedules must not be related to or based on the sex of the employees.

While the more obvious cases of discrimination exist where employees of different sexes are paid different wages on jobs which require substantially equal skill, effort and responsibility and are performed under similar working conditions, compensation practices with respect to any jobs where males or females are concentrated will be scrutinized closely to assure that sex has played no role in the setting of levels of pay.

(b) *Placements.* The Contractor may not discriminatorily restrict one sex to certain jobs. In such a situation, the contractor shall provide appropriate relief and shall ensure that all jobs are made available to all qualified employees without regard to sex. (Example: An electrical manufacturing company may have a production division with three functional units: One (assembly) all female; another (wiring), all male; and a third (circuit boards), also all male. The highest wage attainable in the assembly unit is considerably less than that in the circuit board and wiring units. In such a case the contractor must take steps to provide qualified female employees opportunity for placement in job openings in the other two units with red circling of wages, where appropriate, and without loss of seniority.)

§ 60-20.6 Affirmative action.

(a) Women typically have not been found in significant numbers in management. In many companies management trainee programs are one of the ladders to management positions. Traditionally, few if any, women have been admitted into these programs. An important element of affirmative action shall be a commitment to include female candidates in such programs.

(b) Distinctions based on sex may not be made in other training programs. Both sexes should have equal access to all training programs and affirmative action programs should demonstrate that such access has been provided.

(c) The contractor shall take affirmative action to recruit women for jobs in which they previously have been excluded or are underrepresented. The contractor also shall take affirmative action to encourage the participation of women in training programs for jobs in which they have been previously excluded or are underrepresented.

Note.—This can be done by various methods. Examples include, but are not limited to (1) Including in itineraries of recruiting trips, (i) women's colleges where graduates with skills desired by the contractor can be found, and (ii) female students of coeducational institutions and (2) stating in advertisements that women will be considered equally with men for jobs.

§ 60-20.7 Pregnancy, childbirth and related medical conditions.

(a) Employees or applicants for employment shall not be denied employment because of pregnancy, childbirth or related medical conditions.

(b) Disabilities caused or contributed to by pregnancy, childbirth, or related medical conditions, for all job-related purposes, shall be treated the same as disabilities caused or contributed to by other medical conditions, under any health or disability insurance or sick leave plan available in connection with employment. Written or unwritten employment policies and practices involving matters such as the commencement and duration of leave, the availability of extensions, the accrual of seniority and other benefits and privileges, reinstatement, and payment under any health or disability insurance or sick leave plan, formal or informal, shall be applied to disability due to pregnancy, childbirth or related medical conditions on the same terms and conditions as they are applied to other disabilities. Health insurance benefits for abortion, except where the life of the mother would be endangered if the fetus were carried to term or where medical complications have arisen from an abortion, are not required to be paid by the contractor; nothing herein, however, precludes the contractor from providing abortion benefits or otherwise affects bargaining agreements in regard to abortion.

(c) Where the termination of an employee who is temporarily disabled is caused by an employment policy under which insufficient or no leave is available, such a termination violates the Order if it has a disparate impact on employees of one sex and is not justified by business necessity.

(d)(1) Any fringe benefit program, or fund, or insurance program which is in effect on October 31, 1978, which does not treat women affected by pregnancy, childbirth, or related medical conditions the same as other persons not so affected but similar in their ability or inability to work, must be in compliance with the provisions of § 60-20.7(b) by April 29, 1979. In order to come into compliance with the provisions of § 60-20.7(b) there can be no reduction of benefits or compensation which were in effect on October 31, 1978, before October 31, 1979, or the expiration of a collective bargaining agreement in effect on October 31, 1978, whichever is later.

(2) Any fringe benefit program implemented after October 31, 1978, must comply with the provisions of § 60-20.7(b) upon implementation.

§ 60-20.8 Sexual harassment and favors.

(a) Unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature are violations of the Order when (1) submission to such conduct is made either explicitly or implicitly a term or condition of an individual's employment, (2) submission to or rejection of such conduct by an individual is used as the basis for employment decisions affecting such individual, or (3) such conduct has the purpose or effect of "unreasonably" interfering with an individual's work performance or creating an intimidating, hostile or offensive work environment.

(b) A contractor is liable under the Order for the acts of its officials, managers and supervisors when these

individuals engage in the activities described in paragraph (a) of this section, regardless of whether their specific acts were authorized or forbidden by the contractor and regardless of whether the contractor knew or should have known of their occurrence.

(c) With respect to conduct between fellow employees, a contractor is responsible for acts of sexual harassment in the workplace where the contractor (or its officials, managers and supervisors) knows or should have known of the conduct and fails to take immediate and appropriate action.

(d) A contractor also may be responsible for the acts of nonemployees, with respect to sexual harassment of employees in the workplace, where the contractor (or its officials, managers and supervisors) knows or should have known of the conduct and fails to take immediate and appropriate corrective action. In reviewing these cases, OFCCP will consider the extent of the contractor's control and any other legal responsibility which the contractor may have with respect to the conduct of such nonemployees.

(e) Where employment opportunity or benefits are granted because of an individual's submission to the contractor's sexual advances or requests for sexual favors, the contractor may be held liable under the Order for unlawful sex discrimination against other persons who were qualified for but denied that employment opportunity or benefit.

PART 60–30—RULES OF PRACTICE FOR ADMINISTRATIVE PROCEEDINGS TO ENFORCE EQUAL OPPORTUNITY UNDER EXECTUVIE ORDER 11246, SECTION 402, AND SECTION 503

General Provisions

Sec.

Prehearing Procedures

Hearings and Related Matters

Sec.

Post Hearing Procedures

Expedited Hearing Procedures

Authority: Secs. 201, 205, 208, 209, 301, 302(b) and 303(a) of the Executive Order 11246, as amended, 30 FR 12319; 32 FR 14303; § 60–1.26 of Part 60–1 of this chapter (41 CFR Part 60–1), as amended by E.O. 12086.

General Provisions

§ 60–30.1 Applicability of rules.

This part provides the rules of practice for all administrative proceedings, instituted to enforce equal employment opportunity under Executive Order 11246, section 402 of the Vietnam Era Veterans Readjustment Assistance Act and section 503 of the Rehabilitation Act. In the absence of a specific provision, procedures shall be in accordance with the Federal Rules of Civil Procedure. This part is not applicable to hearings held by the Director under §§ 60–1.9, 60–1.27, or 60–1.48 of this chapter.

§ 60–30.2 Waiver, modification.

Upon notice to all parties, the Administrative Law Judge may, with respect to matters pending before him/her modify or waive any rule herein upon a determination that no party will be prejudiced and that the ends of justice will be served thereby.

§ 60–30.3 Computation of time.

In computing any period of time under the rules in this part or in an order issued hereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government in which event it includes the next business day. When the period of time allowed is less than seven days, intermediate Saturdays, Sundays and legal holidays observed by the Federal Government shall be excluded from the computation.

§ 60–30.4 Form, filing, service of pleadings and papers.

(a) *Form.* The original of all pleadings and papers in a proceeding conducted under the regulations in this part shall be filed with the Administrative Law Judge assigned to the case or with the Chief Administrative Law Judge if the case has not been assigned. Every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case file number assigned by the Administrative Law Judge, and a designation of the pleading or paper (e.g., complaint, motion to dismiss, etc.). The pleading or papers shall be signed and shall contain the address and telephone number of the person representing the party or the person on whose behalf the pleading or paper was filed. Unless the Administrative Law Judge otherwise orders with respect to specific pleadings and papers in a specific case, all such papers and pleadings are public documents.

(b) *Service.* Service upon any party shall be made by the party filing the pleading or document by delivering a copy to the party or by mailing a copy to the party's last known address. When a party is represented by an attorney, service shall be made upon the attorney.

(c) *Proof of service.* A certificate of the person serving the pleading or other document by personal delivery or by mailing, setting forth the manner of service, shall be proof of service.

Prehearing Procedures

§ 60–30.5 Administrative complaint.

(a) *Filing.* The Solicitor of Labor, Associate Solicitor for Civil Rights and Regional Solicitors, upon referral from the Office of Federal Contract Compliance Programs, are authorized to institute enforcement proceedings by filing a complaint and serving the complaint upon the contractor which shall be designated as the defendant. The Department of Labor, OFCCP, shall be designated as plaintiff.

(b) *Contents.* The complaint shall contain a concise jurisdictional statement, and a clear and concise statement sufficient to put the defendant

on notice of the acts or practices it is alleged to have committed in violation of the Order, or section 402 or 503. The complaint shall also contain a prayer regarding the relief being sought, a statement of whatever sanctions the Government will seek to impose and the name and address of the attorney who will represent the Government. The notice pleading contemplated by this paragraph (b) shall conform to notice pleading under the Federal Rules of Civil Procedure.

(c) *Amendment.* The complaint may be amended once as a matter of course before an answer is filed, and the defendant may amend its answer once as a matter of course not later than 10 days after the filing of the original answer. Other amendments of the complaint or of the answer to the complaint shall be made only by leave of the Administrative Law Judge or by written consent of the adverse party; and leave shall be freely given where justice so requires. An amended complaint shall be answered within 14 days of its service, or within the time for filing an answer to the original complaint, whichever period is longer. If a response is required to an amended answer, such response shall be made within 14 days of service of the amended answer.

§ 60-30.6 Answer.

(a) *Filing and service.* Within 20 days after the service of the complaint, the defendant shall file an answer; the answer shall be filed with the Chief Administrative Law Judge if the case has not been assigned to an Administrative Law Judge. The answer shall be signed by the defendant or its attorney, and served on the Government in accordance with § 60-30.4(b).

(b) *Contents; failure to file.* The answer shall (1) contain a statement of the facts which constitute the grounds of defense, and shall specifically admit, explain, or deny, each of the allegations of the complaint unless the defendant is without knowledge, in which case the answer shall so state; or (2) state that the defendant admits all the allegations of the complaint. The answer may contain a waiver of hearing; and if not, a separate paragraph in the answer shall request a hearing. The answer shall contain the name and address of the defendant, or of the attorney representing the defendant. Failure to file an answer or to plead specifically to any allegation of the complaint shall constitute an admission of such allegation.

(c) *Procedure upon admission of facts.* The admission, in the answer or by failure to file an answer, of all the material allegations of fact contained in the complaint shall constitute a waiver of hearing. Upon such admission, the Administrative Law Judge, without further hearing, may prepare his/her decision in which he/she shall adopt as his/her proposed findings of fact the material facts alleged in the complaint. The parties shall be given an opportunity to file exceptions to the decision and to file briefs in support of the exceptions.

§ 60-30.7 Notice of prehearing conference.

Within 45 days after the answer is filed, the Administrative Law Judge shall notice the parties for a prehearing conference. The Administrative Law Judge shall conduct a final prehearing conference in accordance with § 60-30.12(c)(1) of this part.

§ 60-30.8 Motions; disposition of motions.

(a) *Motions.* Motions shall state the relief sought, the authority relied upon and the facts alleged, and shall be filed with the Administrative Law Judge. If made before or after the hearing itself, the motions shall be in writing. If made at the hearing, motions may be stated orally; but the Administrative Law Judge may require that they be reduced to writing and filed and served on all parties in the same manner as a formal motion. Unless otherwise ordered by the Administrative Law Judge, written motion shall be accompanied by a supporting memorandum. Within 10 days after a written motions is served, or such other time period as may be fixed, any party may file a response to a motion.

(b) *Disposition of motions.* The Administrative Law Judge may not grant a written motion prior to expiration of the time for filing responses thereto, except upon consent of the parties or following a hearing, but may overrule or deny such motion without awaiting response. The Administrative Law Judge shall make every reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing: *Provided,* That prehearing conferences, hearings, and decisions need not be delayed pending disposition of motions.

(c) *Motions to compel discovery.* Prior to filing a motion to compel discovery under sections 60-30.9 through 60-30.11 of this part, counsel for the moving party shall communicate with opposing counsel concerning the matter in dispute and attempt to resolve it. Counsel for the moving party shall file with the motion a certificate of compliance with this rule.

§ 60-30.9 Interrogatories, and admissions as to facts and documents.

(a) *Interrogatories.* Any party may serve upon a party written interrogatories. Each interrogatory shall be answered separately and fully in writing under oath, unless objected to. Answers are to be signed by the person making them and objections are to be signed by the attorney or by whomever is representing the party. Answers and objections shall be filed and served within 25 days of service of the interrogatory. Where the answer to an interrogatory may be derived or ascertained from the business records of the party upon whom the interrogatory has been served or from an examination, audit or inspection of such business records, or from a compilation, abstract or summary based thereon, and the burden of deriving or ascertaining the answer is substantially the same for the party serving the interrogatory as for the party served, it is a sufficient answer to such interrogatory to specify the records from which the answer may be derived or ascertained and to afford to the party serving the interrogatory reasonable opportunity to examine, audit or inspect such records and to make copies, compilations, abstracts or summaries.

(b) *Admissions.* Any party may serve upon a party a written request for the admission of the genuineness and authenticity of any relevant documents described in and exhibited with the request, or for the admission of the truth of any relevant matters of fact stated in the request. Each of the matters as to which an admission is requested shall be deemed admitted, unless within 25 days after service, the party to whom the request is directed serves upon the requesting party a sworn statement either (1) denying specifically the matter as to which an admission is requested, or (2) setting forth in detail the reasons why it cannot truthfully either admit or deny such matters.

(c) *Objections or failures to respond.* The party submitting the interrogatory or request may move for an order with respect to any objection or other failure to respond.

(d) *Filing with Administrative Law Judge.* All interrogatories and requests for admissions, and all responses thereto, shall be filed with the Administrative Law Judge and shall become a part of the record of the case.

§ 60-30.10 Production of documents and things and entry upon land for inspection and other purposes.

(a) After commencement of the action, any party may serve on any other party a request to produce and/or permit the

party, or someone acting on its behalf, to inspect and copy any unprivileged documents, phonorecords, and other compilations, including computer tapes and printouts, which contain or may lead to relevant information and which are in the possession, custody, or control of the party upon whom the request is served. If necessary, translation of data compilations shall be done by the party furnishing the information.

(b) After commencement of the action, any party may serve on any other party a request to permit entry upon designated property which may be relevant to the issues in the proceeding and which is in the possession or control of the party upon whom the request is served, for the purpose of inspection, measuring, surveying or photographing, testing, or sampling the property or any designated object or area.

(c) Each request shall set forth with reasonable particularity the items to be inspected and shall specify a reasonable time and place for making the inspection and performing the related acts.

(d) The party upon whom the request is served shall respond within 25 days after the service of the request. The response shall state, with respect to each item, that inspection and related activities will be permitted as requested, unless there are objections, in which case the reasons for each objection shall be stated. The party submitting the request may move for an order with respect to any objection or other failure to respond.

§ 60-30.11 Depositions upon oral examination.

(a) *Depositions; notice of examination.* After commencement of the action, any party may take the testimony of any person, including a party, having personal or expert knowledge of the matters in issue, by deposition upon oral examination. A party desiring to take a deposition shall give reasonable notice in writing to every other party to the proceeding, and may use an administrative subpena. The notice shall state the time and place for taking the deposition and the name and address of each person to be examined, if known, and, if the name is not known, a general description sufficient to identify the person or the particular class or group to which the person belongs. The notice shall also set forth the categories of documents the witness is to bring to the deposition, if any. A copy of the notice shall be furnished to the person to be examined unless his/her name is unknown.

(b) *Production of witnesses; obligation of parties; objections.* It shall be the obligation of each party to produce for examination any person, along with such documents as may be requested, at the time and place, and on the date, set forth in the notice, if that party has control over such person. Each party shall be deemed to have control over its officers, agents, employees, and members. Unless the parties agree otherwise, depositions shall be held within the county in which the witness resides or works. The party or prospective witness may file with the Administrative Law Judge an objection within 5 days after notice of production of such witness is served, stating with particularity the reasons why the party cannot or ought not to produce a requested witness. The party serving the notice may move for an order with respect to such objection or failure to produce a witness. All errors or irregularities in compliance with the provisions of this section shall be deemed waived unless a motion to suppress the deposition or some part thereof is made with reasonable promptness after such defect is or, with due diligence, might have been ascertained.

(c) *Before whom taken; scope of examination; failure to answer.* Depositions may be taken before any officer authorized to administer oaths by the laws of the United States or of the place where the deposition is held. At the time and place specified in the notice, each party shall be permitted to examine and cross-examine the witness under oath upon any matter which is relevant to the subject matter of the proceeding, or which is reasonably calculated to lead to the production of relevant and otherwise admissible evidence.

Errors which might be cured at the taking of the deposition, including errors in the manner of taking the deposition, in the form of the questions or answers, in the oath, or in the conduct of the parties, are waived unless objection is made at the taking of the deposition. All other objections may, in the discretion of the objecting party, be raised at the taking of the deposition or reserved until the hearing. All objections made at the taking of the deposition shall be noted by the officer upon the deposition. Evidence objected to shall be taken subject to the objections. A refusal or failure on the part of any person under the control of a party to answer a question shall operate to create a presumption that the answer, if given, would be unfavorable to the controlling party, unless the question is subsequently ruled improper by the Administrative Law Judge or the Administrative Law Judge rules that there was valid justification for the witness' failure or refusal to answer the answer the question: *Provided*, That the examining party shall note on the record during the deposition the question which the deponent has failed, or refused to answer, and state his/her intention to invoke the presumption if no answer is forthcoming.

(d) *Subscription; certification; filing.* The testimony shall be reduced to typewriting, either by the officer taking the deposition or under his/her direction, and shall be submitted to the witness for examination and signing. If the deposition is not signed by the witness because he/she is ill, dead, cannot be found, or refuses to sign it, such fact shall be noted in the certificate of the officer and the deposition may then be used as fully as though signed. The officer shall immediately deliver the original copy of the transcript, together with his/her certificate, in person or by mail to the Administrative Law Judge. Copies of the transcript and certificate shall be furnished to all persons desiring them, upon payment of reasonable charges, unless distribution is restricted by order of the Administrative Law Judge for good cause shown.

(e) *Rulings on admissibility; use of deposition.* Subject to the provisions of this section, objection may be made at the hearing to receiving in evidence any deposition or part thereof for any reason which would require the exclusion of the evidence if the witness were then present and testifying. Any part or all of a deposition, so far as admissible in the discretion of the Administrative Law Judge, may be used against any party who was present or represented at the taking of the deposition or who had reasonable notice, in accordance with the following provisions:

(1) Any deposition may be used by any party for the purpose of contradicting or impeaching the testimony of the deponent as a witness.

(2) The deposition of a party or of any one who at the time of taking the deposition was an officer, director, or managing agent, or was designated to testify on behalf of a public or private corporation, partnership, association, or governmental agency which is a party may be used by the adverse party for any purpose.

(3) The deposition of a witness, whether or not a party, may be used by any party for any purpose if the Administrative Law Judge finds: (i) that the witness is dead; or (ii) that the witness is unable to attend or testify because of age, illness, infirmity, or imprisonment; or (iii) that the party offering the deposition has been unable to procure the attendance of the witness

by subpoena; or (iv) upon application and notice, that such exceptional circumstances exist as to make it desirable to allow the deposition to be used.

(4) If only part of a deposition is introduced in evidence by a party, any party may introduce any other parts by way of rebuttal and otherwise.

(f) *Stipulations.* If the parties so stipulate in writing, depositions may be taken before any person at any time or place, upon any notice and in any manner, and when so taken may be used like other depositions.

§ 60-30.12 Prehearing conferences.

(a) Upon his/her own motion or a motion of a party, the Administrative Law Judge may direct the parties or their counsel to meet with him/her for a conference to consider:

(1) Simplification of the issues;

(2) Necessity or desirability of amendments to pleadings for purposes of clarification, simplification, or limitation;

(3) Stipulation, admissions of fact and contents and authenticity of documents;

(4) Limitation of the number of witnesses;

(5) Scheduling dates for the exchange of witness lists and of proposed exhibits; and

(6) Such other matters as may tend to expedite the disposition of the proceedings.

(b) The record shall show the matters disposed of by order and by agreement in such pretrial conferences. The subsequent course of the proceeding shall be controlled by such action.

(c)(1) A final prehearing conference shall be scheduled by the Administrative Law Judge a reasonable time in advance of the hearing to develop a prehearing order. The prehearing order shall contain any matters described in subparagraph (a) of this section agreed upon by the parties or ordered by the Administrative Law Judge. The prehearing order also shall contain the general factual and legal contentions of the parties.

(2) Witness lists and hearing exhibits shall be exchanged at least 10 days in advance of the hearing, or such other later time as is set by the Administrative Law Judge. Each party shall provide to all other parties copies of all exhibits that it then plans to use at the hearing.

(3) All discovery should be concluded at least 30 days prior to the hearing or by such other later time as ordered by the Administrative Law Judge for good cause shown. Administrative Law Judges, however, shall allow adequate time for discovery.

§ 60-30.13 Consent findings and order.

(a) *General.* At any time after the issuance of a complaint and prior to or during the reception of evidence in any proceeding, the parties may jointly move to defer the receipt of any evidence for a reasonable time to permit negotiation of an agreement containing consent findings and an order disposing of the whole or any part of the proceeding. The allowance of such deferment and the duration thereof shall be in the discretion of the Administrative Law Judge after consideration of the nature of the proceeding, the requirements of the public interest, the representations of the parties, and the probability of an agreement being reached which will result in a just disposition of the issues involved.

(b) *Content.* Any agreement containing consent findings and an order disposing of a proceeding shall also provide:

(1) That the order shall have the same force and effect as an order made after full hearing;

(2) That the entire record on which any order may be based shall consist solely of the complaint and the agreement;

(3) That any further procedural steps are waived; and

(4) That any right to challenge or contest the validity of the findings and order entered into in accordance with the agreement is waived.

(c) *Submission.* On or before the expiration of the time granted for negotiations, the parties or their counsel may:

(1) Submit the proposed agreement to the Administrative Law Judge for his/her consideration;

(2) Inform the Administrative Law Judge that agreement cannot be reached.

(d) *Disposition.* In the event an agreement containing consent findings and an order is submitted within the time allowed, the Administrative Law Judge, within 30 days, shall accept such agreement by issuing his/her decision based upon the agreed findings, and the decision shall constitute the final Administrative Order.

Hearings and Related Matters

§ 60-30.14 Designation of Administrative Law Judges.

Hearings shall be held before an Administrative Law Judge of the Department of Labor who shall be designated by the Chief Administrative Law Judge of the Department of Labor. After commencement of the proceeding but prior to the designation of an Administrative Law Judge, pleadings and papers shall be filed with the Chief Administrative Law Judge.

§ 60-30.15 Authority and responsibilities of Administrative Law Judges.

The Administrative Law Judge shall have the duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. He/she shall have all powers necessary to those ends, including but not limited to, the power to:

(a) Hold conferences to settle, simplify, or fix the issues in a proceeding, or to consider other matters that may aid in the expeditious disposition of the proceeding by consent of the parties or upon his/her own motion;

(b) Require parties to state their position with respect to the various issues in the proceedings;

(c) Require parties to produce for examination those relevant witnesses and documents under their control; and require parties to answer interrogatories, and requests for admission, in full and produce documents for examination and copying;

(d) Administer oaths;

(e) Rule on motions and other procedural items or matters pending before him/her;

(f) Regulate the course of the hearing and conduct of participants therein;

(g) Examine and cross-examine witnesses and introduce into the record documentary or other evidence;

(h) Receive, rule on, exclude, or limit evidence and limit lines of questioning or testimony which are irrelevant, immaterial, or unduly repetitious;

(i) Fix time limits for submission of written documents in matters before him/her and extend any time limits established by this part upon a determination that no party will be prejudiced and that the ends of justice will be served thereby;

(j) Impose appropriate sanctions against any party or person failing to obey an order under these rules which may include:

(1) Refusing to allow the disobedient party to support or oppose designated claims or defenses, or prohibiting it from introducing designated matters into evidence;

(2) Excluding all testimony of an unresponsive or evasive witness, or determining that the answer of such witness, if given, would be unfavorable to the party having control over him/her;

(3) Expelling any party or person from further participation in the hearing; and

(4) Invoking a presumption that the answers or actions ordered if made, would be unfavorable or adverse to the party ordered to answer or act.

(k) Take official notice of any material fact not appearing in evidence in the record, which is among the traditional matters of judicial notice;

(l) Recommend whether the defendant violated the Order, section 402 or section 503, as well as the nature of the relief necessary to ensure the full enjoyment of the rights secured by the Order, section 402 or section 503;

(m) Issue subpenas;

(n) Render interlocutory decisions for the Department of Labor in preliminary enforcement proceedings under § 60–30.38; and

(o) Take any action authorized by these rules.

§ 60-30.16 Appearances.

(a) *Representation.* The parties or other persons or organizations participating pursuant to this part 60–30 have the right to be represented by counsel.

(b) *Failure to appear.* In the event that a party appears at the hearing and no party appears for the opposing side, the party who is present shall have an election to present its evidence in whole or such portion thereof sufficient to make a prima facie case before the Administrative Law Judge. Failure to appear at the hearing shall not be deemed to be a waiver of the right to be served with a copy of the Administrative Law Judge's recommended decision and to file exceptions to it.

§ 60-30.17 Appearance of witnesses.

(a) A party wishing to procure the appearance at the hearing of any person having personal or expert knowledge of the matters in issue shall serve on the prospective witness a notice, which may be accomplished by an administrative subpena, setting forth the time, date, and place at which he/she is to appear for the purpose of giving testimony. The notice shall also set forth the categories of documents the witness is to bring with him/her to the hearing, if any. A copy of the notice shall be filed with the Administrative Law Judge and additional copies shall be served upon the parties.

(b) It shall be the obligation of each party to produce for examination any person, along with such documents as may be requested, at the time and place, and on the date, set forth in the notice, if that party has control over such person. Each party shall be deemed to have control over its officers, agents, employees, and members. Due regard shall be given to the convenience of witnesses in scheduling their testimony so that they will be detained no longer than reasonably necessary.

(c) The party or prospective witness may file an objection within 5 days after notice of production of such witness is served stating with particularity the reasons why the party cannot produce a requested witness. The party serving the notice may move for an order with respect to such objection or failure to produce a witness.

§ 60-30.18 Evidence; testimony.

Formal rules of evidence shall not apply, but rules or principles, including the Federal Rules of Evidence, designed to assure production of the most probative evidence available shall be applied. Testimony shall be given orally by witnesses at the hearing. Except as set forth in § 60–30.11(e), depositions may not be introduced into evidence in lieu of testimony given at the hearing. A witness shall be available for cross-examination, and, at the discretion of the Administrative Law Judge, may be cross-examined without regard to the scope of direct examination as to any matter which is relevant and material to the proceeding. The Administrative Law Judge may exclude evidence which is immaterial, irrelevant, or unduly repetitious.

§ 60-30.19 Objections; exceptions; offer of proof.

(a) *Objections.* If a party objects to the admission or rejection of any evidence or to the limitation of the scope of any examination or cross-examination or the failure to limit such scope, it shall state briefly the grounds for such objection. Rulings on all objections shall appear in the record. Only objections made on the record may be relied upon subsequently in the proceedings.

(b) *Exceptions.* Formal exception to an adverse ruling is not required. Rulings by the Administrative Law Judge shall not be appealed prior to the transfer of the case to the Secretary. Exceptions to such rulings shall be filed in accordance with 41 CFR 60–30.28.

(c) *Offer of proof.* An offer of proof made in conection with an objection taken to any ruling excluding proffered oral testimony shall consist of a statement of the substance of the evidence which counsel contends would be adduced by such testimony; and, if the excluded evidence consists of evidence in written form or consists of references to documents, a copy of such evidence shall be marked for identification and shall accompany the record as the offer of proof. The offer of proof should clearly and specifically indicate the significance of the excluded evidence, unless the substance is apparent from the context. Allowance of an offer of proof is within the discretion of the Administrative Law Judge.

§ 60-30.20 Ex parte communications.

The Administrative Law Judge shall not consult any person, or party, on any fact in issue unless upon notice and opportunity for all parties to participate. No employee or agent of the Federal Government engaged in the investigation and prosecution of this case shall participate or advise in the rendering of the recommended or final decision in the case, except as witness or counsel in the proceeding.

§ 60-30.21 Oral argument.

Any party shall be entitled upon request to a reasonable period between the close of evidence and termination of the hearing for oral argument. Oral arguments shall be included in the official transcript of the hearing.

§ 60-30.22 Official transcript.

The official transcripts of testimony taken, together with any exhibits, briefs, or memorandums of law, shall be filed with the Administrative Law Judge. Transcripts of testimony may be obtained from the official reporter by the parties and the public as provided in section 11(a) of the Federal Advisory Committee Act (86 Stat. 770). Upon notice to all parties, the Administrative Law Judge may authorize such corrections to the transcript as are necessary to reflect accurately the testimony.

§ 60-30.23 Summary judgment.

(a) *For the Government.* At any time after the expiration of 20 days from the commencement of the action, or after service of a motion for summary judgment by the defendant, the Government may move with or without supporting affidavits for a summary judgment upon all claims of any part.

(b) *For defendant.* The defendant may, at any time after commencement of the action, move with or without supporting affidavits for summary judgment in its favor as to all claims or any part.

(c) *Other parties.* Any other party to a formal proceeding under this part may support or oppose motions for summary judgment made by the Government or defendant, in accordance with this section, but may not move for summary judgment in its own behalf.

(d) *Statement of uncontested facts.* All motions for summary judgment shall be accompanied by a "Statement of Uncontested Facts" in which the moving party sets forth all alleged uncontested material facts which shall provide the basis for its motion. At least 5 days prior to the time fixed for hearing on the

motion, any party contending that any material fact regarding the matter covered by the motion is in dispute, shall file a "Statement of Disputed Facts." Failure to file a "Statement of Disputed Facts" shall be deemed as an admission to the "Statement of Uncontested Facts."

(e) *Motion and proceedings.* The motion shall be served upon all parties at least 15 days before the time fixed for the hearing on the motion. The adverse party or parties may serve opposing affidavits prior to the day of hearing. The judgment sought shall be rendered forthwith if the complaint and answer, depositions, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. Summary judgment rendered for or against the Government or the defendant shall constitute the findings and recommendations on the issues involved. Hearings on motions made under this section shall be scheduled by the Administrative Law Judge.

(f) *Case not fully adjudicated on motion.* If on motion under this section judgment is not rendered upon the whole case or for all the relief asked and a final hearing is necessary, the Administrative Law Judge at the hearing of the motion, by examining the notice and answer and the evidence before him/her and by interrogating counsel, shall, if practicable, ascertain what material facts exist without substantial controversy and what material facts are actually and in good faith controverted. He/she shall thereupon make an order specifying the facts that appear without substantial controversy, including the extent to which relief is not in controversy, and directing such further proceedings as are just. At the hearing on the merits, the facts so specified shall be deemed established, and the final hearing shall be conducted accordingly.

§ 60-30.24 Participation by interested persons.

(a)(1) To the extent that proceedings hereunder involve employment of persons covered by a collective bargaining agreement, and compliance may necessitate a revision of such agreement, any labor organization which is a signatory to the agreement shall have the right to participate as a party.

(2) Other persons or organizations shall have the right to participate as parties if the final Administrative Order could adversely affect them or the class they represent, and such participation may contribute materially to the proper disposition of the proceedings.

(3) Any person or organization wishing to participate as a party under this section shall file with the Administrative Law Judge and serve on all parties a petition within 25 days after the commencement of the action or at such other time as ordered by the Administrative Law Judge, so long as it does not disrupt the proceeding. Such petition shall concisely state: (i) Petitioner's interest in the proceedings; (ii) who will appear for petitioner; (iii) the issues on which petitioner wishes to participate; and (iv) whether petitioner intends to present witnesses.

(4) The Administrative Law Judge shall determine whether each petitioner has the requisite interest in the proceedings and shall permit or deny participation accordingly. Where petitions to participate as parties are made by individuals or groups with common interest, the Administrative Law Judge may request all such petitioners to designate a single representative to represent all such petitioners: *Provided,* That the representative of a labor organization qualifying to participate under paragraph (a)(1) of the section must be permitted to participate in the proceedings. The Administrative Law Judge shall give each petitioner written notice of the decision on its petition; and if the petition is denied, he/she shall briefly state the grounds for denial and shall then treat the petition as a request for participation as amicus curiae. The Administrative Law Judge shall give written notice to each party of each petition granted.

(b)(1) Any other interested person or organization wishing to participate as amicus curiae shall file a petition before the commencement of the final hearing with the Administrative Law Judge. Such petition shall concisely state: (i) The petitioner's interest in the hearing; (ii) who will represent the petitioner; and (iii) the issues on which petitioner intends to present argument. The Administrative Law Judge may grant the petition if he/she finds that the petitioner has a legitimate interest in the proceedings, and that such participation may contribute materially to the proper disposition of the issues. An amicus curiae is not a party but may participate as provided in this section.

(2) An amicus curiae may present a brief oral statement at the hearing at the point in the proceeding specified by the Administrative Law Judge. He/she may submit a written statement of position to the Administrative Law Judge prior to the beginning of a hearing and shall serve a copy on each party. He/she may also submit a brief or written statement at such time as the parties submit briefs and exceptions, and he/she shall serve a copy on each party.

Post-Hearing Procedures

§ 60-30.25 Posthearing briefs.

Each party and amicus may file a brief. The time for filing briefs shall be established by the Administrative Law Judge. Such briefs shall be served simultaneously on all parties and amici, and a certificate of service shall be furnished to the Administrative Law Judge. Requests for additional time in which to file a brief shall be made in writing, and copies shall be served simultaneously on the other parties. Requests for extensions shall be received not later than 3 days before the date such briefs are due. No reply brief may be filed except by special permission of the Administrative Law Judge.

§ 60-30.26 Record for recommended decision.

The transcript of testimony, exhibits, and all papers, documents, and requests filed in the proceedings, including briefs, but excepting the correspondence section of the docket, shall constitute the record for decision.

§ 60-30.27 Recommended decision.

Within a reasonable time after the filing of briefs, the Administrative Law Judge shall recommend findings, conclusions, and a decision. These recommendations shall be certified, together with the record to the Secretary of Labor for a final Administrative Order. The recommended findings, conclusions, and decision shall be served on all parties and amici to the proceeding.

§ 60-30.28 Exceptions to recommended decisions.

Within 30 days after receipt of the recommended findings, conclusions, and decision, any party may submit exceptions to said recommendation. These exceptions may be responded to by other parties within 14 days of their receipt by said parties. All exceptions and responses shall be filed with the Secretary. Service of exceptions and responses shall be made simultaneously on all parties to the proceeding. Requests to the Secretary for additional time in which to file exceptions and responses shall be in writing and copies shall be served simultaneously on other parties. Requests for extensions must be received no later than 3 days before the exceptions are due.

§ 60-30.29 Record.

After expiration of the time for filing exceptions and responses, the Secretary shall make a final decision, which shall be the final Administrative Order, on the basis of the record. The record shall consist of the record for recommended decision, the rulings and recommended decision of the Administrative Law Judge and the exceptions and responses filed subsequent to the Administrative Law Judge's decision.

§ 60-30.30 Final Administrative Order.

After expiration of the time for filing exceptions, and responses thereto, the Secretary or the Under Secretary, in the absence of the Secretary or if the Secretary disqualifies himself or herself for any reason, shall make a final Administrative Order which shall be served on all parties. If the Secretary concludes that the defendant has violated the Order, section 402 or section 503, an Administrative Order shall be issued which shall enjoin the violations, and require the contractor to provide whatever remedies are appropriate, and which shall impose whatever sanctions are appropriate, or any of the above. In any event, failure to comply with the Administrative Order shall result in the immediate termination and suspension of the defendant's contracts and/or debarment of the defendant from further contracts: *Provided*, That the portion of any order under Executive Order 11246 terminating, cancelling, or suspending contracts shall not become effective until the consultation requirements of section 209(a)(5) of the Order, as amended by Executive Order 12086, have been satisfied.

Expedited Hearing Procedures

§ 60-30.31 Expedited hearings—when appropriate.

Expedited Hearings may be used, *inter alia*, when a contractor or subcontractor has violated a conciliation agreement; has not adopted and implemented an acceptable affirmative action program; has refused to give access to or to supply records or other information as required by the equal opportunity clause; or has refused to allow an on-site compliance review to be conducted.

§ 60-30.32 Administrative complaint and answer.

(a) Expedited hearings shall be commenced by filing an administrative complaint in accordance with 41 CFR 60-30.5. The complaint shall state that the hearing is subject to these expedited hearing procedures.

(b) The answer shall be filed in accordance with 41 CFR 60-30.6 (a) and (b).

(c) Failure to request a hearing within the 20 days provided by 41 CFR 60-30.6(a) shall constitute a waiver of hearing, and all the material allegations of fact contained in the complaint shall be deemed to be admitted. If a hearing is not requested or is waived, within 25 days of the complaint's filing, the Administrative Law Judge shall adopt as findings of fact the material facts alleged in the complaint, and shall order the appropriate sanctions and/or penalties sought in the complaint. The Administrative Law Judge's findings and order shall constitute a final Administrative Order, unless the Office of the Solicitor, U.S. Department of Labor, files exceptions to the findings and order within 10 days of receipt thereof. If the Office of the Solicitor, U.S. Department of Labor, files exceptions, the matter shall proceed in accordance with § 60-30.36 of this Part.

(d) If a request for a hearing is received within 20 days as provided by 41 CFR 60-30.6(a), the hearing shall be convened within 45 days of receipt of the request and shall be completed within 15 days thereafter, unless more hearing time is required.

§ 60-30.33 Discovery.

(a) Any party may serve requests for admissions in accordance with § 60-30.9 (b) and (c).

(b) Witness lists and hearing exhibits will be exchanged at least 10 days in advance of the hearing.

(c) For good cause shown, and upon motion made in accordance with § 60-30.8, the Administrative Law Judge may allow the taking of depositions. Other discovery will not be permitted.

§ 60-30.34 Conduct of hearing.

(a) At the hearing, the Government shall be given an opportunity to demonstrate the basis for the request for sanctions and/or remedies, and the contractor shall be given an opportunity to show that the violation complained of did not occur and/or that good cause or good faith efforts excuse the alleged violations. Both parties shall be allowed to present evidence and argument and to cross-examine witnesses.

(b) The hearing shall be informal in nature, and the Administrative Law Judge shall not be bound by formal rules of evidence.

§ 60-30.35 Recommended decision after hearing.

Within 30 days after the hearing is concluded, the Administrative Law Judge shall recommend findings, conclusions, and a decision. The Administrative Law Judge may permit the parties to file written post-hearing briefs within this time period, but the Administrative Law Judge's recommendations shall not be delayed pending receipt of such briefs. These recommendations shall be certified, together with the record, to the Secretary for a final Administrative Order. The recommended decision shall be served on all parties and amici to the proceeding.

§ 60-30.36 Exceptions to recommendations.

The provisions of 41 CFR 60-30.28 shall be applicable to exceptions to the Administrative Law Judge's recommendations.

§ 60-30.37 Final Administrative Order.

(a) After expiration of the time for filing exceptions, and responses thereto, the Secretary shall issue a final Administrative Order which shall be served on all parties. Unless the Secretary issues a final Administrative Order within 45 days after the expiration of the time for filing exceptions, and responses thereto, the Administrative Law Judge's recommended decision shall become a final Administrative Order which shall become effective on the 46th day after expiration of the time for filing exceptions and responses thereto. Except as to specific time periods required in this subsection, 41 CFR 60-30.30 shall be applicable to this subsection.

§ 60-30.38 Preliminary administrative enforcement proceedings.

(a) A preliminary enforcement proceeding is commenced by filing an administrative complaint. (See 41 CFR 60-1.29(e).) An administrative complaint may combine general allegations and prayers for relief and sanctions with a prayer for preliminary relief and sanctions or it may be limited to preliminary relief and sanctions, in the event an administrative complaint seeks preliminary and general enforcement, the allegations relating to preliminary enforcement shall be so designated and stated separately in the complaint.

An administrative complaint which is limited to preliminary relief and sanctions may be amended in accordance with 41 CFR 60-30.5(c) to make general allegations of violations and to request general relief and sanctions.

(b) The administrative complaint, as it relates to preliminary enforcement proceeding issues, shall contain a clear and concise factual statement sufficient

to inform the defendant with reasonable definiteness of the acts and practices it is alleged to have committed which constitute a violation. That is, fact pleading in lieu of notice pleading which applies under § 60–30.5 of this part, shall apply to preliminary enforcement proceeding issues. The complaint also shall contain a statement of any relief being sought and/or any sanctions which are sought to be imposed.

(c) No answer, as required by 41 CFR 60–30.6 of this part, shall be required with respect to the issues in the complaint which seek preliminary enforcement proceedings. However, the Administrative Law Judge shall notify the parties of the time and place of the hearing within 10 days after the complaint is filed.

(d) The plaintiff shall submit with the administrative complaint any affidavits and other documentation and a supporting memorandum. The defendant shall have 15 days after service of the complaint to submit any affidavits and other documentation and supporting memorandum.

(e) The Administrative Law Judge is authorized to conduct any prehearing conferences or procedures to expedite the hearing process.

(f) Discovery with regard to preliminary enforcement issues shall be granted only upon leave of the Administrative Law Judge for compelling reasons.

(g) The preliminary administrative enforcement proceeding is intended to provide a speedy hearing and decision on limited issues, and the Administrative Law Judge shall take all measures consistent with these rules and procedural fairness to achieve this end. The hearing shall commence within 20 days of the date of the notice of hearing specified in 41 CFR 60–30.38(c).

(h) If an administrative complaint is limited to preliminary relief and/or sanctions, the Administrative Law Judge shall follow the procedures in this § 60–30.38. If the Administrative complaint combines general allegations and prayers for relief with a prayer for preliminary relief and sanctions, the Administrative Law Judge shall bifurcate the proceeding. The hearing regarding the preliminary enforcement issues shall proceed in accordance with the procedures in this § 60–30.38. The issues involving the general allegations shall proceed in accordance with the regulations in this part but shall be stayed by the Administrative Law Judge pending his/her resolution of the preliminary enforcement proceeding.

(i) The decision of the Administrative Law Judge regarding the preliminary enforcement hearing issues shall be issued within 10 working days after the conclusion of the hearing. The decision shall not be delayed to await the preparation of a transcript of posthearing submissions by the parties. The decision shall set forth findings of fact and conclusions of law, including the imposition of sanctions and/or relief, where appropriate, against the contractor.

(j) If the contractor's eligibility as a Government contractor or subcontractor is an issue in the preliminary enforcement proceeding and if, at the conclusion of such proceeding, the Administrative Law Judge determines that the contractor's practices violate the Order or section 402 or 503, the decision and order shall state whether the contractor is eligible or ineligible for the award of Government contracts or subcontracts or under what circumstances the contractor will be eligible for such contracts or subcontracts during the pendency of the proceeding involving the general allegations of the administrative complaint if any were alleged in addition to the preliminary enforcement issues. In addition, it shall state whether existing contracts and subcontracts, if any, are to be cancelled, terminated, or suspended, and if so, under what conditions. Provided, however, that such cancellation termination or suspension is subject to the contracting agency consultation required by Section 209(a)(5) of the Order. Such decision and order, for purposes of judicial review, shall constitute the final administrative decision of the Department of Labor on the preliminary enforcement issues. The decision and order entered at the conclusion of the preliminary enforcement stage of a bifurcated proceeding shall not prejudice either party with regard to the appropriateness of relief and sanctions which may be obtained against the contractor at the conclusion of the hearing on the general allegations in the administrative complaint.

PART 60–50—GUIDELINES ON DISCRIMINATION BECAUSE OF RELIGION OR NATIONAL ORIGIN

Sec.

§ 60–50.1 Purpose and scope.

(a) The purpose of the provisions in this part is to set forth the interpretations and guidelines of the Office of Federal Contract Compliance Programs regarding the implementation of Executive Order 11246, as amended, for promoting and ensuring equal employment opportunities for all persons employed or seeking employment with Government contractors or with contractors performing under federally assisted construction contracts, without regard to religious or national origin.

(b) Members of various religious and ethnic groups continue to be excluded from executive, middle-management, and other job levels because of discrimination based upon their religion and/or national origin. These guidelines are intended to remedy such unfair treatment.

(c) These guidelines also are intended to clarify the obligations of contractors with respect to accommodating to the religious observances and practices of employees and prospective employees.

(d) The employment problems of blacks, Hispanics, Asians or Pacific Islanders, American Indians or Alaskan natives are treated under Part 60–2 of this chapter and under other regulations and procedures implementing the requirements of Executive Order 11246, as amended. Accordingly, the remedial provisions of § 60–50.2(b) shall not be applicable to the employment problems of these groups.

(e) Nothing contained in this Part 60–50 is intended to supersede or otherwise limit the exemption set forth in § 60–1.5(a)(5) of this chapter for contractors with certain educational institutions.

§ 60–50.2 Equal employment policy.

(a) *General requirements.* Under the equal opportunity clause contained in section 202 of Executive Order 11246, as amended, contractors are prohibited from discriminating against employees or applicants for employment because of religion or national origin, and must take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their religion or national origin. Such action includes, but is not limited to the following: Employment, upgrading, demotion, or transfer; recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship.

(b) *Outreach and positive recruitment.* Contractors shall review their employment practices to determine whether members of the various religious and/or ethnic groups are receiving fair consideration for job opportunities. Special attention shall be directed toward executive and middle-management levels, where employment

problems relating to religion and national origin are most likely to occur. Based upon the findings of such reviews, contractors shall undertake appropriate outreach and positive recruitment activities, such as those listed below, in order to remedy existing deficiencies. It is not contemplated that contractors necessarily will undertake all the listed activities. The scope of the contractor's efforts shall depend upon all the circumstances, including the nature and extent of the contractor's deficiences and the contractor's size and resources.

(1) Internal communication of the contractor's obligation to provide equal employment opportunity without regard to religion or national origin in such a manner as to foster understanding, acceptance, and support among the contractor's executive, management, supervisory, and all other employees and to encourage such persons to take the necessary action to aid the contractor in meeting this obligation.

(2) Development of reasonable internal procedures to ensure that the contractor's obligation to provide equal employment opportunity without regard to religion or national origin is being fully implemented.

(3) Periodically informing all employees of the contractor's commitment to equal employment opportunity for all persons, without regard to religion or national origin.

(4) Enlisting the assistance and support of all recruitment sources (including employment agencies, college placement directors, and business associates) for the contractor's commitment to provide equal employment opportunity without regard to religion or national origin.

(5) Reviewing employment records to determine the availability of promotable and transferable members of various religious and ethnic groups.

(6) Establishment of meaningful contacts with religious and ethnic organizations and leaders for such purposes as advice, education, technical assistance, and referral of potential employees.

(7) Engaging in significant recruitment activities at educational institutions with substantial enrollents of students from various religious and ethnic groups.

(8) Use of religious and ethnic media for institutional and employment advertising.

§ 60-50.3 Accommodations to religious observance and practice.

A contractor must accommodate to the religious observances and practices of an employee or prospective employee unless the contractor demonstrates that it is unable to reasonably accommodate to an employee's or prospective employee's religious observance or practice without undue hardship on the conduct of the contractor's business. As part of this obligation, a contractor must make reasonable accommodations to the religious observances and practices of an employee or prospective employee who regularly observes Friday evening and Saturday, or some other day of the week, as the Sabbath and/or who observes certain religious holidays during the year and who is conscientiously opposed to performing work or engaging in similar activity on such days, when such accommodations can be made without undue hardship on the conduct of the contractor's business. In determing the extent of the contractor's obligations under this section, at least the following factors shall be considered; (a) Business necessity, (b) financial costs and expenses, and (c) resulting personnel problems.

60-50.4 Enforcement.

The provisions of this part are subject to the general enforcement, compliance review, and complaint procedures set forth in Part 60-1 of this chapter.

§ 60-50.5 Nondiscrimination.

The provisions of this part are not intended and shall not be used to discriminate against any qualified employee or applicant for employment because of race, color, religion, sex, or national origin.

PART 60-60—CONTRACTOR EVALUATION PROCEDURES FOR CONTRACTORS FOR SUPPLIES AND SERVICES [REMOVED]

PART 60-250—AFFIRMATIVE ACTION OBLIGATIONS OF CONTRACTORS AND SUBCONTRACTORS FOR DISABLED VETERANS AND VETERANS OF THE VIETNAM ERA

Subpart A—Preliminary Matters, Affirmative Action Clause, Compliance

Sec.

Subpart B—General Enforcement and Complaint Procedures

Subpart C—Ancillary Matters

Sec.

Authority: Sec. 503(a), Pub. L. 92-540, 86 Stat. 1097 (38 U.S.C. 2012), as amended by Sec. 402, Pub. L. 93-508, 88 Stat. 1593 (38 U.S.C. 2012).

Subpart A—Preliminary Matters, Affirmative Action Clause, Compliance

§ 60-250.1 Purpose and application.

The purpose of the regulations in this part is to assure compliance with section 402 of the Vietnam Era Veterans Readjustment Assistance Act of 1974, which requires Government contractors to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era. The regulations in this part apply to all Government contracts, including Federal deposit or share insurance, for the furnishing of supplies or services or for the use of personal property (including construction) for $10,000 or more.

§ 60-250.2 Coverage and waivers.

(a) *General.* (1) *Transactions for less than $10,000.* Contracts and subcontracts for less than $10,000 are not covered by the Act. No agency or contractor shall procure supplies or services in less than usual quantities to avoid the applicability of the affirmative action clause.

(2) *Contracts for indefinite quantities.* With respect to indefinite delivery-type contracts (including, but not limited to, open end contracts, requirement-type contracts, Federal Supply Schedule contracts, "call-type" contracts, and purchase notice agreements), the affirmative action clause shall be included unless the contracting agency has reason to believe that the amount to be ordered in any year under such contract will be less than $10,000. The applicability of the affirmative action clause shall be determined at the time of award for the first year, and annually thereafter for succeeding years, if any. Notwithstanding the above, the affirmative action clause shall be applied to such contract whenever the amount of a single order is $10,000 or more. Once the affirmative action clause is determined to be applicable, the contract shall continue to be subject to such clause for its duration, regardless of the amounts ordered, or reasonably expected to be ordered in any year.

(3) *Work outside of the United States.* The requirements of the affirmative action clause are waived with respect to

contracts with regard to work performed outside of the United States by employees who were not recruited within the United States.

(4) *Contracts with State or local governments.* The requirements of the affirmative action clause in any contract with a State or local government (or any agency, instrumentality or subdivision thereof) shall not be applicable to any agency, instrumentality or subdivision of such government which does not participate in work on or under the contract.

(5) *Facilities not connected with contracts.* The Director may waive the requirements of the affirmative action clause with respect to any of a contractor's facilities which he or she finds to be in all respects separate and distinct from activities of the contractor related to the performance of the contract, provided that he or she also finds that such a waiver will not interfere with or impede the effectuation of the Act. Such waivers shall be considered only upon the request of the contractor.

(b) *Waivers.* (1) *Specific contracts and classes of contracts.* The head of an agency, with the concurrence of the Director, may waive the application to any contract of any part of or all the affirmative action clause when he or she deems that special circumstances in the national interest so require. The agency head, with the concurrence of the Director, may also grant such waivers to groups or categories of contracts of the same type where it is (i) in the national interest, (ii) found impracticable to act upon each request individually, and (iii) where such waiver will substantially contribute to convenience in administration of the Act.

(2) *National security.* Any requirement set forth in the regulations in this Part 60–250 shall not apply to any contract whenever the head of the contracting agency determines that such contract is essential to the national security and that its award without complying with such requirements is necessary to the national security. Upon making such a determination, the head of the agency will notify the Director in writing within 30 days.

(c) *Withdrawal of waiver.* When a waiver has been granted for any class of contracts under this section other than contracts granted waivers under paragraph (b)(2) of this section, the Director may withdraw the waiver for a specific contract or group of contracts to be awarded, when in his or her judgment such action is necessary or appropriate to achieve the purposes of the Act. The withdrawal shall not apply to contracts awarded prior to the withdrawal, except that in procurement entered into by formal advertising, or the various forms of restricted formal advertising, such withdrawal shall not apply unless the withdrawal is made more than 10 calendar days before the date set for the opening of the bids.

§ 60–250.3 Affirmative action clause.

Each agency and each contractor shall include the following affirmative action clause in each of its covered Government contracts (and modifications, renewals, or extensions thereof if not included in the original contract):

Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era

(a) The conctractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment and otherwise treat qualified disabled veterans and veterans of the Vietnam era without discrimination based upon their disability or veterans status in all employment practices such as the following: Employment upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

(b) The contractor agrees that all suitable employment openings of the contractor which exist at the time of the execution of this contract and those which occur during the performance of this contract, including those not generated by this contract and including those occurring at an establishment of the contractor other than the one wherein the contract is being performed but excluding those of independently operated corporate affiliates, shall be listed at an appropriate local office of the State employment service system wherein the opening occurs. The contractor further agrees to provide such reports to such local office regarding employment openings and hires as may be required.

State and local government agencies holding Federal contracts of $10,000 or more shall also list all the suitable openings with the appropriate office of the State employment service, but are not required to provide those reports set forth in paragraphs (d) and (e).

(c) Listing of employment openings with the employment service system pursuant to this clause shall be made at least concurrently with the use of any other recruitment source or effort and shall involve the normal obligations which attach to the placing of a bona fide job order, including the acceptance of referrals of veterans and nonveterans. This listing of employment openings does not require the hiring of any particular job applicant or from any particular group of job applicants, and nothing herein is intended to relieve the contractor from any requirements in Executive Orders or regulations regarding nondiscrimination in employment.

(d) The reports required by paragraph (b) of this clause shall include, but not be limited to, periodic reports which shall be filed at least quarterly with the appropriate local office or, where the contractor has more than one hiring location in a State, with the central office of that State, employment service. Such reports shall indicate for each hiring location (1) the number of individuals hired during the reporting period, (2) the number of nondisabled veterans of the Vietnam era hired, (3) the number of disabled veterans of the Vietnam era hired, and (4) the total number of disabled veterans hired. The reports should include covered veterans hired for on-the-job training under 38 U.S.C. 1787. The contractor shall submit a report within 30 days after the end of each reporting period wherein any performance is made on this contract identifying data for each hiring location. The contractor shall maintain at each hiring location copies of the reports submitted until the expiration of one year after final payment under the contract, during which time these reports and related documentation shall be made available, upon request, for examination by any authorized representatives of the contracting officer or of the Secretary of Labor. Documentation would include personnel records respecting job openings, recruitment and placement.

(e) Whenever the contractor becomes contractually bound to the listing provisions of this clause, it shall advise the employment service system in each State where it has establishments of the name and location of each hiring location in the State. As long as the contractor is contractually bound to these provisions and has so advised the State system, there is no need to advise the State system of subsequent contracts. The contractor may advise the State system when it is no longer bound by this contract clause.

(f) This clause does not apply to the listing of employment openings which occur and are filled outside of the 50 States, the District of Columbia, Puerto Rico, Guam, and the Virgin Islands.

(g) The provisions of paragraphs (b), (c), (d), and (e) of this clause do not apply to openings which the contractor proposes to fill from within its own organization or to fill pursuant to a customary and traditional employer-union hiring arrangement. This exclusion does not apply to a particular opening once the contractor decides to consider applicants outside of its own organization or employer-union arrangement for that opening.

(h) As used in this clause: (1) "All suitable employment openings" includes, but is not limited to, openings which occur in the following job categories: Production and non-production; plant and office; laborers and mechanics; supervisory and nonsupervisory; technical; and executive, administrative, and professional openings as are compensated on a salary basis of less than $25,000 per year. This term includes full-time employment, temporary employment of more than 3 days' duration, and part-time employment. It does not include openings which the contractor proposes to fill from within its own organization or to fill pursuant to a

customary and traditional employer-union hiring arrangement nor openings in an educational institution which are restricted to students of that institution. Under the most compelling circumstances an employment opening may not be suitable for listing, including such situations where the needs of the Government cannot reasonably be otherwise supplied, where listing would be contrary to national security, or where the requirement of listing would otherwise not be for the best interest of the Government.

(2) "Appropriate office of the State employment service system" means the local office of the Federal-State national system of public employment offices with assigned responsibility for serving the area where the employment opening is to be filled, including the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

(3) "Openings which the contractor proposes to fill from within its own organization" means employment openings for which no consideration will be given to persons outside of the contractor's organization (including any affiliates, subsidiaries, and the parent companies) and includes any openings which the contractor proposes to fill from regularly established "recall" lists.

(4) "Openings which the contractor proposes to fill pursuant to a customary and traditional employer-union hiring arrangement" means employment openings which the contractor proposes to fill from union halls, which is part of the customary and tradional hiring relationship which exists between the contractor and representatives of its employees.

(i) The contractor agrees to comply with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(j) In the event of the contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(k) The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices in a form to be prescribed by the Director, provided by or through the contracting officer. Such notice shall state the contractor's obligation under the law to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era for employment, and the rights of applicants and employees.

(l) The contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding, that the contractor is bound by the terms of the Vietnam Era Veterans Readjustment Assistance Act, and is committed to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era.

(m) The contractor will include the provisions of this clause in every subcontract or purchase order of $10,000 or more unless exempted by rules, regulations, or orders of the Secretary issued pursuant to the Act, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the Director of the Office of Federal Contract Compliance Programs may direct to enforce such provisions including action for noncompliance.

§ 60-250.4 Applicability of the affirmative action program requirement.

(a) Within 120 days of the commencement of a contract, every Government contractor which has 50 or more employees and (1) has a contract of $50,000 or more or (2) has contracts (at least one of which is at least $10,000) which total $50,000 or more in any 12-month period shall prepare and maintain an affirmative action program at each establishment which shall set forth the contractor's policies, practices and procedures in accordance with § 60-250.5 of this part. This program may be integrated into or kept separate from other affirmative action programs of the contractor which OFCCP requires it to maintain pursuant to this chapter.

(b) The affirmative action program shall be reviewed and updated annually. If there are any significant changes in procedures, rights or benefits as a result of the annual updating, those changes shall be communicated to employees and applicants for employment.

(c) The contractor shall submit the affirmative action program within 15 days of receipt of a request from OFCCP. The contractor shall also submit the affirmative action program upon OFCCP's request when a complaint is being investigated or a preaward compliance review is being conducted.

(d) The full affirmative action program shall be available to any employee or applicant for employment for inspection upon request. The location and hours during which the program may be obtained shall be posted at each establishment.

(e) The contractor shall invite all disabled veterans and veterans of the Vietnam era who wish to benefit under the affirmative action program to identify themselves to the contractor. The invitation shall state that the information is voluntarily provided, that it will be kept confidential, that refusal to provide it will not subject the applicant or employee to any adverse treatment and that it will be used only in accordance with the Act, and regulations in this part. If an applicant or employee so identifies himself or herself, the contractor should also seek the advice of the applicant or employee regarding proper placement and appropriate accommodation (an acceptable form for such an invitation is set forth in appendix A attached). Nothing in this section shall preclude an employee from informing a contractor at a future time of his or her desire to benefit from this program. Nothing in this section shall relieve a contractor from liability for discrimination under the Act.

§ 60-250.5 Affirmative action policy, practices and procedures.

(a) *General requirements.* Under the affirmative action obligation imposed by the Vietnam Era Veterans Readjustment Assistance Act of 1974, contractors are required to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era at all levels of employment, including the executive level. Such action shall apply to all employment practices, including, but not limited to, the following: hiring, upgrading, demotion or transfer, recruitment, or recruitment advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship and on-the-job training programs under 38 U.S.C. 1787.

(b) *Proper consideration of qualifications.* Contractors shall review their personnel processes to determine whether their present procedures assure careful, thorough and systematic consideration of the job qualifications of known disabled veteran applicants and Vietnam era veteran applicants for job vacancies filled either by hiring or promotion, and for all training opportunities offered or available. In determining the qualifications of a covered veteran, the contractor shall consider only that portion of the military record, including discharge papers, relevant to the specific job qualifications for which the veteran is being considered. To the extent that it is necessary to modify their personnel procedures, contractors shall include the development of new procedures for this purpose in their affirmative action program required under this part. These procedures must be designed so as to facilitate a review of the implementation of this requirement by the contractor or the Government. (The appendix attached is an example of an appropriate set of procedures. The procedures in appendix B are not required and contractors may develop other procedures which are appropriate to their circumstances.)

(c) *Physical and mental qualifications.* (1) The contractor shall provide in its affirmative action program, and shall adhere to, a schedule for the review of all physical or mental job qualification requirements to ensure that, to the extent qualification requirements tend to screen out qualified disabled veterans, they are job related and are consistent with business necessity and the safe performance of the job.

(2) Whenever a contractor applies physical or mental job qualification requirements in the selection of applicants or employees for employment or other change in employment status such as promotion, demotion, or training, to the extent that qualification requirements tend to screen out qualified disabled veterans, the requirements shall be related to the specific job or jobs for which the individual is being considered and shall be consistent with business necessity and the safe performance of the job. The contractor shall have the burden to demonstrate that it has complied with the requirements of this paragraph.

(3) Nothing is this section shall prohibit a contractor from conducting a comprehensive medical examination prior to employment provided that the results of such an examination shall be used only in accordance with the requirements of this section. Whenever a contractor inquires into an applicant's or employee's physical or mental condition or conducts a medical examination prior to employment or change in employment status information obtained in response to such inquiries or examination shall be kept confidential except that:

(i) Supervisors and managers may be informed regarding restrictions on the work or duties of disabled veterans and regarding accommodations; and

(ii) first aid and safety personnel may be informed, where and to the extent appropriate, if the condition might require emergency treatment; and

(iii) Government officials investigating compliance with the Act shall be informed.

(d) *Accommodation to physical and mental limitations of employees.* A contractor must make a reasonable accommodation to the physical and mental limitations of a disabled veteran unless the contractor can demonstrate that such an accommodation would impose an undue hardship on the conduct of the contractor's business. In determining the extent of a contractor's accommodation obligations, the following factors among others may be considered: (1) Business necessity and (2) financial costs and expenses.

(e) *Compensation.* In offering employment or promotions to disabled veterans, and veterans of the Vietnam era, the contractor may not reduce the amount of compensation offered because of any disability income, pension or other benefit the applicant or employee receives from another source.

(f) *Outreach, positive recruitment, and external dissemination of policy.* Contractors shall review their employment practices to determine whether their personnel programs provide the required affirmative action for employment and advancement of qualified disabled veterans and veterans of the Vietnam era. Based upon the findings of such reviews, contractors shall undertake appropriate outreach and positive recruitment activities, such as those listed below. It is not contemplated that contractors will necessarily undertake all the listed activities or that their activities will be limited to those listed. The scope of a contractor's efforts shall depend upon all the circumstances, including the contractor's size and resources and the extent to which existing employment practices are adequate.

(1) The contractor should develop internal communication of its obligation to engage in affirmative action efforts to employ qualified disabled veterans and veterans of the Vietnam era in such a manner as to foster understanding, acceptance and support among the contractor's executive, managment, supervisory and all other employees and to encourage such persons to take the necessary action to aid the contractor in meeting this obligation.

(2) The contractor should develop reasonable internal procedures to ensure that its obligation to engage in affirmative action to employ and promote qualified disabled veterans and veterans of the Vietnam era is being fully implemented.

(3) The contractor should periodically inform all employees and prospective employees of its commitment to engage in affirmative action to increase employment opportunities for qualified disabled veterans and veterans of the Vietnam era.

(4) The contractor should enlist the assistance and support of all recruiting sources including as follows:

(i) The local Veterans Employment Representative or his or her designee in the State Employment Service Office nearest each establishment where hiring takes place to recruit job ready veterans and to develop on-the-job training opportunities for covered veterans wherever feasible;

(ii) The Veterans Administration Regional Office nearest each establishment to develop on-the-job training opportunities for covered veterans, and to recruit job ready veterans;

(iii) The office of the National Alliance of Businessmen nearest each establishment where hiring takes place in order to cooperate in the Jobs for Veterans' Program;

(iv) The veterans' counselors and coordinators ("Vet-Reps" and "VCIPS") on college campuses for the recruitment of covered veterans;

(v) The service officers of the national veterans groups active in the area of each establishment where hiring takes place for the recruitment of covered veterans; and

(vi) Local veterans' groups and veterans' service centers in the area of each establishment where employment services are performed near major cities, for the recruitment of covered veterans.

(5) The contractor should establish meaningful contacts with appropriate veterans' service organizations which service disabled veterans or veterans of the Vietnam era, for such purposes as advice, technical assistance and referral of potential employees. Technical assistance from the resources listed in this paragraph may consist of advice on proper placement, recruitment, training and accommodations contractors may undertake, but no such resource providing technical assistance shall have the authority to approve or disapprove the acceptability of affirmative action programs.

(6) The contractor should review employment records to determine the availability of promotable and transferrable qualified known disabled veterans and veterans of the Vietnam era presently employed, and to determine whether their present and potential skills are being fully utilized or developed.

(7) The contractor should send written notification of company policy to all subcontractors, vendors and suppliers, requesting appropriate action on their part.

(8) The contractor should consider all qualified disabled veterans and veterans of the Vietnam era not currently in the workforce having requisite skills who can be recruited through affirmative action measures.

(g) *Internal dissemination of policy.* A strong outreach program will be ineffective without adequate internal support from supervisory and management personnel and other employees. In order to assure greater employee cooperation and participation in the contractor's efforts, the contractor should adopt, implement and disseminate this policy internally as follows:

(1) Include it in the contractor's policy manual.

(2) Publicize it in the company newspaper, magazine, annual report and other media.

(3) Conduct special meetings with executive, management, and supervisory personnel to explain the intent of the policy and individual responsibility for effective implementation, making clear the chief executive officer's attitude.

(4) Schedule special meetings with all employees to discuss policy and explain individual employee responsibilities.

(5) Discuss the policy thoroughly in both employee orientation and management training programs.

(6) Meet with union officials to inform them of the contractor's policy, and request their cooperation.

(7) Include nondiscrimination clauses in all union agreements, and review all contractual provisions to ensure they are nondiscriminatory.

(8) Include articles on accomplishments of disabled veterans and veterans of the the Vietnam era in company publications.

(9) Post the policy on company bulletin boards, including a statement that employees and applicants are protected from coercion, intimidation, interference or discrimination for filing a complaint or assisting in an investigation under the Act.

(h) *Responsibility for implementation.* An executive of the contractor should be designated as director or manager of company affirmative action activities under these regulations. His or her identity should appear on all internal and external communications regarding the company's affirmative action programs. This executive should be given necessary top management support and staff to manage the implementation of this program, including the following activities:

(1) Develop policy statements, affirmative action programs, and internal and external communication techniques. The latter techniques should include regular discussions with local managers, supervisors and employees to be certain the contractor's polcies are being followed. In addition, supervisors should be advised that:

(i) Their work performance is being evaluated on the basis of their affirmative action efforts and results, as well as other criteria.

(ii) The contractor is obligated to prevent harassment of employees placed through affirmative action efforts, as set forth in 41 CFR 60–1.28.

(2) Identify problem areas in conjunction with line management and known disabled veterans, in the implementation of the affirmative action programs, and develop solutions. This is particularly important for the accommodations requirements.

(3) Design and implement audit and reporting systems that will:

(i) Measure effectiveness of the contractor's programs.

(ii) Indicate need for remedial action.

(iii) Determine the degree to which the contractor's objectives have been attained.

(iv) Determine whether known disabled veterans and veterans of the Vietnam era have had the opportunity to participate in all company sponsored educational, training, recreational and social activities.

(v) Ensure that each location is in compliance with the Act and the regulations in this Part 60–250.

(4) Serve as liaison between the contractor and enforcement agencies.

(5) Serve as liaison between the contractor and organizations of and for disabled veterans and veterans of the Vietnam era, and arrange for the active involvement by company representatives in the community service programs of local organizations of and for disabled veterans and veterans of the Vietnam era.

(6) Keep management informed of the latest developments in the entire affirmative action area.

(7) Arrange for career counseling for known disabled veterans and veterans of the Vietnam era.

(i) *Development and execution of affirmative action programs.* (1) Job qualification requirements reviewed pursuant to paragraph (c) of this section should be made available to all members of management involved in the recruitment, screening, selection, and promotion process.

(2) The contractor should evaluate the total selection process including training and promotion to ensure freedom from stereotyping disabled veterans and veterans of the Vietnam era in a manner which limits their access to all jobs for which they are qualified.

(3) All personnel involved in the recruitment, screening, selection, promotion, disciplinary, and related processes should be carefully selected and trained to ensure that the commitments in its affirmative action program are implemented.

(4) Formal briefing sessions should be held, preferably on company premises, with representatives from recruiting sources. Plant tours, clear and concise explanations of current and future job openings, position descriptions, worker specifications, explanations of the company's selection process, and recruiting literature should be an integral part of the briefings. Formal arrangements should be made for referral of applicants, follow up with sources, and feedback on disposition of applicants.

(5) A special effort should be made to include qualified disabled veterans or veterans of the Vietnam era on the personnel relations staff.

(6) Active participation in veterans "job fairs" is desirable.

(7) Recruiting efforts at all educational institutions should incorporate special efforts to reach disabled veterans and veterans of the Vietnam era.

(8) An effort should be made to participate in workstudy programs with Veterans' Administration rehabilitation facilities which specialize in training or educating disabled veterans.

(9) The contractor should use all available resources to continue or establish federally assisted apprenticeship and on-the-job training programs under 38 U.S.C. 1787.

§ 60–250.6 Determination of disability.

Any disabled veteran filing a complaint under this part shall submit documentation from the Veterans Administration or military service from which the person was discharged or released which indicates the disability. Such documentation shall be updated within one year prior to filing the complaint if there has been a major change in the veteran's condition or if the Veterans Administration is reviewing the veteran's case.

Subpart B—General Enforcement and Complaint Procedure

§ 60–250.20 Subcontracts.

Each nonexempt contractor shall include the affirmative action clause prescribed in § 60–250.3 in each of its nonexempt subcontracts. The clause may be incorporated by reference in accordance with 41 CFR 60–1.46.

§ 60–250.21 Duties of agencies.

Each agency shall cooperate with the Director in the performance of his or her responsibilities under the Act. Such cooperation shall include the responsibility to ensure that contractors are fully cognizant of their obligations under the Act and this part, to provide the Director with any information which comes to its attention that the contractor is not in compliance with the Act or this part, and to take such actions for noncompliance as set forth in this chapter as may be ordered by the Director.

§ 60–250.22 Evaluations by the OFCCP Assistant Regional Administrators.

The Assistant Regional Administrators, OFCCP, shall be primarily responsible for undertaking compliance reviews and investigations of complaints against contractors as may be necessary to assure that the purposes of the Acts are being carried out effectively.

§ 60–250.23 Complaint procedures.

(a) *Filing complaints.* Complaints shall be filed within 180 days of the alleged violation unless the time for filing is extended for good cause shown.

(b) *Where to file.* Complaints may be filed with the OFCCP, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210, or with any OFCCP regional or area office.

Complaints also may be filed with the Veterans Employment Service of the Department of Labor. Complaints filed with the Veterans Employment Service shall be referred to OFCCP promptly for investigation.

(c) *Contents of complaints.* Complaints must be signed by the complainant or an authorized representative and must contain the following information. (1) name and address (including telephone number) of the complainant; (2) name and address of the contractor who committed the alleged violation; (3) a description of the act or acts considered to be a violation; (4) a statement that the alleged discriminatee is a disabled or Vietnam era veteran; and (5) any other pertinent information available which will assist in the investigation and resolution of the complaint, including the name of any known Federal agency with which the employer has contracted. Complaints alleging class-type violations which do not identify the alleged discriminatee or discriminatees will be accepted provided the other requirements of this paragraph are met. Signed third party complaints which do not identify the alleged discriminatee will be accepted, whether or not the third party signing the complaint is an authorized representative provided that the other information required by this paragraph is included.

(d) *Incomplete information.* If a complaint contains incomplete information, OFCCP shall seek the needed information from the person who filed the complaint. If the information is not furnished within 60 days of the date of the request, the case may be closed.

(e) *Investigations.* The OFCCP shall institute a prompt investigation of each complaint, and shall be responsible for developing a complete case record.

(f) *Referral to contractor.* When a complaint concerns an employee of a contractor and the contractor has an applicable internal review procedure, the complaint may be referred to the contractor for processing under that procedure if the employee gives his/her consent. The contractor shall be informed of the elements of the complaint either by being furnished a copy or a sanitized version. The complaint and all actions taken thereunder shall be kept confidential by the contractor. If the contractor is able to resolve the complaint to the satisfaction of the employee prior to the OFCCP investigation, the contractor shall notify OFCCP of the results in writing within 60 days of the referral. The case will be closed upon verification with the employee.

(g) *Resolution of matters.* (1) If the complaint investigation shows no violation of the Act or regulations, or if the matter is not recommended to the Office of the Solicitor for legal enforcement proceedings, the matter shall be closed and the complainant shall be so notified.

(2) If an investigation indicates that the contractor has not complied with the requirements of the Act, efforts shall be made to secure compliance through conciliation and persuasion within a reasonable time. Before the contractor can be found to be in compliance, it must make a specific commitment in accordance with the procedure in 41 CFR 60–1.26.

(3) If a complaint investigation or compliance review indicates a violation of the Act, and the matter has not been resolved by informal means, OFCCP may refer the matter in accordance with the procedure in 41 CFR 60–1.29(a) for consideration of any action authorized under 41 CFR 60–1.29. After a matter arising under the Act is referred to the Office of the Solicitor, the provisions of 41 CFR 60–1.29 through 60–1.31 shall be applicable to the matter in the same way those provisions apply to a matter arising under Executive Order 11246.

Subpart C—Ancillary Matters

§ 60–250.30 Responsibilities of the Deputy Assistant Secretary for Veterans' Employment.

(a) In accordance with the provisions of 38 U.S.C. 2002A, the Deputy Assistant Secretary for Veterans' Employment (DASVE) has responsibilities in all Department of Labor employment and training programs for veterans. The DASVE is responsible for assuring that the Veterans Employment Service shall monitor and evaluate adherence to the contractor job listing provisions of § 60–250.3 by state employment security agencies. Deficiencies noted by the Veterans Employment Service shall be reported through the DASVE to OFCCP. OFCCP, in coordination with the DASVE, will review contractor compliance with the mandatory job listing requirements in the course of regularly scheduled compliance reviews.

(b) Any job openings listed pursuant to § 60–250.3, which requires contractors to list their job openings with state employment services offices, shall be utilized by state employment security agencies to refer qualified disabled veterans and veterans of the Vietnam era. (See 20 CFR 653.221(a)(7).)

(c) The local offices of the Federal-state employment service shall give priority in referral of disabled veterans and veterans of the Vietnam era to such employment openings listed by contractors pursuant to this part.

(d) The local state employment service staff shall make appropriate job development contacts with identified contractors to obtain orders for job openings. Information so obtained which is pertinent to determining compliance with the requirements to list job openings and to take affirmative action shall be made available to OFCCP.

§ 60–250.31 Recordkeeping.

(a) Each contractor shall maintain for a period not less than one year records regarding complaints and actions taken thereunder, and such employment or other records as required by the Director or by this part and shall furnish such information in the form required by the Director or as the Director deems necessary for the administration of the Act.

(b) Failure to maintain complete and accurate records as required under this section or failure to update annually the affirmative action program as required by § 60–250.4(b) constitutes noncompliance with the contractor's obligations under the Act and is a ground for the imposition of appropriate sanctions.

Appendix A

This employer is a Government contractor subject to Section 402 of the Vietnam Era Veterans Readjustment Assistance Act of 1974 which require Government contractors to take affirmative action to employ and advance in employment qualified disabled veterans and veterans of the Vietnam era. If you are a disabled veteran covered by this program and would like to be considered under the affirmative action program, please tell us. This information is voluntary and refusal to provide it will not subject you to discharge or disciplinary treatment. Information obtained concerning individuals shall be kept confidential, except that (i) supervisors and managers may be informed regarding restrictions on the work or duties of disabled veterans, and regarding necessary accommodations, and (ii) first aid personnel may be informed, when and to the extent appropriate, if the condition might require emergency treatment. In order to assure proper placement of all employees, we do request that you answer the following question: If you have a disability which might affect your performance or create a hazard to yourself or others in connection with the job for which you are applying, please state the following: (1) The skills and procedures you use or intend to use to perform the job notwithstanding the disability and (2) the accommodations we could make which would enable you to perform the job properly and safety, including special equipment, changes in the physical layout of the job, elimination of certain duties relating to the job or other accommodations.

Appendix B

The following is a set of procedures which contractors may use to meet the requirements of § 60–250.5(b).

(1) The application or personnel form of each known protected veteran should be annotated to identify each vacancy for which he or she was considered, and the form should be quickly retrievable for review by the agency, the Department of Labor and the contractor's personnel officials for use in investigations and internal compliance activities.

(2) The personnel or application records of each known protected veteran should include (i) the identification of each promotion for which he or she was considered, and (ii) the identification of each training program for which he or she was considered.

(3) In each case where a protected veteran is rejected for employment, promotion or training, a statement of the reasons should be appended to the personnel file or application form. This statement should include a comparison of the qualifications of the protected veteran and the person(s) selected, as well as a description of the accommodations considered. This statement should be available to the applicant or employee concerned upon request.

(4) Where applicants or employees are selected for hire, promotion or training and the contractor undertakes any acommodation which makes it possible for the contractor to place a protected veteran on the job, the application form or personnel record should contain a description of that accommodation.

PART 60–741—AFFIRMATIVE ACTION OBLIGATIONS OF CONTRACTORS AND SUBCONTRACTORS FOR HANDICAPPED WORKERS

Subpart A—Preliminary Matters, Affirmative Action Clause, Compliance

Sec.

Subpart B—General Enforcement and Complaint Procedure

Subpart C—Ancillary Matters

Authority: Sec. 503, Pub. L. 93–1112, 87 Stat. 393 (20 U.S.C. 793), as amended by sec. 111, Pub. L. 93–516, 88 Stat. 1619 (29 U.S.C. 706) and Executive Order 11758.

Subpart A—Preliminary Matters, Affirmative Action Clause, Compliance

§ 60–741.1 Purpose and application.

The purpose of the regulations in this Part 60–741 is to assure compliance with section 503 of the Rehabilitation Act of 1973, which requires Government contractors to take affirmative action to employ and advance in employment qualified handicapped individuals. The regulations in this part apply to all Government contracts, including Federal deposit or share insurance, for the furnishing of supplies or services or for the use of personal property (including construction) in excess of $2,500. Compliance of a contractor with the provisions of this part will not necessarily determine its compliance with the requirements of section 504 of the Rehabilitation Act of 1973 and compliance with section 504 will not necessarily determine compliance with section 503 and the regulations in this part.

§ 60–741.2 Coverage and waivers.

(a) *General.*—(1) *Transactions for $2,500 or less.* Contracts for $2,500 or less are not covered by the Act. No agency or contractor shall procure supplies or services in less than usual quantities to avoid the applicability of the affirmative action clause.

(2) Contracts for indefinite quantities. With respect to indefinite delivery-type contracts (including, but not limited to, open end contracts, requirement-type contracts, Federal Supply Schedule contracts, "call-type" contracts, and purchase notice agreements), the affirmative action clause shall be included unless the contracting agency has reason to believe that the amount to be ordered in any year under such contract will be $2,500 or less. The applicability of the affirmative action clause shall be determined at the time of award for the first year, and annually thereafter for succeeding years, if any. Notwithstanding the above, the affirmative action clause shall be applied to such contract whenever the amount of a single order is in excess of $2,500. Once the affirmative action clause is determined to be applicable, the contract shall continue to be subject to such clause for its duration, regardless of the amounts ordered, or reasonably expected to be ordered in any year.

(3) Work outside of the United States. The requirements of the affirmative action clause are waived with respect to contracts with regard to work performed outside of the United States by employees who were not recruited within the United States.

(4) Contracts with state or local governments. The requirements of the affirmative action clause in any contract with a state or local government (or any agency, instrumentality or subdivision thereof) shall not be applicable to any agency, instrumentality or subdivision of such government which does not participate in work on or under the contract.

(5) Facilities not connected with contracts. The Director may waive the requirements of the affirmative action clause with respect to any of a contractor's facilities which he or she finds to be in all respects separate and distinct from activities of the contractor related to the performance of the contract, provided that he or she also finds that such a waiver will not interfere with or impede the effectuation of the Act. Such waivers shall be considered only upon the request of the contractor.

(b) *Waivers.* (1) Specific contracts and classes of contracts. The head of an agency, with the concurrence of the Director, may waive the application to any contract of any part of or all the affirmative action clause when he or she deems that special circumstances in the national interest so require. The agency head, with the concurrence of the Director, may also grant such waivers to groups or categories of contracts of the same type where it is (i) in the national interest, (ii) found impracticable to act upon each request individually, and (iii) where such waiver will substantially contribute to convenience in administration of section 503 of the Act.

(2) National security. Any requirement set forth in the regulations in this Part 60–741 shall not apply to any contract whenever the head of the contracting agency determines that such contract is essential to the national security and that its award without complying with such requirements is necessary to the national security. Upon making such a determination the head of the agency will notify the Director in writing within 30 days.

(c) *Withdrawal of waiver.* When a waiver has been granted for any class of contracts under this section other than contracts granted waivers under paragraph (b)(2) of this section, the Director may withdraw the waiver for a specific contract or group of contracts to be awarded, when in his or her judgment such action is necessary or appropriate to achieve the purposes of the Act. The withdrawal shall not apply to contracts awarded prior to the withdrawal, except that in procurements entered into by formal advertising, or the various forms of restricted formal advertising, such withdrawal shall not

apply unless the withdrawal is made more than 10 calendar days before the date set for the opening of the bids.

§ 60-741.3 Affirmative action clause.

Each agency and each contractor and subcontractor shall include the following affirmative action clause in each of its covered Government contracts (and modifications, renewals, or extensions thereof if not included in the original contract).

Affirmative Action for Handicapped Workers

(a) The contractor will not discriminate against any employee or applicant for employment because of physical or mental handicap in regard to any position for which the employee or applicant for employment is qualified. The contractor agrees to take affirmative action to employ, advance in employment and otherwise treat qualified handicapped individuals without discrimination based upon their physical or mental handicap in all employment practices such as the following: Employment, upgrading, demotion or transfer, recruitment, advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

(b) The contractor agrees to comply with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(c) In the event of the contractor's noncompliance with the requirements of this clause, actions for noncompliance may be taken in accordance with the rules, regulations, and relevant orders of the Secretary of Labor issued pursuant to the Act.

(d) The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices in a form to be prescribed by the Director, provided by or through the contracting officer. Such notices shall state the contractor's obligation under the law to take affirmative action to employ and advance in employment qualified handicapped employees and applicants for employment, and the rights of applicants and employees.

(e) The contractor will notify each labor union or representative of workers with which it has a collective bargaining agreement or other contract understanding, that the contractor is bound by the terms of section 503 of the Rehabilitation Act of 1973, and is committed to take affirmative action to employ and advance in employment physically and mentally handicapped individuals.

(f) The contractor will include the provisions of this clause in every subcontract or purchase order in excess of $2,500 unless exempted by rules, regulations, or orders of the Secretary issued pursuant to section 503 of the Act, so that such provisions will be binding upon each subcontractor or vendor. The contractor will take such action with respect to any subcontract or purchase order as the Director of the Office of Federal Contract Compliance Programs may direct to enforce such provisions, including action for noncompliance.

§ 60-741.4 Applicability of the affirmative action program requirement.

(a) Within 120 days of the commencement of a contract, every Government contractor which has 50 or more employees and (1) has a contract of $50,000 or more or (2) has contracts (at least one of which exceeds $2,500) which total $50,000 or more in any 12-month period shall prepare and maintain an affirmative action program at each establishment which shall set forth the contractor's policies, practices and procedures in accordance with § 60-741.5 of this part. This program may be integrated into or kept separate from other affirmative action programs of the contractor which OFCCP requires it to maintain pursuant to this chapter.

(b) The affirmative action program shall be reviewed and updated annually. If there are any significant changes in procedures, rights or benefits as a result of the annual updating, those changes shall be communicated to employees and applicants for employment.

(c) The contractor shall submit the affirmative action program within 15 days of a request from OFCCP. The contractor shall also submit the affirmative action program upon OFCCP's request when a complaint is being investigated or a preaward compliance review is being conducted.

(d) The full affirmative action program shall be available to any employee or applicant for employment for inspection upon request. The location and hours during which the program may be obtained shall be posted at each establishment.

(e)(1) The contractor shall invite all applicants and employees who believe themselves covered by the Act and who wish to benefit under the affirmative action program to identify themselves to the contractor. The invitation shall state that the information is voluntarily provided, that it will be kept confidential, that refusal to provide it will not subject the applicant or employee to any adverse treatment, and that it will be used only in accordance with the Act and the regulations in this part. If an applicant or employee so identifies himself or herself, the contractor should also seek the advice of the applicant or employee regarding proper placement and appropriate accommodation. (An acceptable form for such an invitation is set forth in Appendix B attached.)

(2) Nothing in this section shall preclude an employee from informing a contractor at any future time of his or her desire to benefit under the program.

(3) Nothing in this section shall relieve a contractor of its obligation to take affirmative action with respect to those applicants or employees of whose handicap the contractor has actual knowledge: *Provided,* That the contractor is not obligated to search the medical files of any applicant or employee to determine the existence of a handicap.

(4) Nothing in this section shall relieve a contractor from liability for discrimination under the Act.

§ 60-741.5 Affirmative action policy, practices, and procedures.

(a) *General requirements.* Under the affirmative action obligation imposed by section 503 of the Rehabilitation Act of 1973, contractors are required to take affirmative action to employ and advance in employment qualified handicapped individuals at all levels of employment, including the executive level. Such action shall apply to all employment practices, including, but not limited to, the following: Hiring, upgrading, demotion or transfer, recruitment or recruitment advertising, layoff or termination, rates of pay or other forms of compensation, and selection for training, including apprenticeship.

(b) *Proper consideration of qualifications.* Contractors shall review their personnel processes to determine whether their present procedures assure careful, thorough and systematic consideration of the job qualifications of known handicapped applicants and employees for job vacancies filled either by hiring or promotion, and for all training opportunities offered or available. To the extent that it is necessary to modify their personnel procedures, contractors shall include the development of new procedures for this purpose in their affirmative action program required under this part. These procedures must be designed so as to facilitate a review of the implementation of this requirement by the contractor or the Government. (Appendix C attached is an example of an appropriate set of procedures. The procedures in Appendix C are not required and contractors may develop other procedures which are appropriate to their circumstances.)

(c) *Physical and mental qualifications.* (1) The contractor shall provide in its affirmative action program, and shall adhere to, a schedule for the review of all physical or mental job qualification requirements to ensure that, to the extent qualification requirements tend to screen out qualified handicapped individuals, they are job related and are consistent with business necessity and the safe performance of the job.

(2) Whenever a contractor applies physical or mental job qualification requirements in the selection of applicants or employees for employment or other change in employment status such as promotion, demotion or training, to the extent that qualification requirements tend to screen out qualified handicapped individuals, the requirements shall be related to the specific job or jobs for which the individual is being considered and shall be consistent with business necessity and the safe performance of the job. The contractor shall have the burden to demonstrate that it has complied with the requirements of this paragraph.

(3) Nothing in this section shall prohibit a contractor from conducting a comprehensive medical examination prior to employment provided that the results of such an examination shall be used only in accordance with the requirements of this section. Whenever a contractor inquires into an applicant's or employee's physical or mental condition or conducts a medical examination prior to employment or change in employment status information obtained in response to such inquiries or examination shall be kept confidential except that:

(i) Supervisors and managers may be informed regarding restrictions on the work or duties of handicapped individuals and regarding accommodations; and

(ii) First aid and safety personnel may be informed, where and to the extent appropriate, if the condition might require emergency treatment; and

(iii) Government officials investigating compliance with the Act shall be informed.

(d) *Accommodation to physical and mental limitations of employees.* A contractor must make a reasonable accommodation to the physical and mental limitations of an employee or applicant unless the contractor can demonstrate that such an accommodation would impose an undue hardship on the conduct of the contractor's business. In determining the extent of a contractor's accommodation obligations, the following factors among others may be considered: (1) business necessity and (2) financial cost and expenses.

(e) *Compensation.* In offering employment or promotions to handicapped individuals, the contractor may not reduce the amount of compensation offered because of any disability income, pension or other benefit the applicant or employee receives from another source.

(f) *Outreach, positive recruitment, and external dissemination of policy.* Contractors shall review their employment practices to determine whether their personnel programs provide the required affirmative action for employment and advancement of qualified handicapped individuals. Based upon the findings of such reviews, contractors shall undertake appropriate outreach and positive recruitment activities, such as those listed below. It is not contemplated that contractors will necessarily undertake all the listed activities or that their activities will be limited to those listed. The scope of a contractor's efforts shall depend upon all the circumstances, incuding the contractor's size and resources and the extent to which existing employment practice are adequate.

(1) The contractor should develop internal communication of its obligation to engage in affirmative action efforts to employ qualified handicapped individuals in such a manner as to foster understanding, acceptance and support among the contractor's executive, managment, supervisory and all other employees and to encourage such persons to take the necessary action to aid the contractor in meeting this obligation.

(2) The contractor should develop reasonable internal procedures to ensure that its obligation to engage in affirmative action to employ and promote qualified handicapped individuals is being fully implemented.

(3) The contractor should periodically inform all employees and prospective employees of its commitment to engage in affirmative action to increase employment opportunities for qualified handicapped individuals.

(4) The contractor should enlist the assistance and support of recruiting sources (including state employment security agencies, state vocational rehabilitation agencies or facilities, sheltered workshops, college placement officers, state education agencies, labor organizations and organizations of or for handicapped individuals) for the contractor's commitment to provide meaningful employment opportunities to qualified handicapped individuals. (A list of numerous national organizations serving the handicapped, many of which have state or local affiliates, is found in the "Directory of Organizations Interested in the Handicapped" published by the Committee for the Handicapped People-to-People Program, Washington, D.C.)

(5) The contractor should engage in recruitment activities at educational institutions which participate in training of the handicapped, such as schools for the blind, deaf, or retarded.

(6) The contractor should establish meaningful contacts with appropriate social service agencies, organizations of and for handicapped individuals, vocational rehabilitation agencies or facilities, for such purposes as advice, technical assistance and referral of potential employees. Technical assistance from the resources described in this paragraph may consist of advice on proper placement, recruitment, training and accommodations contractors may undertake, but no such resource providing technical assistance shall have the authority to approve or disapprove the acceptability of affirmative action programs.

(7) The contractor should review employment records to determine the availability of promotable and transferable qualified known handicapped individuals presently employed, and to determine whether their present and potential skills are being fully utilized or developed.

(8) The contractor should include handicapped workers when employees are pictured in consumer, promotional or help wanted advertising.

(9) The contractor should send written notification of company policy to all subcontractors, vendors and suppliers, requesting appropriate action on their part.

(10) The contractor should take positive steps to attract qualified handicapped persons not currently in the work force who have requisite skills and can be recruited through affirmative action measures. These persons may be located through the local chapters of organizations of and for handicapped individuals described in paragraph (f)(4) of this section.

(g) *Internal dissemination of policy.* A strong outreach program will be ineffective without adequate internal support from supervisory and management personnel and other employees, who may have had limited contact with handicapped persons in the past. In order to assure greater employee cooperation and participation in the contractor's efforts, the contractor should adopt, implement and disseminate this policy internally as follows:

(1) Include it in the contractor's policy manual.

(2) Publicize it in the company newspaper, magazine, annual report and other media.

(3) Conduct special meetings with executive, management, and supervisory personnel to explain the intent of the policy and individual responsibility for effective implementation, making clear the chief executive officer's attitude.

(4) Schedule special meetings with all employees to discuss policy and explain individual employee responsibilities.

(5) Discuss the policy thoroughly in both employee orientation and management training programs.

(6) Meet with union officials to inform them of the contractor's policy, and request their cooperation.

(7) Include nondiscrimination clauses in all union agreements, and review all contractual provisions to ensure they are nondiscriminatory.

(8) Include articles on accomplishments of handicapped workers in company publications.

(9) Post the policy on company bulletin boards, including a statement that employees and applicants are protected from coercion, intimidation, interference or discrimination for filing a complaint or assisting in an investigation under the Act.

(10) When employees are featured in employee handbooks or similar publications for employees, include handicapped employees.

(h) *Responsibility for implementation.* An executive of the contractor should be designated as director or manager of company affirmative action activities under these regulations. His or her identity should appear on all internal and external communications regarding the company's affirmative action programs. This executive should be given necessary top management support and staff to manage the implementation of this program, including the following activities:

(1) Develop policy statements, affirmative action programs, and internal and external communication techniques. The latter techniques should include regular discussions with local managers, supervisors and employees to be certain the contractor's policies are being followed. In addition, supervisors should be advised that:

(i) Their work performance is being evaluated on the basis of their affirmative action efforts and results, as well as other criteria.

(ii) The contractor is obligated to prevent harassment of employees placed through affirmative action efforts, as set forth in 41 CFR 60–1.28.

(2) Identify problem areas in conjunction with line management and known handicapped employees, in the implementation of the affirmative action programs, and develop solutions. This is particularly important for the accommodations requirements.

(3) Design and implement audit and reporting systems that will:

(i) Measure effectiveness of the contractor's programs.

(ii) Indicate need for remedial action.

(iii) Determine the degree to which the contractor's objectives have been attained.

(iv) Determine whether known handicapped employees have had the opportunity to participate in all company sponsored educational, training, recreational and social activities.

(v) Ensure that each location is in compliance with the Act and the regulations in this part.

(4) Serve as liaison between the contractor and OFCCP.

(5) Serve as liaison between the contractor and organizations of and for handicapped persons, and arrange for the active involvement by company representatives in the community service programs of local organizations of and for the handicapped.

(6) Keep management informed of the latest developments in the entire affirmative action area.

(7) Arrange for career counseling for known handicapped employees.

(i) *Development and execution of affirmative action programs.* (1) Job qualification requirements reviewed pursuant to paragraph (c) of this section should be made available to all members of management involved in the recruitment, screening, selection, and promotion process.

(2) The contractor should evaluate the total selection process including training and promotion to ensure freedom from stereotyping handicapped persons in a manner which limits their access to all jobs for which they are qualified.

(3) All personnel involved in the recruitment, screening, selection, promotion, disciplinary, and related processes should be carefully selected and trained to ensure that the commitments in the contractor's affirmative action program are implemented.

(4) Formal briefing sessions should be held, preferably on company premises, with representatives from recruiting sources. Plant tours, clear and concise explanations of current and future job openings, position, descriptions, worker specifications, explanations of the company's selection process, and recruiting literature should be an integral part of the briefings. Formal arrangements should be made for referral of applicants, follow up with sources, and feedback on disposition of applicants.

(5) A special effort should be made to include qualified handicapped persons on the personnel relations staff.

(6) Handicapped employees should be made available for participation in career days, youth motivation programs, and related activities in their communities.

(7) Recruiting efforts at all schools should incorporate special efforts to reach handicapped students.

(8) An effort should be made to participate in workstudy programs with rehabilitation facilities and schools which specialize in training or educating handicapped individuals.

(9) The contractor should use all available resources to continue or establish on the job training programs.

(j) *Sheltered workshops.* Contracts with sheltered workshops do not constitute affirmative action in lieu of employment and advancement of qualified handicapped individuals in the contractor's own workforce. Contracts with sheltered workshops may be included within an affirmative action program if the sheltered workshop trains employees for the contractor and the contractor is obligated to hire trainees at full compensation when such trainees become qualified as "qualified handicapped individuals" as defined in this chapter.

§ 60–741.6 Determination of handicap.

(a) Any handicapped individual filing a complaint with the Director under this part shall submit with his or her complaint a signed statement specifying the handicapping impairment or situation (see 41 CFR 60–1.3 definition of "handicapped individual"). If the Director determines that further documentation is necessary, he or she may require the complainant to provide additional information.

(b) Any contractor requiring a determination of an applicant's or employee's handicap may require the applicant or employee to provide medical,documentation of the impairment or, in the alternative, may require the applicant or employee to undergo a medical examination at the contractor's expense.

(c) Any determination of handicap required pursuant to paragraph (b) of this section must meet the requirements of § 60–741.4(c) and must be for the purpose of affirmative action and proper job placement. Information obtained therefrom shall not be used to exclude or otherwise limit the employment opportunities of qualified handicapped individuals.

(d) All medical documentation required under this section shall be based upon the American Medical Association Guides to the Evaluation of Permanent Impairment, provided that the Guides shall be used only to determine the existence of impairment without regard to the degree of impairment.

§ 60–741.7 Listing of employment openings.

Contractors should request state employment security agencies to refer qualified handicapped individuals for consideration under their affirmative action programs.

Subpart B—General Enforcement and Complaint Procedure

§ 60–741.20 Subcontracts.

Each nonexempt contractor shall include the affirmative action clause prescribed in § 60–741.3 in each of its nonexempt subcontracts. The clause may be incorporated by reference in accordance with 41 CFR 60–1.46.

§ 60–741.21 Duties of agencies.

(a) General responsibility. Each agency shall cooperate with the Director in the performance of his or her responsibilities under the Act. Such cooperation shall include the responsibility to ensure that contractors are fully cognizant of their obligations under the Act and this part, to provide the Director with any information which comes to its attention that the contractor is not in compliance with the Act or this part, and to take such actions for noncompliance as set forth in this chapter as may be ordered by the Director.

§ 60–741.22 Evaluations by the OFCCP Assistant Regional Administrator.

The Assistant Regional Administrators, OFCCP, shall be primarily responsible for undertaking such investigations of complaints against contractors and conducting compliance reviews as may be necessary to assure that the purposes of the Act are being carried out effectively.

§ 60–741.23 Complaint procedures.

(a) *Filing complaints.* Complaints shall be filed within 180 days of the alleged violation unless the time for filing is extended for good cause shown.

(b) *Where to file.* Complaints may be filed with the OFCCP, 200 Constitution Avenue, N.W., Washington, D.C. 20210, or with any OFCCP regional or area office.

(c) *Contents of complaints.* Complaints must be signed by the complainant or an authorized representative and must contain the following information: (1) Name and address (including telephone number) of the complainant; (2) name and address of the contractor who committed the alleged violation; (3) a description of the act or acts considered to be a violation; (4) a statement that the alleged discriminatee is handicapped, has a history of a handicap, has documentation of impairment, or was regarded by the contractor as having an impairment; and (5) any other pertinent information available which will assist in the investigation and resolution of the complaint, including the name of any known Federal agency with which the employer has contracted. Complaints alleging class-type violations which do not identify the alleged discriminatee or discriminatees will be accepted, provided the other requirements of this paragraph are met. Signed third party complaints which do not identify the alleged discriminatee will be accepted, whether or not the third party signing the complaint is an authorized representative provided that the other information required by this paragraph is included.

(d) *Incomplete information.* If a complaint contains incomplete information, OFCCP shall seek the needed information from the person who filed the complaint. If the information is not furnished within 60 days of the date of the request, the case may be closed.

(e) *Investigations.* The OFCCP shall institute a prompt investigation of each complaint, and shall be responsible for developing a complete case record.

(f) *Referral to contractor.* When a complaint concerns an employee of a contractor and the contractor has an applicable internal review procedure, the complaint may be referred to the contractor for processing under that procedure if the employee gives his/her consent. The contractor shall be informed of the elements of the complaint either by being furnished a copy or a sanitized version. The complaint and all actions taken thereunder shall be kept confidential by the contractor. If the contractor is able to resolve the complaint to the satisfaction of the employee prior to the OFCCP investigation, the contractor shall notify OFCCP of the results in writing within 60 days of the referral. The case will be closed upon verification with the employee.

(g) *Resolution of matters.* (1) If the complaint investigation shows no violation of the Act or regulations in this part, or if the matter is not referred to the Office of the Solicitor for consideration of legal enforcement proceedings, the matter shall be closed and the complainant shall be so notified.

(2) If an investigation indicates that the contractor has not complied with the requirements of the Act, efforts shall be made to secure compliance through conciliation and persuasion within a reasonable time. Before the contractor can be found to be in compliance, it must make a specific commitment in accordance with the procedure in 41 CFR 60–1.26.

(3) When a complaint investigation or compliance review indicates a violation of the Act, and the matter has not been resolved by informal means, OFCCP may refer the matter in accordance with the procedure in 41 CFR 60–1.29(a) for consideration of any action authorized under 41 CFR 60–1.29. After a matter arising under the Act is referred to the Office of the Solicitor, the provisions of 41 CFR 60–1.29 through 60–1.31 shall be applicable to the matter in the same way those provisions apply to a matter arising under Executive Order 11246.

Subpart C—Ancillary Matters

§60–741.30 Recordkeeping.

(a) Each contractor shall maintain for a period not less than one year records regarding complaints and actions taken thereunder, and such employment or other records as required by the Director or by this part and shall furnish such information in the form required by the Director or as the Director deems necessary for the administration of the Act.

(b) Failure to maintain complete and accurate records as required under this section or failure to update annually the affirmative action program as required by § 60–741.4(b) constitutes noncompliance with the contractor's obligations under the Act and is a ground for the imposition of appropriate sanctions.

Appendix A—Guidelines on the Application of the Definition "Handicapped Individual."

The Rehabilitation Act of 1973, as amended, defines a handicapped individual for the purposes of the program as any person who has a physical or mental impairment which substantially limits one or more of such person's major life activities, has a record of such impairment, or is regarded as having such an impairment.

"Life activties" may be considered to include communication, ambulation, selfcare, socialization, education, vocational training, employment, transportation, adapting to housing, etc. For the purpose of section 503 of the Act, primary attention is given to those life activities that affect employability.

The phrase *"substantially limits"* means the degree that the impairment affects employability. A handicapped individual who is likely to experience difficulty in securing retaining or advancing in employment would be considered substantially limited.

"Has a record of such an impairment" means that an individual may be completely recovered from a previous physical or mental impairment. It is included because the attitude of employers, supervisors, and coworkers toward that previous impairment may result in an individual experiencing difficulty in securing, retaining, or advancing in employment. The mentally restored and

those who, for example, have had heart attacks or cancer often experience such difficulty. Also, this part of the definition would include individuals who may have been erroneously classified and may experience discrimination based on this misclassification. This group may include persons such as those who have been misclassified as mentally retarded or mentally restored.

"Is regarded as having such an impairment" refers to those individuals who are perceived as having a handicap, whether an impairment exists or not, but who, because of attitudes or for any other reason, are regarded as handicapped by employers or supervisors who have an effect on the individual securing retaining or advancing in employment.

Appendix B

1. This employer is a Government contractor subject to section 503 of the Rehabilitation of Act of 1973, which requires Government contractors to take affirmative action to employ and advance in employment qualified handicapped individuals. If you have such a handicap and would like to be considered under the affirmative action program, please tell us. Submission of this information is voluntary and refusal to provide it will not subject you to discharge or disciplinary treatment. Information obtained concerning individuals shall be kept confidential, except that (i) supervisors and managers may be informed regarding restrictions on the work or duties of handicapped individuals, and regarding necessary accommodations, (ii) first aid and safety personnel may be informed, when and to the extent appropriate, if the condition might require emergency treatment, and (iii) Government officials investigating compliance with the Act shall be informed.

2. If you are handicapped, we would like to include you under the affirmative action program. It would assist us if you tell us about (1) any special methods, skills and procedures which qualify you for positions that you might not otherwise be able to do because of your handicap, so that you will be considered for any positions of that kind, and (2) the accommodations which we could make which would enable you to perform the job properly and safely, including special equipment, changes in the physical layout of the job, elimination of certain duties relating to the job, or other accommodations.

Appendix C

The following is a set of procedures which contractors may use to meet the requirement of § 60–741.5(b).

(1) The application or personnel form of each known handicapped applicant should be annotated to identify each vacancy for which the applicant was condsidered, and the form should be quickly retrievable for review by the Department of Labor and the contractor's personnel officials for use in investigations and internal compliance activities.

(2) The personnel or application records of each known handicapped employee should include (i) the identification of each promotion for which the handicapped employee was considered, and (ii) the identification of each training program for which the handicapped employee was considered.

(3) In each case where a handicapped employee or applicant is rejected for employment, promotion or training, a statement of the reason should be appended to the personnel file or application form. This statement should include a comparison of the qualifications of the handicapped appliance or employee and the person(s) selected, as well as a description of the accommodations considered. This statement should be available to the applicant or employee concerned upon request.

(4) Where applicants or employees are selected for hire, promotion or training and the contractor undertakes any accommodation which makes it possible for the contractor to place a handicapped individual on the job, the application form or personnel record should contain a description of that accommodation.

CHAPTERS 60–60 THROUGH 60–100 [RESERVED.]

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December 30, 1980

Part VII

Department of Health and Human Services

Food and Drug Administration

Recycled Animal Waste

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 500

[Docket No. 77N-0245]

Recycled Animal Waste

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its announced policy regarding the use of poultry litter as an animal feed ingredient. This will leave the regulation of the use of recycled animal waste to the individual States.

EFFECTIVE DATE: December 29, 1980.

FOR FURTHER INFORMATION CONTACT: Jack C. Taylor, Bureau of Veterinary Medicine (HFV-136), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION:

I. Introduction

Livestock and poultry producers, including egg-laying operations, accumulate large quantities of animal waste that present ecological and economic problems of disposal. The use of animal waste as a fertilizer is a partial solution to the disposal problem. A great deal of research has established that these animal wastes have nutrient value as an ingredient of certain animal feeds. Information available to FDA shows that edible products derived from animals receiving feeds containing recycled animal waste are indistinguishable from food products derived from animals receiving feeds not containing animal waste.

In the **Federal Register** of September 2, 1967 (32 FR 12714), FDA issued a statement of policy regarding the use of poultry litter as animal feed (21 CFR 500.40). It stated that FDA did not sanction the use of poultry litter as a feed or as a component of feed for animals and that poultry litter offered for animal feed use that was under the jurisdiction of the Federal Food, Drug, and Cosmetic Act would be considered adulterated within the meaning of section 402(a)(1), (a)(2)(C), and/or (a)(3) of the act. Subsequently, FDA adopted this policy for all animal waste with potential for use as an ingredient in animal feeds because the amount of information then available was not considered adequate to provide a basis for concluding that recycled animal waste is safe as a feed ingredient.

In the **Federal Register** of December 27, 1977 (42 FR 64662) (hereinafter cited as the 1977 notice), FDA issued a request for submission of data, information, and views to provide additional data regarding the use of recycled animal waste as an animal feed ingredient. The notice was in response to a growing interest in the use of animal waste as an animal feed ingredient. The 1977 notice discussed in detail the information then available to FDA including the historical development of the practice of feeding waste to animals, economic and environmental considerations, human health and aesthetics, animal health, and legal considerations.

The initial comment period, which closed June 26, 1978, was subsequently extended by FDA to September 25, 1978 by notice published in the **Federal Register** of July 28, 1978 (43 FR 32867).

Seventy-three responses were received including 28 from university researchers and administrators, 6 from State and Federal departments of agriculture, and 7 from national societies and organizations. Many of the comments included published research and research reports that added substantially to the information previously available to the agency. This information and copies of the comments may be seen in the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857 (Docket Number 77N-0245, Recycled Animal Waste).

Since publication of the agency's policy statement, extensive research has provided a great deal of additional information. The scope of additional information comprises approximately 1,000 publications in the scientific and periodical literature.

The agency concludes from its extensive review that some processing of animal waste intended for use as a feed ingredient is necessary to minimize the possibility of harmful levels of pathogenic microorganisms that may be present in the waste. Procedures that have been used successfully as practical processing methods include dehydration, ensiling, composting, physical fractionation, fermentation, heat treatment, and addition of preservative chemicals such as formaldehyde. These treatment procedures, and the extent to which some processing of waste is mandated by practical considerations (e.g., the requirement for dehydration to reduce handling costs and difficulties and to preserve the quality of dietary components) were discussed in the 1977 notice. FDA recognizes the numerous difficulties in setting microbiological standards for a nonuniform product subject to differing processing methods. Nevertheless, the agency emphasizes the need for processing for control of pathogens of all animal waste intended for use as a feed ingredient and encourages development by the State feed regulatory bodies of quality standards in this area.

The agency recognizes that there are questions concerning the composition of wastes and effects of processing on animal wastes which research has not yet answered. The development of research efforts to add to the information on the extent to which drug residues and possible drug metabolites are present and biologically available in recycled waste presents formidable research problems. Quantifying drug metabolites and residues would require major expenditures of resources, with the possibility of results being dependent upon variables such as recycling systems, feeding and management practices, processing methods, and animal species. Additional research in this area may or may not strengthen the basis for future judgments concerning safety.

As noted in the summary of the section on human health and aesthetics in the 1977 notice, the data available to FDA as a result of extensive literature review and provided in response to the 1977 notice do not resolve all the questions of safety that are raised by the possible occurrence of residues of drugs and drug metabolites in recycled waste. Moreover, it has become clear that such questions might not be answerable in the foreseeable future even if extensive research efforts were devoted solely to this purpose. Hence, the agency recognizes that it is necessary to weigh associated safety factors such as the levels likely to be fed, the consuming species and production classes of animals, the probability of practical withdrawal periods following feeding, and the overall extent of the practice of recycling animal wastes in this country in order to develop an assessment of the safety impact of such feeding practices. A number of these safety factors were discussed in some detail in the 1977 notice.

Additional relevant information was submitted pertaining to the extent to which animal waste feeding is now being practiced in the United States (Ref. *1*). The usage level has been assessed by sending questionnaires to producers and to individuals active in animal waste management in 50 States and Puerto Rico. Other questionnaires were forwarded to the Directors of the Cooperative Extension Services in land-

grant universities. Thirty-seven responses were received, and there were indications that recycled animal waste was being used for feed to some degree in 27 of the 37 states responding. The data presented (Ref. *1*), although approximate, indicate that a maximum of slightly more than 1 percent in any category of animals in production are being fed wastes as a part of their ration. The category in which the estimated usage level was approximately 1 percent was the case in which cattle waste was being fed to beef feeder cattle. From this information, it appears that the extent of use in this country of recycled animal waste as feed is very small.

II. FDA Regulatory Policy

The recycling of animal waste is primarily a local practice. The bulk and weight of the end product are such that shipment to distant places is uneconomic because of transportation costs. Thus, the use of such material is largely a local matter. For this reason, the State feed control agencies have taken the initiative in promulgating standards regarding the use of animal waste as an animal feed ingredient. Indeed, some State agencies have established programs which control the use of such waste more directly and in greater detail than would be feasible from the Federal level.

Because of the local character of animal waste use and because the States have the capacity to effectively regulate this use, FDA has decided to revoke its previous policy statement (§ 500.40 *Use of poultry litter as animal feed* (21 CFR 500.40)). The revocation of the policy statement represents a lessening of Federal regulatory intervention in favor of State control. Although FDA's regulatory action regarding recycled animal waste has been extremely limited and no enforcement actions involving this product have been brought in court, the agency believes its position should be clear. The revocation of the policy statement does not constitute a positive endorsement of the use of recycled animal waste, make any regulatory classificaiton of waste (e.g., generally recognized as safe or food additive), or represent a concession that FDA lacks authority to regulate animal waste in the future if there exists the necessary connection with interstate commerce, e.g., interstate shipment of a component. FDA is merely stepping back from its current regulatory role in the control of animal waste. If, in the future, the agency determines that the use of recycled animal waste as a feed ingredient has ceased being largely a local activity and that this practice presents risks to the health of animals or humans that are not controlled by State agencies, FDA will take an active role in the regulatory control of recycled animal waste.

The foregoing policy will not preclude FDA's taking regulatory action on an ad hoc basis against a particular shipment of animal waste that clearly presents a health hazard. Such action would likely be taken only if the State(s) involved were unable to take necessary action.

Comments from several States and the Association of American Feed Control Officials (AAFCO) argued persuasively for control at the State level and have expressed a willingness to superintend the commerce of animal waste used as a feed ingredient in a manner similar to that used for traditional feed ingredients. AAFCO has developed a Model Regulation for processed animal wastes and adopted this regulation in 1979 (Ref. *2*). AAFCO's model regulation will enhance control at the State level to the extent that the regulation and its provisions are adopted by States where the feeding of animal wastes is practiced. In addition, regulatory uniformity will be enhanced. State feed control agencies have authority to impose various sanctions against violative feed products. For example, such products may be seized and other sanctions may be imposed by a State's refusing to permit further registration or shipment of a product. Moreover, the model regulation contains a provision that requires recordkeeping for each day's production or other identifiable lot for a period of 2 years including information on the source of the animal waste, quantity produced, sales and distribution, and assay records of testing. By monitoring these records, State feed control agencies will be able to judge the degree of acceptance and volume of use of animal waste as a commercial product.

Valuable cumulative data on the quality and composition of processed animal waste products sold commercially in California have recently been made available (Ref. *3*). This publication documents California's experience since 1974 in administering that State's commercial feed license regulations regarding the sale of processed animal waste products for feed. The publication describes the procedures whereby the processing methods, quality standards, and product safety have been controlled by the State.

The AAFCO model regulation and the States with specific regulations governing animal waste usage have recognized two categories of animal wastes: (1) those that are collected from animals that have been fed drugs, or have been tested and found to contain drug residues; and (2) those that are collected from animals that have not been fed drugs, or have been tested and found to be free of drug residues. FDA recommends that this distinction between the types of animal wastes be maintained for maximum safety. FDA encourages application of future research and State-level emphasis on testing for possible drug residues in animal waste because the agency views the use of animal waste that contains possible drug residues or metabolites with greater concern than the use of that which does not. Present consideration and future research should be directed toward the presence, accumulation, and depletion of such drugs or residues including (1) whether these substances are present in the waste products, (2) whether they are in sufficient levels to be considered unsafe or transmitted to food, and (3) if present, how processing and proper management can ensure the safety of such food products.

III. Comments

1. Several comments opposed the continued use of recycled animal waste as a feed ingredient, asserting that animal waste may contain drug residues, microorganisms that could increase transmission of disease, excessive amounts of minerals, or possibly toxic end products of metabolism.

The agency recognizes that animal waste, while also a source of nutritional value, shares the other characteristics of more traditional feed ingredients in that waste may be contaminated by undesirable microorganisms through spoilage or improper processing, or may occasionally contain elevated levels of minerals or toxic contaminants. Thus, as is true for other feed ingredients, animal waste must be monitored for contaminants as well as for nutritional values. Potential contamination problems due to industrial chemicals or pesticides, for example, would be common to both the well-known animal feed ingredients such as corn and soybean meal and the less well-known byproduct feeds and animal wastes.

2. One comment (Ref. *4*) provided mineral element profiles of animal wastes and of edible tissues from cattle fed animal wastes. Samples of waste from broilers, caged layers, cattle, and swine from several regions in the United States were analyzed. Broiler litter arsenic and copper values were 54 and 441 parts per million, respectively. Dried poultry waste contained variable levels of ash, crude protein, cadmium, and

selenium. Aluminum, cadmium, and copper levels of cattle waste were higher than values reported in the literature.

Only a small amount of data on mineral content of wastes was available at the time the 1977 notice was published. The data provided by the comment are significant because they present values from a wider range of sampling than previously available. The data are directly related to and support the discussion in the 1977 notice. In that discussion, the occurrence of traces of toxic mineral elements in conventional feed constituents was described and compared with the present and potential bioaccumulation in recycled animal waste.

Excessive intake of some minerals by livestock occurs under many natural circumstances and the effect of ingestion at higher levels on tissue mineral content is variable. Levels of some minerals may be elevated in cattle waste and broiler litter when soil is incidentally included when the animal waste is collected. It has been reported that cattle may consume substantial quantities of mineral-containing soil during normal grazing, especially when grazing areas with sparse herbage (Ref. *5*). The analytical level of minerals in feeds and the degree of biological absorption often do not correspond, so quantitative mineral data on feeds are often misleading in regard to extent of absorption or toxicity (Ref. *6*). Information submitted in a separate comment (Ref. *7*) presented evidence that the mineral content of animal waste-containing diets was not a potential hazard unless the feedstuff to which the animal waste was added contained excessive levels.

Thus, the effects on animals and edible tissues of ingestion of minerals from feeding animal waste do not appear to differ from the results of ingestion of minerals contained in other feedstuffs.

3. One comment stated that an outbreak of disease in cattle in Israel in 1977 resulted from feeding poultry litter and that *Clostridium botulinum* was the suspected cause. References from Refuah Veterinarith submitted with the comment report on the followup examination of this incident in Israel, but do not conclude that the poultry litter or faulty processing of the poultry litter was the cause of the deaths (Ref. *8*). Another comment explained that the botulinum microorganism is endemic in that country, especially in southern Israel, and that this is a recurring problem with all feed ingredients, the poultry wastes presenting no more of a problem than other feeds (Ref. *8*).

In Israel, animals in some places are periodically vaccinated to prevent botulism outbreaks. A large amount of controlled testing has been carried out with animal wastes in Israel. Sterilization by heat treatment and ensiling are extensively used for processing. The officially sanctioned use of animal wastes in feedmills began in 1972. At the time of the botulism outbreak in 1977, it has been estimated that 15,000 to 18,000 tons of heat sterilized waste and 3 to 4 times this amount of ensiled and other types of poultry waste were being fed annually. After the outbreak of botulism and followup investigations, the feeding of wastes to cattle in Israel was resumed.

4. One comment submitted extensive information on the presence and survival of Leptospires in animal waste (Ref. *9*). Leptospirosis is a contagious disease of animals and man due to infection with *Leptospira spp.* Following acute infections, the organisms localize in the kidney and may be excreted in the urine for months or years. If infected shedder animals are introduced into a herd which has been free of the disease, leptospirosis is rapidly disseminated through physical contact or, by the most common mode, from contact with urine or contaminated feed or water. Control is usually achieved by fencing the herd from surface waters, by rodent depopulation, or by vaccination of animals.

Studies have been conducted on leptospiral survival in cattle manure and the possibilities of an animal health problem from this source (Ref. *9*). Specifically, information using a model oxidation ditch treatment system has been reported. In this model, hamsters susceptible to leptospiral infection were exposed to aerosols from aerated cattle manure under oxidation ditch conditions and also fed recycled feed which had been suspended in a contaminated slurry. Hamsters exposed to the ambient air of the oxidation ditch and hamsters fed the recycled feed were serologically and culturally negative to leptospiral infection. However, Leptospires were detected surviving in the model oxidation ditch for at least 136 days. Leptospires isolated from the slurry of the model oxidation ditch 17 days after seeding lost measurable virulence, so there is a possibility that the disease-transmission factor or virulence is reduced by the aerobic slurry environment.

The effects of treatment systems other than oxidation ditch methods on leptospiral pathogens are not available. Investigators are considering methods to efficiently and economically process animal wastes for disease control. For example, ensiling, deep-stacking, heat treatment, and use of chemicals have been investigated (Ref. *10*). As this problem becomes better defined, it may be possible to determine the extent to which the feeding of recycled waste contributes to the transmission of this pathogen and the extent to which transmission may differ from that accepted for land application or other means of waste disposal.

The oxidation ditch method of enhancing the protein quality of waste has been used very little, and then primarily for experimental purposes. Most pathogenic organisms do not compete effectively in an oxidation ditch (Ref. *10*), and few have been observed as health problems. Price increases of electrical power for mechanically aerated liquid manure as in the oxidation ditch method have reduced interest in the aerobic treatment of livestock manure (Ref. *11*).

5. A comment stated that further studies should be made of the male hormone content of animal waste products and of the possible adverse or beneficial effects of feeding animal waste to other animals (Ref. *12*). The comment cited research published during the years 1947 to 1956 showing that dried manure from female ruminant animals induced an androgenic response when fed to chicks. The authors suggested that progesterone might be converted by microorganisms in the rumen into androgens, since fecal androgenic activity seemed to be related to endogenous and exogenous progesterone metabolism. Parallel studies have been conducted (Ref. *13*) to determine the kind and amount of hormonal activity present in poultry excreta processed for use as livestock feed. These more recent studies indicated that caged laying hen excreta under certain processing conditions contained androgenic activity that ranged from 2.2 to 7.4 micrograms of testosterone equivalents per gram of dried excreta. This activity was not present in fresh excreta. The information reported suggests that a metabolite may be converted to androgens by bacteria in the manure, and that the androgenic activity is not eliminated by subsequent heating.

In the years since the early work was reported there has been very little information on the subject of hormonal activity in waste, and no additional information was supplied by the comments submitted in response to the agency's request for data, information, and views. Hormonal activity was not, however, identified as a problem in

reviews of the health aspects of feeding animal waste (Refs. *14* and *15*) or in the numerous research articles received by the agency during the comment period. The early research has apparently not been confirmed with regard to practical significance. The agency is unable to conclude from the information in this comment or from the information submitted to the agency that there is a safety problem due to androgenic activity in waste.

6. A comment expressed concern that avian tuberculosis could be transmitted to swine as a result of swine coming into contact with chicken excreta (Ref. *16*). The comment referenced supporting documentation (Ref. *17*) printed since publication of the agency's 1977 notice. The supporting documentation did not specifically refer to poultry waste, but to the general subject of disease transfer to swine.

Relevant information on disease-producing bacteria in animal waste was discussed in the 1977 notice. Limited information concerning processing that would inactivate mycobacteria was referenced. In addition, the general discussion in the 1977 notice of microbiological contamination as related to human health is applicable. The concerns of the agency in regard to proper processing of animal waste that may be recycled were expressed as a part of that discussion.

Information recently received by the agency from the United States Department of Agriculture (Meat and Poultry Inspection, Food Safety and Quality Service) indicates that the rate of condemnation due to avian tuberculosis in mature poultry (includes both heavy and light hens) has been 0.01 percent or less in recent years; the disease has therefore practically been eradicated from national flocks. Lesions of this disease are not found at all in broiler chickens which constitute by far the largest portion of commerical flocks in this country.

In any event, as explained in the 1977 notice, the feeding of waste from chickens to swine would typically never occur, or occur only rarely, since the uric acid nitrogen in the chicken waste is not useable by swine. Because of the high fiber content and the nonprotein nitrogen in poultry waste, the material can readily be used by ruminants, but not by nonruminants. Swine, as nonruminants, require a source of preformed protein for efficent utilization of feed ingredients.

The agency concludes that the potential for infection of swine with mycobacteria from properly processed chicken waste is small. Research projects are underway, however, to investigate the degree of freedom from microbiological contamination that can be achieved by ensiling and other processing methods (Ref. *18*).

7. One comment stated that there were questions concerning transfer of R-plasmids in enteric microorganisms when animal waste was recycled (Ref. *19*).

Experimental studies which relate the effect of recycling animal waste to antibiotic resistance in enteric bacteria are not known to the agency. Animal wastes may contain antibiotics, as described in FDA's 1977 notice, because a large percentage of all animal feeds contain antibiotics which are included to increase the rate of weight gain and to improve feed efficiency.

It is recognized that plasmid-mediated or R-factor resistence is the most significant form of antibiotic resistance. In the 1977 notice, the agency did not discuss R-factor resistance in relation to antibiotics in animal wastes because the circumstance of antibiotic resistance appears to involve the entire spectrum of animal feeding as well as human and animal therapeutic treatment. It was not, therefore, considered to be particularly related to animal waste utilization.

No information has been has received since 1977 which would lead the agency to conclude that the presence of such antibiotics or possibly antibiotic-resistant bacteria in animal waste would present any more of a problem than is usual in mixed feeds for animals, which may contain similar amounts of antibiotics and antibiotic-resistant organisms (Refs. *20* and *21*).

8. One comment noted that there was an incorrect entry on page 64669 of the 1977 notice, that the statement, "data collected indicated that treatment of cattle waste with 0.74 percent formaldehyde solution destroys microbial activity and prevents mold growth for a *minimum of 3 months*" should read "* * * prevents mold growth for *up to 3 months.*"

The agency agrees with the comment which is supported by reference number 5 cited in the 1977 notice. Because the statement as published in the **Federal Register** was only one of many in the broad discussion of numerous preservation and treatment techniques, it would not materially alter the general nature of the discussion or any subsequent agency conclusions concerning the subject.

References.

1. Comment C–21, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the **Federal Register** of December 27, 1977; 42 FR 64662. Survey of extent of use of animal waste feeding in the United States. Hewins, S. O., *Health and Other Considerations of Animal Refeeding as an Alternative to Animal Waste Disposal*, M.S. Thesis, University of North Carolina, Chapel Hill, 143 pp., 1977.

2. Association of American Feed Control Officials, Inc., Official Publication, pp. 198–201, 1979.

3. Helmer, J. W., "Monitoring the Quality and Safety of Processed Animal Waste Products Sold Commercally as Feed," *Journal of Animal Science*, 50(2):349, 1980.

4. Comment RPT–03, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the **Federal Register** of December 27, 1977; 42 FR 64662. Information on Mineral Element Profiles of Animal Wastes and Edible Tissues from Cattle Fed Animal Wastes.

5. Thornton, I., "Biogeochemical and Soil Ingestion Studies in Relation to the Trace-element Nutrition of Livestock," *in* W. G. Hoekstra, J. W. Suttie, H. E. Ganther and W. Mertz (Eds.), *Trace Element Metabolism in Animals–2*, University Park Press, Baltimore, 1974.

6. Underwood, E. J. *Trace Elements in Human and Animal Nutrition*, 4th ed., Academic Press, New York, pp. 1–12, 472–478, 1977.

7. Comment C–41, received in response to Recycled Animal Waste, Request for Data, Information, and Views published in the **Federal Register** of December 27, 1977; 42 FR 64662. Comment comparing mineral content of recycled animal waste and original feedstuffs.

8. Comments C–37, C–49, and RPT–07, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the **Federal Register** of December 27, 1977; 42 FR 64662. Information on a botulism outbreak in Israel.

9. Comment REF–02, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the **Federal Register** of December 27, 1977; 42 FR 64662. Information concerning the survival of pathogens in animal manure; Environmental Protection Agency Report 660/2–75–012.

10. Day, D. L. and B. G. Harmon, "A Recycled Feed Source from Aerobically Processed Swine Wastes." *Transact. American Society of Agricultural Engineers*, 17(1):82, 1974.

11. Comments C–33 and C–42, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the **Federal Register** of December 27, 1977; 42 FR 64662. Information submitted on aerobic processing by oxidation ditch methods.

12. Comment C–27, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the **Federal Register** of December 27, 1977; 42 FR 64662. Information and research article citations concerning hormonal activity in cattle waste.

13. Calvert, C. C., L. W. Smith, and T. R. Wrenn, "Hormonal Activity in Poultry Excreta Processed for Livestock Feed," Poultry Science, 57(1):265, 1978.

14. Fontenot, J. P. and K. E. Webb, "Health Aspects of Recycling Animal Wastes by

Feeding," *Journal of Animal Science*, 40:1267, 1975.

15. Bhattacharya, A. N. and J. C. Taylor, "Recycling Animal Waste as a Feedstuff," *Journal of Animal Science*, 41(5): 1438, 1975.

16. Comment MT–01, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the **Federal Register** of December 27, 1977; 42 FR 64662. Telephone communication concerning tuberculosis in swine.

17. Baker, R. (ed.), "Tuberculosis" *Maryland Agri-Views*, Maryland Department of Agriculture, Annapolis, Vol. 5, No. 1, p. 1, August 1978.

18. Comment RPT–04, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the **Federal Register** of December 27, 1977; 42 FR 64662. Information on research plans of S–139 Regional Technical Committee in regard to animal health and food safety aspects of feeding animal wastes.

19. Comment C–22, received in response to Recycled Animal Waste, Request for Data, Information, and Views, published in the **Federal Register** of December 27, 1977; 42 FR 64662. Comment relating concern about transfer of R-plasmids in microorganisms.

20. Hartley, C. L., K. Howe, A. H. Linton, K. B. Linton, and M. H. Richmond, "Distribution of R-Plasmids Among the O-Antigen Types of *Escherichia coli* Isolated from Human and Animal Sources," *Antimicrobial Agents and Chemotherapy*, 8:122–131, 1975.

21. Huber, W. G., D. Korica, T. P. Neal, P. R. Schnurrenberger, and R. J. Martin, "Antibiotic Sensitivity Patterns and R-Factors in Domestic and Wild Animals," *Archives of Environmental Health*, 22:561–567, 1971.

IV. Environmental Impact

The agency has determined pursuant to 21 CFR 25.24 (b)(5) and (b)(11) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

§ 500.40 [Removed]

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 402(a) (1), (2)(C), and (3) and 701(a), 52 Stat. 1046 as amended, 52 Stat. 1055 (21 U.S.C. 342(a) (1), (2)(C), and (3) and 371(a))) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 500 is amended by removing §500.40 *Use of poultry litter as animal feed.*

Effective date. This revocation is effective December 29, 1980.

(Secs. 402(a) (1), (2)(C), and (3) and 701(a), 52 Stat. 1046 as amended, 52 Stat. 1055 (21 U.S.C. 342(a) (1), (2)(C), and (3) and 371(a)))

Dated: December 17, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80–40282 Filed 12–26–80; 8:45 am]

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federal register

Tuesday
December 30, 1980

Part VIII

Environmental Protection Agency

Pressure Sensitive Tape and Label Surface Coating Operations; Standards of Performance for New Stationary Sources; Public Hearing and Proposed Rulemaking

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[AD-FRC 1533-8]

Standards of Performance for New Stationary Sources; Pressure Sensitive Tape and Label Surface Coating Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule and Notice of Public Hearing.

SUMMARY: Standards of performance are proposed to limit the emission of volatile organic compounds (VOC) from new, modified, or reconstructed pressure sensitive tape and label (PSTL) manufacturing facilities. Emissions would be limited to 0.20 kilograms of VOC per kilogram of coating solids applied for each affected coating line as measured by Reference Methods 24 and 25 (promulgated in the **Federal Register** on October 3, 1980 45 FR 65956). As an alternative, the owner or operator may demonstrate either a 90 percent overall VOC emission reduction or an overall percent emission reduction which is equivalent to the 0.20 kilograms per kilogram of coating solids applied level, whichever is less stringent. This overall reduction is based on the amount of solvent applied with the coating solids.

The proposed standards implement Section 111 of the Clean Air Act and are based on the Administrator's determination that industrial paper coating facilities contribute significantly to air pollution which may reasonably be anticipated to endanger public health or welfare. Pressure sensitive tape and label manufacturing is one of the largest contributors to air pollution in the industrial paper coating category. The intended effect of this proposal is to require new, modified, and reconstructed pressure sensitive tape or lable manufacturing facilities to use the best demonstrated system of continuous emission reduction, considering costs, nonair quality health, and environmental and energy impacts.

A public hearing will be held to provide interested persons an opportunity for oral presentation of data, views, or arguments concerning the proposed standards.

DATES: *Comments.* Comments must be received on or before March 2, 1981.

Public Hearing. A public hearing will be held on January 30, 1981 (about 30 days after proposal) beginning at 9 a.m.

Request to Speak at Hearing. Persons wishing to present oral testimony should contact EPA by January 23, 1981.

ADDRESSES: *Comments.* Comments should be submitted (in duplicate if possible) to: Central Docket Section (A-130), Attention: Docket Number A-79-38, U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

Public Hearing. The public hearing will be held at OA Auditorium EPA, R.T.P. North Carolina. Persons wishing to present oral testimony should notify Mrs. Naomi Durkee, Standards Development Branch (MD-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5331.

Background Information Document. The Background Information Document (BID) for the proposed standards may be obtained from the U.S. EPA Library (MD-35), Research Triangle Park, North Carolina 27711, telephone number (919) 541-2777. Please refer to "Pressure Sensitive Tape and Label Surface Coating Industry, Background Information Document for Proposed Standards, "EPA-450/3-80-003a.

Docket. Docket Number A-79-38, containing supporting information used in developing the proposed standards, is available for public inspection and copying between 8 a.m. and 4 p.m., Monday through Friday, at EPA's Central Docket Section, Room 2902, Waterside Mall, 401 M Street SW., Washington, D.C. 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Mr. Gene W. Smith, Standards Development Branch, Emission Standards and Engineering Division (M-13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-5421.

SUPPLEMENTARY INFORMATION:

Proposed Standards

The proposed standards would apply to new, modified, and reconstructed adhesive, release, and precoat coating lines used in the manufacture of PSTL. The emission of VOC would be limited to 0.20 kilograms per kilogram of coating solids applied. As an alternative, the owner or operator may demonstrate either a 90 percent overall VOC emission reduction or an overall percent emission reduction which is equivalent to the 0.20 kilograms per kilogram of coatings solids applied level, whichever is less stringent. Compliance will be determined over a calendar month averaging period by Reference Method 24. Reference Method 25 will be used to performance test coating lines controlled by incineration systems. Coating lines which emit no more than 125 kilograms of VOC per day and 15 megagrams of VOC per year are not subject to the emission limits of the proposed standard. If either the daily or yearly limit is exceeded, the coating line will become subject to the proposed emission limit of 0.20 kg VOC per kg coating solids applied. If the daily or yearly limits are not exceeded an affected facility is only subject to the recordkeeping and reporting requirements of the proposed standard.

The proposed standards are based on an overall VOC emission reduction. The overall reduction is calculated by multiplying the operational efficiency of the control device (carbon adsorbers or incinerators) by the operational efficiency of the vapor capture system (hooding or enclosures). The resultant efficiency is the overall VOC emission reduction achievable by a coating facility.

The proposed standard allows for compliance by using either low-solvent coatings or add-on control equipment. Carbon adsorption and thermal incineration control systems are capable of meeting the proposed standard. Generally, hot melt and waterborne adhesive coatings and 100 percent solid and waterborne release coatings would comply with the proposed standard because they would contain less than 0.20 kilograms of VOC per kilogram of coating solids applied.

Summary of Environmental, Energy, and Economic Impacts

The environmental, energy, and economic impacts of a new source performance standard (NSPS) are expressed as incremental differences between the impacts for facilities complying with the proposed standard and for those complying with a typical State Implementation Plan (SIP) emission standard. Most existing PSTL surface coating operations are located in areas which are considered nonattainment areas for purposes of achieving the National Ambient Air Quality Standard (NAAQS) for ozone. New facilities are expected to locate in similar areas. For the purpose of this analysis it is assumed that states have adopted or will adopt the recommended guidelines in the control techniques guideline (CTG) document, "Control of Volatile Organic Emissions from Existing Stationary Sources—Volume II: Surface Coating of Cans, Coil, Paper, Fabrics, Automobiles and Light-Duty Trucks" (EPA-450/2-77-008 [CTG]). The States, however, are not legally bound to adopt the recommended emission

limits of the CTG document. In this analysis the CTG limits were used as a comparison baseline because they reflect the control level most likely to be instituted in the states' air pollution control regulations (State Implementation Plans).

Compared to emission control levels recommended in the CTG document, the proposed standards of performance would further reduce emissions of VOC from new, modified, or reconstructed pressure sensitive tapes and labels manufacturing operations by about 16 percent in 1985. National emissions of VOC would be reduced by about 4,300 megagrams (metric tons) per year in 1985.

National wastewater discharges would be 13 percent greater than those occurring from plants controlled to the CTG level. National discharges of wastewater would increase in 1985 by about 2.5 million liters (661,000 gallons) as a result of the 13 percent change. This increase is reasonable in light of the nationwide reduction in VOC emissions being achieved.

The solid waste impact of the proposed standards would be small compared to the amount of solid waste generated by the daily production operations of a PSTL coating facility. A coating facility can generate large quantities of solid waste consisting of flawed coated products, imperfect face stock, substandard release paper, empty cartons, and spools. The only additional solid waste from a controlled facility is spent activated carbon from carbon adsorption units. In 1985 the maximum expected increase in national solid waste as a direct result of the NSPS would be about 55 megagrams (metric tons). The proposed standard is reasonable despite this solid waste increase.

The national energy impact would be dependent on whether the majority of new solvent-based coating lines used incineration, carbon adsorption, or low-solvent coatings for VOC control purposes. Because the Agency is unable to predict with certainty the fraction of new facilities which will use each of these technologies, this analysis is performed on the two technologies—carbon adsorption and incineration—which would result in the extreme impacts. The best case energy situation would result if all lines used carbon adsorption. If, in 1985, all solvent-based lines used carbon adsorption controls, a potential net national energy savings equivalent to 27,100 barrels (4.3 million liters) of crude oil per year is projected. A savings is possible because of the large credit received for usable recovered solvent. The worst case energy situation would occur if all solvent-based coating lines used incinerators to control VOC emissions. All solvent would be destructed and no recovery value could be obtained. A potential national energy demand of 31,000 barrels (4.9 million liters) of crude oil for VOC control is estimated. The proposed standard is reasonable even taking into account the worst case energy estimate.

The proposed standards would have minimal economic impact on the PSTL industry. The maximum expected price increase necessary to offset the impact of the proposed standards would be 0.9 percent. Nationwide in 1985, the anticipated incremental annualized cost of compliance, including depreciation and interest, would be $2.6 million. Effects on growth, industry structure, and profitability would not cause significant inflationary impacts or market withdrawals.

In addition to emission reductions beyond those achieved by a typical SIP, standards of performance have other benefits. They establish a degree of national uniformity to avoid situations in which some States may attract industries by relaxing air pollution standards relative to other States. Further, standards of performance improve the efficiency of case-by-case determinations of best available control technology (BACT) for facilities located in attainment areas, and lowest achievable emission rates (LAER) for facilities located in nonattainment areas, by providing a starting point for these determinations. This results from the process for developing a standard of performance, which involves a comprehensive analysis of regulatory alternatives. Detailed cost and economic analyses of various regulatory alternatives are presented in the supporting documents for the proposed standards.

Rationale

Selection of Source

The "Priority List and Additions to the List of Categories of Stationary Sources for New Source Performance Standards under the Clean Air Act Amendments of 1977", promulgated at 44 FR 49222 on August 21, 1979, ranked sources according to the impact that the standards promulgated in 1980 would have on emissions and public health in 1990. The paper coating industry ranked fourth on this list of 59 sources to be controlled for air pollutants. The manufacture of pressure sensitive tapes and labels is the largest organic solvent-using segment of the paper coating industry.

Approximately 80 percent of all pressure sensitive tapes and labels are coated with organic solvent-based coatings. All but a very small percentage of this solvent is emitted during the manufacturing process. The pressure sensitive tape and label surface coating source consists of any rollcoating operation which applies pressure sensitive adhesives, release coatings or precoats on a continuous web material. Decals and adhesive specialty products are included in the definition of pressure sensitive tapes and labels because plant visits and industry literature showed that the manufacturing operations and coating formulations for all of these products are similar.

In 1978 nationwide emissions of VOC from the pressure sensitive tape and label industry were estimated at 600,000 megagrams (metric tons). This estimate was based on PSTL industry production data and typical formulation data. Very few of these emissions were controlled by State regulations.

Selection of Pollutants and Affected Facilities

VOC are the primary air pollutants emitted from pressure sensitive tape and label surface coating operations. VOC along with nitrogen oxides are precursors to the formation of ozone and oxygenated organic aerosols (photochemical smog). Ozone and oxygenated organic aerosols result in a variety of adverse impacts on health and welfare, including impaired respiratory function, eye irritation, deterioration of materials such as rubber, and necrosis of plant tissue. Further information on these effects can be found in the April 1978 EPA document "Air Quality Criteria for Ozone and Other Photochemical Oxidants", EPA–600/8–78–004. This document can be obtained from the EPA Library (MD–35), Research Triangle Park, North Carolina 27711, telephone number (919) 541–2777.

Solvent drying ovens are potentially a source of pollutants other than VOC (for example NO_x, SO_2, and particulates). The drying ovens are operated with electricity, indirect heat sources, or direct-fired burners. The electrical ovens do not add to the pollutants expected at the source. The indirect-heated ovens are usually steam-tube heaters with an on-site steam boiler. Control of the boiler emissions is being examined by EPA in a separate strdy of industrial boilers.

Generally, natural gas or liquid petroleum gas is used in the direct-fired heaters. Coal and fuel oil are not used because fly ash material in the oven gases can adversely affect the expected

tape or label quality. The SO_2 emissions rate from the combustion of natural gas is very low. Also, the relatively low temperature environments in the direct-fired burners would result in low NO_x emissions.

Based on their overall volume magnitude and their severity as an air pollutant problem, VOC emissions would be the only pollutants regulated by this standard.

For the purposes of this standard, a single coating line, consisting primarily of an adhesive, release, or precoating head, a drying/curing oven, and the flashoff area between the coating head and oven, if defined as the affected facility. For systems which have tandem coating facilities, each individual coating line would be considered as an affected facility. A tandem coating facility is one which coats releases and adhesives in series on one line.

The choice of the affected facility for this standard is based on the Agency's interpretation of Section 111 of the Act, and judicial construction of its meaning.* Under Section 111, the NSPS must apply to "new sources"; "source" is defined as "any building, structure, facility, or installation which emits or may emit any air pollutant" (Section 111(a)(3)). Most industrial plants, however, consist of numerous pieces or groups of equipment which emit air pollutants, and which might be viewed as "sources." EPA therefore uses the term "affected facility" to designate the equipment, within a particular kind of plant, which is chosen as the "source" covered by a given standard.

In choosing the affected facility, EPA must decide which pieces or groups of equipment are the appropriate units for separate emission standards in the particular industrial context involved. The Agency must do this by examining the situation in light of the terms and purpose of Section 111. One major consideration in this examination is that the use of a narrower definition results in bringing replacement equipment under the NSPS sooner; if, for example, an entire plant were designated as the affected facility, no part of the plant would be covered by the standard unless the plant as a whole is "modified." If, on the other hand, each piece of equipment is designated as the affected facility, then as each piece is replaced, the replacement piece will be a new source subject to the standard. Since the purpose of Section 111 is to minimize emissions by the application of the best demonstrated control technology (considering cost, other health and environmental effects, and energy requirements) at all new and modified sources, there is a presumption that a narrower designation of the affected facility if proper. This ensures that new emission sources within plants will be brought under the coverage of the standards as they are installed. This presumption can be overcome, however, if the Agency concludes that the relevant statutory factors (technical feasibility, cost, energy, and other environmental impacts) point to a broader definition. The application of these factors is discussed below.

Designation of the entire coating operation from unwind to rewind as an affected facility was also considered. Such a designation would allow those sources that achieve highly effective control on some coating sections (of a single coating line) to provide less control on other sections, so long as the aggregate emissions from the coating line are less than or equal to those allowed under the proposed standard. The proponents of a broader designation of affected facility (as the operation from unwind to rewind) believe it would provide additional incentive to industry for the innovative use of low-solvent technology in processes where it is not currently available.

Based on currently available information, EPA believes that the cost and energy savings already associated with using low solvent technology are so great that any additional incentive derived through the use of the broader designation of affected facility will have little or no impact on the rate of innovation. If this is true, the proposed designation of affected facility would give more total emission reduction than the alternative broader designation because the low-solvent materials would be used regardless and the other sections of the coating line would still have to be fully controlled with a capture system and a control device.

In order to promulgate the broader designation, EPA would have to find that it would achieve greater total emission reductions or equivalent total reductions with significant other benefits such as reduced costs, energy consumption or other environmental impacts. EPA solicits comments on this issue.

Persons urging consideration of the alternative broader designation should specifically address the issue of how much additional incentive (or disincentive) the designation of affected facility is likely to provide for an owner or operator's decision to use low-solvent coatings. Where possible the comments should present an economic and environmental analysis to support the position taken.

New coating lines which do not discharge into the atmosphere more than 125 kilograms of VOC per day or 15 megagrams of VOC per year would not be subject to the emission limits of the proposed new source standard. A major factor influencing the institution of these limits was PSTL industry comment concerning the treatment of research and development (R&D) coating lines. The industry felt that R&D lines should not be subject to the same emission limits as a production facility. Upon examination of these operations, the EPA determined that: the cost to control R&D emissions would be high, the achievable emissions reduction would be minimal, and normal production coating lines would operate well above the stated daily and yearly limits. For these reasons the exemption limits were developed. The limits were based on industry information concerning R&D operations. The exemption limits, however, apply to all new, modified, or reconstructed coating lines, and not just to R&D facilities. If either the daily or yearly limit is exceeded, the coating line would be subject to all the requirements of the proposed standard. If the exemption limits are not exceeded, the owner or operator must only record solvent usage at the coating line and report it to the Administrator.

The daily and yearly exemption limits are based on data received from tape and label companies on their R&D facilities and on the model plant analysis in Chapter 6 of the BID Manufacturers in the tape and label industry have indicated that 61 cm (24 in) coaters are very popular for use in R&D projects. This size corresponds to the small size model plant in the BID analysis. Industry sources also stated that R&D coaters, when used, only run about two hours a day. The model plant analysis determined that a 61 cm coater will use, on the average, about 29 kg (64 lb) of solvent per hour. A typical PSTL facility will then consume about 58 kg (128 lb) of solvent per day for R&D purposes. Taken on an annual basis, this translates to about 15 megagrams of solvent for a facility operating 6000 hours a year. The EPA feels this number is reasonable because industry sources proposed exemption emission limits of 5 to 10 megagrams per year for R&D coating lines.

Manufacturers also indicated that R&D projects are run for more than two hours a day in some cases. These cases occur when larger quantities of material are needed for quality testing and marketing purposes. Industry sources

*The most important case if *ASARCO, Inc.* v. EPA, 578 F. 2d 319 (D.C. Cir. 1978).

estimated that one-half a day or 4 hours is usually sufficient for these R&D coating situations. Based on this information and the model plant figures, the daily emission limit of 125 kg (275 lb) was calculated and determined to be reasonable. The level of the daily limit allows coating firms greater flexibility in their R&D operations.

The affected facility was chosen to incorporate the primary sources of VOC emissions from PSTL coating. The drying/curing oven represents the major source of VOC emissions within the affected facility. The coated web is heated in the oven where 80 to 95 percent of the solvent is evaporated and vented either to the atmosphere or to a control device. These oven emissions can be effectively controlled by ducting them so they discharge to the atmosphere through either a carbon adsorption or a thermal incineration system. One to eighteen percent of the total applied solvent escapes as fugitive emissions and zero to five percent ends up trapped in the final coated product. The area from the coating head to the entrance of the oven is potentially the highest source of fugitive VOC emissions. Hoods or enclosures can be used in this area to effectively capture fugitive emissions. Once captured the fugitives may be ducted to either the oven or to a control device.

Other equipment such as wind and rewind stations are a part of the affected coating line, but are not VOC emission sources. VOC emissions from formulation, storage, and cleanup operations are not included in this regulation. These emissions are not being regulated at this time because: (1) Formulation emissions are already controlled to low levels due to occupational safety reasons and (2) the solvent cleanup emissions are generally low concentration, low volume sources which are very difficult to capture and control.

Selection of Basis of Proposed Standards

This section describes the emission control technology applicable to the PSTL industry and the regulatory alternatives considered by EPA in the development of this standard. Included is a summary of the environmental, energy, and economic impacts, and nonair quality health impacts of the aternatives and a description of the basis of the proposed standards.

Control Technologies. Available control technologies for reducing VOC emissions from PSTL facilities include the use of low-solvent coatings or an emission capture and control system. Low-solvent coatings provide the best environmental alternative for reducing VOC emissions. By 1985, it is estimated that 80 percent of all pressure sensitive coatings will be low-solvent-type coatings. These alternative coatings are available for both adhesives and releases and can be purchased as waterborne, emulsion, or 100 percent solids formulations. Advantages of these coatings include low cost, low energy use, good viscosity even at a high solids content, and negligible air pollution, toxicity, or fire hazards. However, low-solvent coatings are not technologically advanced to the point where they can be interchanged with all solvent-based formulations. Major technical problem areas for low-solvent coatings include cohesive strength, solvent resistance, UV degradation, wettability, and dimensional stability. The added difficulty of total customer acceptance further reduces the range of product substitutability for low-solvent coatings. Because low-solvent coatings cannot be applied in all cases, they cannot be used as the sole basis for the proposed standard.

Carbon adsorption and thermal incineration used in conjunction with emission capture systems have both been used as control devices to reduce VOC emissions from pressure sensitive tape and label coating facilities. Available performance data indicate that the two devices are equivalent in reducing VOC emissions. Although both control devices have experienced operating problems, it has been demonstrated that they can be successfullly used. Two of the problems are: (1) Poor control performance on low VOC concentration gas streams and (2) plugging or fouling problems resulting from volatilization of oligomeric adhesive and release materials. Both of these problems can be reduced or eliminated through proper design and operation of drying ovens and the control devices to the extent that a facility will comply with the proposed standard.

A thermal incinerator is an effective VOC emission control device for all types of solvents. Thermal incinerators operating at temperatures greater than 760°C (1400°F) have demonstrated the ability to achieve at least 95 percent reduction of all VOC in the incinerator feed. The EPA document, "Control of Volatile Organic Emissions from Existing Stationary Sources—Volume I: Control Methods for Surface Coating Operations" (EPA–450/2–76–028), verifies that this level of reduction is achievable. Catalytic incineration has also been demonstrated, in the same EPA document, to be capable of achieving at leat 95 percent efficiency in reducing VOC from an inlet feed stream. Chapter 4 of the BID examines the use of catalytic incineration for PSTL plants. However, the primary incineration focus in this rationale was devoted to thermal incineration, because no catalytic incineration was found in use in PSTL facilities for VOC emissions control.

Thermal incineration is most cost effective when heat exchange equipment is used to recover the heat from the combustion of the solvent and any additional fuels. At 40 percent of the lower explosive limit (LEL), the implementation of primary (preheating of the incinerator feed gases) and secondary heat recovery could supply the primary and secondary heat requirements for one coating line and the secondary requirements for another line. At the very least, primary heat recovery should be included in new incinerator design. Additional heat can be easily recovered and used as heat energy for work area space heating.

The question of LEL is important for safety and economic reasons. The LEL is the lowest vapor concentration in air, expressed as volume percent, at which the mixture would support a flame or explosion at temperatures below 121°C (250°F). Insurance safety regulations require normal operation at less than about 25 percent of the LEL. Operation up to 50 to 60 percent of the LEL is permitted when continuous vapor monitoring systems are employed to control the vapor concentration in the air. The operation of an incinerator at higher LEL values is cost effective because less supplemental fuel is required. While optimal, operating at high LEL levels is not always possible in every coating facility. Factors such as poor coating line design, operation at slow line speeds, and stream dilution by excess ventilation air may limit the achievable LEL. Occupational Safety and Health Administration (OSHA) rules may require excess ventilation air in some facilities to meet certain maximum solvent concentrations in the worker area.

Heat exchanger fouling has been one of the greatest problems with incineration systems. This is especially true in silicone release and adhesive systems. The silicone monomers which volatilize are oxidized in the incinerator and coat the heat exchanger surfaces as a silica material. Operating experience has indicated that routine heat exchanger surface cleanup is required for proper incinerator operation. The experience of one manufacturer with this type of system and these operating

problems is detailed in Chapter 4 of the BID.

The second means of effectively controlling VOC emissions from pressure sensitive tape and label coating lines is carbon adsorption. Several plants in the industry presently use this technology with success. Test data from PSTL plants and self-monitoring data supplied by PSTL manufacturers have indicated that operational efficiency levels of at least 95 percent or greater are attainable with carbon adsorbers. For the purposes of this analysis, carbon adsorbers were assumed to be 95 percent efficient in reducing VOC emissions. This efficiency level has been attained in PSTL facilities despite the occurrence of problems such as: bed fires, carbon fouling, freeze damage, corrosion, and low LEL inlet streams. Carbon adsorption systems are generally regenerated with steam, although any hot, non-reactive gas can be used to strip the beds. If steam is used, the carbon adsorption system is generally limited to solvents which are not water soluble (unless the operator uses add-on distillation or separation processes). All systems currently operating on PSTL coating lines in the United States use steam for carbon bed regeneration. Fouling of the carbon beds by volatilized adhesives and releases is a recurring operational problem. This problem can be adequately reduced by filtering the feed gas before it enters the carbon beds. Again silicone materials are a greater problem than the adhesive resins. Generally carbon beds on silicone coating lines are changed twice as often as beds on rubber or acrylic resin coating lines.

Low VOC concentration gas streams (less than 10 percent LEL) are a problem for both carbon adsorption and incineration VOC control equipment. In incinerators the low concentration gas stream will require much more fuel to incinerate the same amount of solvent gases as in a high concentration stream. The higher fuel usage will mean higher operating costs. Data from existing PSTL facilities demonstrate that the attainment of a 90 percent overall VOC emission reduction, on a monthly basis, is possible at less than 10 percent LEL.

For carbon adsorption systems, the low VOC concentration means poor bed performance. The beds are usually designed for a certain maximum VOC concentration based on a desired outlet VOC concentration. Operating experience has shown that at low solvent concentrations the performance of the bed decreases resulting in a lower overall VOC reduction. Higher gas stream, VOC concentrations can be maintained through design of drying ovens with high turn down ratios and air tight gas ducting systems. Operators can also minimize the low VOC concentration problem by, whenever possible, coating products with similar solvent loadings on the same coating line.

The use of hoods or enclosures can be an effective means for capturing fugitive solvent emissions around the coater area. Fugitive solvent is that solvent which is emitted from the coating applicator and flashoff areas. The hood can be located directly over the web to capture vapors released from the coated surface. In small lines the time interval between when the web is coated and when it enters the oven is about two to five seconds. In large and medium lines the interval is two seconds or less. Since most solvents are heavier than air, floor seeps and hooding under the web can also be used to effectively capture emissions. The ideal situation is to totally enclose the coater and get an effective 100 percent VOC capture. When a hood or enclosure is used, all of the captured fugitive solvent emissions should be ducted back into the system and the control device. If the captured gases are used as makeup air to the ovens, the dilution of the oven gases is minimized.

Presently no total enclosure structures are used in the pressure sensitive tape and label industry. However, when surveyed, firms engaged in similar coating operations (for example, zinc oxide paper coating) responded favorably concerning the use of totally enclosed coaters. No problems related to enclosure use were given. In addition to environmental benefits, occupational safety concerns were also given as a reason for enclosure use. Enclosures were useful in reducing VOC levels along the floor and in the general work area around the coater, thereby lessening any potential explosion hazards.

In the tape and label industry one firm does operate a total building air evacuation system. This system removes all air from the coating building and sends it to a carbon adsorber. In effect the plant operates a total building enclosure. Calculations on the overall efficiency of this system indicate that a solvent capture efficiency of 95 percent is being obtained.

The best controlled coating operating examined in the tape and label manufacturing industry has four coating lines controlled by one carbon adsorption unit. Three of the lines are 0.71 meters (28 inches) wide and one line is 1.4 meters (56 inches) wide. The company produces a wide variety of label stock materials. Their operations are typified by short products runs (less than four hours), varied line speeds, and varied solvent-adhesive mixtures. These operating conditions make this facility a more difficult control situation than operations which run on a continuous basis. Over a four week period this system has shown an overall solvent recovery efficiency of slightly greater than 93 percent. During that time the company performed 140 runs and used such solvents as toluene, acetone, hexane, ethyl acetate, methyl ethyl ketone, rubber solvent, heptane, xylene, ethyl alcohol, isopropanol and recovered solvents. The coating lines use hoods to capture VOC emissions over the freshly coated web. The hoods are ducted into the ovens. The oven makeup air is pulled from the coater room with the ovens running at a slightly negative pressure with respect to the room. The overall effect is to draw all fugitive emissions into the oven with their eventual discharge through the carbon adsorption system. This plant demonstrated that high VOC reductions can be achieved even with low VOC concentration streams. During this four week recovery period the LEL in the system was less than ten percent.

A second tape coating facility with a carbon adsorption control system has a near 90 percent overall reduction. This system has hoods over the coating areas; however, all hood gases are vented directly to the atmosphere. Test data indicate that if the solvent vapors captured by the hoods are ducted back into the ovens the system would show a greater than 90 percent overall VOC reduction. Further data from this plant indicated an average overall VOC reduction of 90 percent for the entire year of 1979. The overall reduction for most of the calendar months was 90 percent or more. In the latter part of the year the overall reduction dropped below 90 percent on a monthly basis. This drop occurred because the carbon life of the control device had been exceeded by several months. With the installation of new carbon the overall reduction efficiency once again reached 90 percent or more. Through April of 1980 an average overall VOC reduction of about 94 percent has been attained.

Regulatory alternatives. The regulatory alternatives considered in developing the standard are based on the methods available to control the VOC emissions from the PSTL industry. In this industry the two primary emission sources are the oven exhausts and fugitives, with the oven exhausts being the more significant source. Therefore, the regulatory alternatives

are designed to control: (1) The oven emissions only or (2) the oven and fugitive emissions together.

Regulatory Alternative I is a no additional regulation alternative. This alternative represents what could happen if no NSPS were written and new sources were regulated by the SIP regulations. The recommended guideline for the SIP regulations represents a system which captures 90 percent of all volatilized solvents and then destroys or recovers 90 percent of those emissions. The overall reduction of VOC emissions from all affected facilities would be about 80 percent. The Alternative I control level is the baseline of comparison for the other regulatory alternatives. Regulatory Alternative I control could be achieved by the use of carbon adsorption, incineration, or low-solvent coatings.

Regulatory Alternative II is based on the control of oven emissions only. This regulatory alternative is very similar to Alternative I except that the efficiency of the add-on control device is selected as 95 percent rather than the 90 prcent control level because it is more indicative of current control system operations. Therefore, with a capture efficiency of 90 percent, the overall VOC reduction for this control system is approximately 85 percent. Carbon adsorption, incineration, or low-solvent coatings could be used to control emissions under this alternative.

Regulatory Alternative III is based on the control of both oven and fugitive VOC emissions. To obtain a high degree of fugitive capture a fugitive control device (such as a hood or a complete enclosure of the coating area) is used between the coater and the oven. The caputured fugitive VOC emissions are ducted into the oven or the add-on control device. The recommended method of ducting is to use the captured gases containing fugitive VOC as makeup air to the drying oven. Control of the fugitives results in a higher VOC capture. In this case, 95 percent of the applied solvent that is volatilized is captured. Under Alternative III the control device reduces 95 percent of the captured emissions, and an overall VOC reduction of 90 percent or greater is achieved. Data from existing well-designed pressure sensitive tape and label coating facilities indicate that up to 93 percent overall VOC reduction can be achieved. Chapter 4 and Appendix C of the BID examine data from well-controlled facilities in greater detail.

Environmental, Energy, and Economic Impacts

The environmental, energy, and economic impacts of the NSPS are based on a comparison of the expected impacts of Regulatory Alternatives II and III to Regulatory Alternative I. The overall impacts of the regulatory alternatives are heavily influenced by the predicted decline in the use of organic solvent-based systems. Currently, 80 to 85 percent of all pressure sensitive tape and label coatings are applied with organic solvent formulations. By the year 1990 it is predicted that organic solvent coating will only constitute 10 percent of PSTL all coatings. Based on total solvent use these numbers represent approximately 600,000 megagrams (metric tons) of solvent used in 1978 while only 91,000 megagrams (metric tons) are expected in 1990. The use of organic solvent coatings will decline because of: (1) The increasing availability of alternative low-solvent coatings, (2) the high cost and lessening supply of organic solvents, and (3) increasing environmental regulations relating to solvent use.

Environmental Impacts. An analysis was made to compare the estimated national impacts of VOC emissions, wastewater effluents, solid waste generation, and energy use associated with the regulatory alternatives. The impacts in 1978 are based only on Regulatory Alternative I which represents no NSPS action and SIP adoption of the CTG recommended emission limit. For all environmental parameters the impacts decrease due to the predicted dramatic increase in the use of energy-efficient, low-solvent coating technology. In 1985 the expected increases in adverse environmental impacts from Regulatory Alternatives II and III are not major.

By 1985 it is predicted that the PSTL industry will use 125,000 megagrams (metric tons) of solvents. Regulatory Alternative I (no NSPS with SIP control only) would result in expected total VOC emissions of 27,400 megagrams (metric tons) per year. If Regulatory Alternative II is applied these emissions are expected to be reduced by 2,600 megagrams (metric tons) to 24,800 megagrams (metric tons) per year. This represents a 9.5 percent reduction in emissions. If Alternative III control is exercised the total VOC emissions are expected to be 23,100 megagrams (metric tons) per year. This represents a 16 percent reduction in total emissions over the projected baseline control level.

Wastewater discharge from PSTL coating operations increases with the use of carbon adsorption systems for VOC control. The additional wastewater comes from steam condensate which is separated from the recovered solvent. Generally this water is routed into local waste treatment systems or is emitted directly to the environment. If one assumes that all VOC emissions from PSTL coating facilities are controlled by carbon adsorption units (worst case estimate), the resulting wastewater flow for Alternative III is 13 percent greater than that expected from systems required to meet the Alternative I control level. In 1985, if all the solvent-based coating facilities used carbon adsorption, the total amount of wastewater would be about 20 million liters per year. The amount of VOC potentially in this volume of water is about 10 megagrams (metric tons). Even in the worst case situation the proposed standard is reasonable.

The solid waste impact from the addition of VOC controls in the PSTL industry is expected to be small. The use of carbon adsorption systems produces waste activateds carbon. The carbon must be replaced every one to six years depending on performance. The waste carbon can be landfilled, burned as a solid fuel, or sold to firms which reactivate the carbon. The landfill operation represents the greatest potential adverse environmental problem. This problem can be minimized by proper design, construction, and operation of the landfill site. In 1985 the estimated national incremental carbon solid waste production from PSTL facilities is approximately 55 megagrams (metric tons). This waste load would occur under Regulatory Alternative III control. The solid waste impact is reasonable when compared to the total nationwide VOC reduction being achieved.

Energy Impact. The total industry-wide use of electricity and fossil fuels is expected to decline in the next ten years. The primary reasons for this decline is the greater use of more fuel efficient, low-solvent systems, such as hot melts and waterborne adhesives and 100 percent solids and waterborne releases. The low-solvent systems eliminate the need for large, full-consuming solvent drying ovens.

For an individual coating facility, the supplement energy use is higher for a solvent-type coating line with an add-on VOC control device than a line with no controls at all. More electrical energy is needed to power an increased number of fans and fans with higher capacities. For coating lines controlled by carbon adsorption units, fossil fuels must be used to run the steam boilers. Coating lines controlled by incineration would have fuel requirements that are dependent on the concentration of the

incinerator feed gases. If the concentration can be maintained near 40 percent LEL, fuel requirements will be low.

There is a potential in the PSTL industry for a net national energy savings. This savings would be possible if many or all solvent-based coating lines used solvent recovery control systems. The recovered solvent more than offsets the supplemental energy needed to operate the systems. The net recovered solvent could be translated into barrels of oil, consequently equaling barrels of oil that would not then have to be imported.

In 1985, Regulatory Alternative II would have an increased energy requirement of about 7,900 barrels (1.26 million liters) of crude oil per year above that required by Regulatory Alternative I. If all solvent-based coating lines were controlled by carbon adsorption to the Alternative II level, a best case, gross energy savings of about 23,600 barrels (3.75 million liters) of crude oil is estimated. By deducting the required energy for controls, a potential net national energy savings of 15,700 barrels (2.5 million liters) of crude oil exists.

Under Regulatory Alternative III an incremental (above Alternative I) energy demand of approximately 12,000 barrels (1.9 million liters) of crude oil is projected. Assuming all controls are carbon adsorption units, a gross national energy savings of about 39,100 barrels (6.2 million liters) of crude oil is predicted. This gross savings equates to a potential net national energy savings of 27,100 barrels (4.3 million liters) of crude oil for Alternative III. This estimate reflects the best case energy impact.

If all sovlent-based coating lines were controlled by incineration the worst case national energy impacts result. Because no solvent is recovered, there are no credits to offset the increased energy used by the VOC control systems. For Alternative II control an annual 17,700 barrels (2.8 million liters) of crude oil may be consumed by the PSTL industry over that required under Alternative I. Under Alternative III incinerations controls would require aproximately 31,000 barrels (4.9 million liters) of crude oil per year.

Neither total carbon adsorption nor total incineration control is anticipated in this industry. The actual use of the two control devices will be determined by the availability and price of solvent, the applicability of alternative fuels, the rapidity with which low-solvent technologies replace solvent-based ones, and the stringency of environmental regulations.

Economic Impact. The economic impacts of all three regulatory alternatives are minimal. In cases where they can be used, owners or operators will invest in low-solvent coating methods such as 100 percent solids or waterborne coatings. If technological constraints prevent the use of waterborne and 100 percent solid technologies, the regulatory alternatives will have a small impact on the industry. Based on the net present value (NPV) analysis, the large lines will generally experience a greater impact than the medium and small lines. Industry-wide, it is estimated that a price increase of 0.0 to 0.9 percent would be required to offset the impact of the NSPS.

The economic impact of the NSPS was evaluated through the costing of model facilities. These model facilities are based on sizes and flow-rates which represent typical new coating facilities. For this study, three line widths (0.61 m, 0.9 m and 1.5 m) and three line speeds (0.13 m/sec, 0.30m/sec, and 1.2 m/sec) were examined. The large width and high speed were combined in one case to represent a facility which is a large volume (39 million m^2/year) producer. The medium and small widths and slower speeds were combined to represent facilities which are small volume (1.7 million m^2/year and 5.8 million m^2/year) coating operations. The adhesive coating cases were examined separately from the silicone release coating operations. Tandem coating facilities were also analyzed during the economic study.

In the impact analysis, alternative low-solvent technologies are used to give a comparison for the systems which required add-on VOC controls. These alternative systems include hot melt and waterborne adhesives and 100 percent solid and waterborne silicone releases.

Detailed cost data were developed for the adhesive and silicone release model plants. All cost data were based on model plants that would be operating for 6,000 hours per year. The model plant costs were used in an economic model to assess the economic impact of the proposed standard. Both control equipment and coating line costs were developed. A discount rate of 16 percent and capacity utilization rates of 75 and 100 percent were used in the analysis. Inputs on different company structures were also used in the economic model. The model takes all the inputs and analyzes the various alternatives to rate them on net present value (NPV). The alternatives with the highest NPV's are considered as the best alternatives. High NPV's are advantageous because they represent the highest annual cash flows generated by an investment. All impacts represent the situation in 1985.

An economic analysis was not performed for the precoat coating lines because the physical and operational characteristics of a precoat line are very similar to those of release coat lines. To avoid duplications of effort and information, only release coat lines were examined in the economic analysis. Conclusions determined for release coat lines would apply to precoat coating lines.

To adequately represent the alternatives available to a coating operation the economic analysis is done from two perspective cases. In the unconstrained case, it is assumed that both low-solvent and high-solvent technologies can be used as identical product substitutes. This means that the 100 percent solid and waterborne formulations will produce a product equal to that of the solvent systems. In the constrained case, it is assumed that neither waterborne nor 100 percent solids coatings can be used as solvent-based product substitutes. A firm may only use solvent-based technology (with controls) to produce a tape or label product.

In the unconstrained cases, Regulatory Alternative II and III would have no impacts on the pressure sensitive tapes and labels industry. Waterborne and 100 percent solids coatings are available that meet the control requirements of these alternatives. Because low-solvent systems are more profitable than solvent-based ones, firms in the PSTL industry would have an economic incentive to adopt them even in the absence of an NSPS based on Alternatives II or III. The regulatory alternatives would not force firms to change the type of coating line they would build in the absence of any regulatory alternatives.

In the constrained cases, Regulatory Alternatives II and III would have minor impacts. Under Alternative II control, a product price increase of 0.0 to 0.4 percent would result if all costs for controls were passed on to the consumer. If all costs were absorbed by the manufacturer, an industry-wide decrease in return on investment (ROI) of 0.0 to 0.6 percent would result. Under Alternative III control, a product price increase of 0.0 to 0.9 percent is predicted. Full cost absorption by the manufacturer would reduce the ROI by 0.0 to 1.0 percent. With both regulatory alternatives, the large coating lines would be slightly more impacted than the medium and small lines.

The regulatory alternatives would have little or no impact on the industry's

growth rate and structure. The availability of low-solvent technologies and the small price and ROI impacts on the conventional solvent-based systems imply that the regulatory alternatives would not deter new investment and adversely affect growth. Although the large facilities would be affected more than the medium and small facilities, the difference is not great enough to put the large facilities at a competitive disadvantage. Thus, the regulatory alternatives would not cause any significant changes in the structure of the industry.

Best System of Emission Reduction

Based on the environmental, energy, and economic impacts, Regulatory Alternative III is selected as the best system of continuous emission reduction. This alternative is considered affordable and the impacts reasonable. Although this alternative is based on the use of a control device operated in conjunction with a well-designed VOC capture system, It is recognized that low-solvent coatings are available for some applications and are just as effective in reducing VOC emissions.

The control device may be either a carbon adsorber or incinerator. Both control devices have been determined to be capable of at least 95 percent efficiency in reducing VOC emissions. The attainable efficiency of VOC capture systems has been estimated based on PSTL facilities' overall VOC emission reduction data and control device efficiencies for these systems. Based on these calculations the best hooding and enclosure systems are 95 percent efficient in capturing all VOC emissions from a coating operation. The remaining five percent of total emissions are trapped in the coated product or are lost as fugitive emissions. The continuous overall emission reduction achievable by the best system is 90 percent. After consideration, the Administrator has determined that under normal operating conditions all affected facilities could achieve the level of the proposed standard using the best system.

Selection of Format of Proposed Standard

The formats were examined based on their effectiveness in ensuring overall VOC control. The criteria for choosing the format are effectiveness, compatibility with existing coatings and control systems, complexity of compliance testing, and ease of application in the industry.

The formats considered for the pressure sensitive tape and label industry were: (1) Total concentration of emissions from all exhaust gases discharged to the atmosphere, (2) kilograms of emissions per unit of production, (3) control efficiency, and (4) kilograms of emissions per unit weight or volume of coating solids. The following paragraphs discuss the advantages and disadvantages of the regulatory formats.

An allowable concentration of emissions in the exhaust gases discharged to the atmosphere is the easiest standard to enforce. Direct emission measurements can be made using Reference Method 25 on a single effluent stream. The major disadvantage of this format is its poor effectiveness in identifying overall VOC control. The level of fugitive emissions capture cannot be determined with a single point measurement. Such a determination requires either absolute containment or material balance testing of all potential points. As stated earlier, fugitives may amount to 18 percent of the total applied solvent. Another disadvantage is that it does not promote efficient oven energy use. In order to reduce oven energy consumption, the operator generally tries to increase the concentration of solvent in the oven exhaust gases. Therefore, more solvent leaves in a smaller volume of gas. This means lower energy consumption because eneregy use is approximately proportional to oven exhaust gas flow rate. With the higher concentration the operator is required to get a higher percent VOC reduction than an operator with less efficient ovens. In fact, concentration limits allow an operator to emit twice as much solvent by simply doubling the amount of dilution air drawn through the ovens. The overall effect is to promote higher energy consumption, while allowing greater total VOC emissions.

A format of kilograms of emissions per unit of production relates emissions to individual plant production on a direct basis. This type of standard would be inequitable for different types of coatings. In the PSTL industry, adhesive coatingss vary in thickness and in kilograms of VOC coated per unit area of production. This is further complicated by the inclusion of solvent silicone release and precoat coatings. These coatings tend to be much thinner and contain less VOC per unit area of production than adhesive coatings. Therefore, if a single value for the standard was used, some solvent coatings would require no additional controls while others would require a very high level of control.

The control efficiency standard would be developed from two viewpoints. The first would be to set a control level across the add-on control device. This form would provide a good means for reducing oven emissions but would not insure the control of fugitive emissions. The second viewpoint would require an overall VOC reduction based on the total amount of solvent in the formulated coating before application. This would include both fugitive VOC emissions and oven emissions. Compliance testing for this situation would require a material balance-type test which is a problem for any standard.

A regulatory format which would relate total allowable mass of VOC emissions to the amount of coating applied would be a very effective standard. For the PSTL industry, this form was examined for mass of VOC emissions with respect to volume of coating, volume of coating solids, and weight of coating solids. Weight of coating solids was chosen as the best of these forms because most formulations are derived on a weight basis. Generally, resin density is constant. Therefore, the weight basis is easy to calculate from formulation data.

The format of the proposed standard is a combination of the percent overall VOC reduction and the mass of VOC emissions per mass of coating solids formats. The percent overall VOC reduction would provide an effective means of requiring an overall VOC control, while not being prohibitive for high-solvent coatings. The mass emission per weight of coating solids would allow the use of low-solvent coatings without the need for all-on VOC control devices. This combination would permit add-on VOC controls for nearly all solvent-based coating systems and promote the development and use of low-solvent coatings.

Selection of Emission Limits

Section 111(a)(1) requires the emission limits to reflect "application of the best technological system of continuous emission reduction which (taking into consideration the cost of achieving such emission reduction, any nonair quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated." Section 111(a)(1). The "best technological system" defined by Section 111(a)(1) is one that is not "exorbitantly costly." *Essex Chemical Corp.* v. *Ruckleshaus*, 486 F. 2d 427, 433 (D.C. Cir. 1973).

Application of the "best technological system" results in a two-step standard: for coatings with VOC contents of 2 kg/kg of coating solids or less, the standard is 0.2 kg/kg; for coatings with greater

than 2 kg/kg VOC content, the standard is a 90 percent reduction in VOC emissions.

As discussed earlier, VOC reductions of 90 percent are achievable by systems of capture and control. However, the cost and energy requirements of achieving VOC emission reductions vary according to the VOC content of the coating being controlled. The lower the VOC content of the coating, the higher are the cost and energy requirements of achieving a given reduction in emissions. This is for two reasons. First, a given percent control of lower VOC coatings generally requires capture and control systems of at least the same size and cost as the same percent control of higher-VOC coatings, but it achieves less mass emission reduction because there is less VOC to be controlled. Second, the cost and energy requirements of controlling lower-VOC coatings in incinerators are further increased by the need to use additional supplemental fuel to operate the incinerator.

In the Administrator's judgment, the cost and energy requirements of a capture and control system that achieves 90 percent reduction are reasonable on coatings with VOC contents of 2.0 kg/kg and greater. Such a control system is therefore the "best technological system," and the standard for such high VOC coatings is 90 percent reduction.

For coatings with lower VOC contents, the "best technological system" is one that can achieve 0.2 kg/kg. In the Administrator's judgment, the cost and energy requirements of achieving significantly greater emission reduction on such lower VOC coatings would be exorbitant. Therefore, the standard for such coatings is 0.2 kg/kg. This can be achieved by all sources at reasonable cost and energy requirments.

The effect of solvent retention in the final tape of label product and its impact on the achievability of a 90 percent overall emission reduction were considered. Test data obtained during this study indicate that the amount of solvent retained in the product does not affect the ability of a facility to achieve the proposed standard. A well-controlled PSTL facility has demonstrated a four-week overall VOC emission reduction of 93 percent. This overall reduction includes the amount of solvent that was retained in the product. During this period the facility coated 18 different adhesives with varying amounts of retained solvent. Neither the four week period nor the many varied adhesive products coated (i.e., varied amounts of retained solvent) affected the plant's ability to achieve the proposed standard. Therefore EPA believes that 90 percent overall emission reduction efficiency can be achieved under all solvent retention conditions.

Selection of Compliance Procedures

After the required initial performance test, compliance with the proposed standard will be determined on a calendar month basis. Every calendar month will be considered a performance test for carbon adsorption-controlled coating lines, for incinerator-controlled coating lines, and for coating lines using low-solvent coating technology. The owner or operator will report to the Administrator within ten days following the end of a calendar month only if an affected facility exceeded the proposed standard for that calendar month being reported.

The variability of operation of the PSTL industry makes it well-suited to a monthly compliance period. Many products are produced in this industry using hundreds of different coatings. Operating parameters such as line speed, line width, length of a coating run, product solvent retention, and control device solvent hold-up vary substantially within this industry on a daily basis. The combination of these factors influences the quantity of emissions and the ability to meet a standard. Compliance with the proposed standard on a monthly basis would allow enough time for coating system fluctuations to average out.

To determine compliance with the proposed standard, an owner or operator of an affected facility using low-solvent coatings must calculate the weighted average of the mass of VOC (solvent) used per mass of coating solids applied each calendar month. The mass of VOC per mass of coating solids applied can be obtained by using a modified version of Reference Method 24 or coating manufacturer's formulation data. At any time the Administrator may require a Reference Method 24 test to verify the VOC content. The reference method must be performed so that mass per mass units are obtained and not mass per volume units as the method is currently written. The mass per mass modification actually simplifies the method. If the calculated weighted average is less than or equal to 0.20 kg VOC per kg of coating solids applied, compliance with the proposed standard would be demonstrated. Affected facilities with weighted averages greater than 0.20 would have to install add-on control devices to achieve compliance with the proposed standard. For enforcement purposes Reference Method 24 and not manufacturer's formulation data would be used.

Every affected facility using add-on control devices to achieve compliance with the proposed standard, must determine the weighted average of the mass of VOC used per mass of coating solids applied each calendar month. The weighted average VOC content would be compared to the 0.20 kg limit each month to determine the required level of overall VOC reduction. The maximum required overall VOC reduction is 90 percent.

Affected facilities controlled by carbon adsorption will determine monthly compliance using a solvent inventory test. The total mass of solvent used every calendar month will be divided by the total mass of solvent recovered by the carbon adsorber every month to determine the overall VOC emission reduction obtained. If the overall VOC emission reduction obtained is greater than or equal to the required overall reduction, compliance with the proposed standard is demonstrated.

Affected facilities controlled by incineration will determine monthly compliance by comparing the required overall VOC emission reduction of each calendar month to the overall VOC emission reduction demonstrated during the most recent performance test which complied with the proposed standard. If the required monthly reduction is less than or equal to the performance test reduction, the affected facility is in compliance with the proposed standard.

Modification and Reconstruction

Facilities which are modified or reconstructed as defined in 40 CFR 60.14 and 60.15 after the date of proposal of this standard are subject to the standard. In the case of PSTL facilities, a modification, and thus an increase in VOC emissions, will most likely be related to an increase in production. Production increases contributing to emission increases can result from changes in web width, line speed, or hours of operation. An increase in the hours of operation is specifically excluded from new source performance standards. If changes in line speed and line width are part of the existing equipment capability and do not require capital expenditures, they are also excluded from new source performance standards.

Production increases, however, may require capital expenditures, although this is not expected to be a frequent occurrence. A coating line with a drying oven is usually designed for a maximum solvent vaporization loading. The limiting factor is the LEL level allowed in the ovens. Line speed and line width can often be readily changed as long as

the production is kept under the maximum design of the oven. If production is increased above the maximum designed for the oven, a significant capital expenditure will be made for larger exhaust fans and possibly larger recirculation fans, and larger drive motors for the coater and wind and unwind equipment. If there is an increase in VOC emissions the facility will be a modification and will have to comply with the proposed standard. All control procedures previously discussed are applicable to modified PSTL facilities, therefore, the proposed standard is determined to be reasonable for such facilities.I11Reconstructed facilities are also a potential occurrence in this industry. Existing control technologies would be applicable to the VOC emissions from such facilities. Because the emissions from reconstructed facilities can be controlled to the level specified in Regulatory Alternative III, the proposed standard would be reasonable for these types of facilities.

Selection of Monitoring Requirements

Monitoring requirements are included in the proposed standard to ensure good operation and maintenance of the VOC emission control equipment. Monitoring procedures for the proposed standard were chosen based on three factors: Reasonable cost, ease of execution, and utility of the resulting data to both the owner and to EPA for assuring continued proper operation.

Affected facilities controlled by incineration must monitor the temperature of the incinerator exhaust gases. The average temperature is being monitored to determine the occurrence of improper incinerator operation. The temperature drops stated below shall be indications of improper incinerator operation. For thermal incinerators the exhaust gas temperature must be continuously monitored and recorded. Any three hour period (during actual coating operations) during which the average temperature of the device is more than 28C° (50F°) less than the average temperature of the device during the most recent performance test complying with the proposed standard shall be reported to the Administrator. For catalytic incinerators the gas temperature upstream and downstream of the catalyst bed must be monitored. Any three hour period (during actual coating operations) during which the average temperature of the device immediately before the catalyst bed is more than 28C° (50F°) less than the average temperature of the device during the most recent performance test complying with the proposed standard, or any three hour period during which the average temperature difference across the catalyst bed is less than 80 percent of the average temperature difference of the device during the most recent performance test complying with the proposed standard shall be reported to the Administrator.

Temperature monitoring equipment is usually a standard feature on most incinerators. For this reason, the requirement to monitor temperature should not be an additional cost burden on the industry. If it is not included, the cost to purchase and install an accurate temperature measurement device and recorder is estimated at $1,200.

Any affected facility which use incinerators to comply with the proposed standard and which uses a hood or enclosure to capture fugitive VOC emissions, must operate a monitoring device which continuously indicates that the hood or enclosure is operating. Examples of such devices include fan amperage meters and flow meters in ducts. No continuous monitoring will be required if the hood or enclosure system is interlocked with the affected facility's oven air recirculation system.

Selection of Performance Tests Methods

Performance test methods are used to determine the solvent content in the coating and the overall control efficiency of the add-on control system. Furthermore, the test method for determining control efficiency differs depending on whether carbon adsorption or incineration is used.

The proposed method for measuring the solvent content in the coating is Reference Method 24 promulgated at October 3, 1980 45 FR 65956 "Determination of Volatile Matter Content, Water Content, Density, Volume Solids, and Weight Solids of Surface Coatings." This method combines several ASTM standard methods to determine the volatile matter content, density of the coating, volume of solid, and water content of the paint, varnish, lacquer, and related surface coatings. From this information, the mass of volatile organic compounds (VOC) per unit volume of solids is calculated.

Because the proposed PSTL regulation for coating is in units of mass of volatile organic compounds per mass of coating solids, Reference Method 24 must be modified so its results are in the same units as the standard. This actually shortens the test method by eliminating several steps because only the non-aqueous volatile content needs to be determined. For non-aqueous coatings, the procedure to be used is ASTM D 2369–73, "Standard Test Method for Volatile Content of Paints." For coatings with water, the previously mentioned procedure (ASTM D 2369–73) is combined with another procedure which determines the water content of the coating. There are two acceptable procedures for this: (1) ASTM D 3792, "Standard Test Method for Water in Water Reducible Paint by Direct Injection into a Gas Chromatograph," and (2) an ASTM draft "Standard Test Method for Water in Paint or Related Coatings by the Karl Fischer Titration Method." The results from these procedures are the nonaqueous volatile content of the coating (as a weight fraction) and the water content (as a weight fraction). The weight fraction solids content in the coating can also be determined from these procedures. The VOC content in the coating, in mass of VOC per mass of coating solids applied, may be determined by dividing the weight fracton of non-aqueous volatiles by the weight fraction of solids.

The estimated cost of analysis per coating sample is $50 for the total volatile content procedure (ASTM D 2369–73). For aqueous coatings, there is an additional $100 per sample for water content determination. Since the testing equipment is standard laboratory apparatus, no additional purchasing costs are expected.

In certain cases, for the proposed PSTL standard, the density of a particular coating may be required. The density may be determined from the coating manufacturer's formulation data or from a procedure that is a part of Reference Method 24. The procedure in Method 24 is ASTM D 1475–60, "Standard Test Method for Density of Paint, Varnish, Lacquer, and Related Products." The analysis of a coating sample would cost about $25. Testing can be performed with standard laboratory equipment.

If the amount of solvent in the coating exceeds 0.20 kg per kg of coating solids applied, then the efficiency of the vapor control system must be determined. The overall efficiency is determined by comparing the amount of solvent controlled (either recovered or destroyed) to the potential amount of solvent emitted with no controls. For the proposed standard two different performance test methods were selected. The method to use depends upon the type of add-on control device being installed. In the PSTL industry, only two types of control devices are expected: carbon adsorbers and incinerators.

For carbon adsorbers, performance is demonstrated by comparing the solvent used versus the solvent recovered. In

using a solvent inventory system, it is necessary to monitor two things: The amount used of each coating, and the amount of solvent recovered by the carbon adsorption system.

The performance test will consist of a one calendar month solvent inventory as opposed to the three test runs method specified in § 60.8(f). Compliance in the months following the performance test will also be determined on a calendar month basis.

To determine the efficiency of the carbon adsorber system, these data would be collected over a period of one calendar month. This time interval allows the test to be conducted using a representative variety of coatings and products, as well as reducing the impact of variations in the process that would otherwise affect the representativeness of a short-term test. It should be noted that this procedure determines the overall control efficiency based on the original amount of solvent used, not on the amount entering the carbon adsorber, and fugitive emissions are allowed as long as the overall control efficiency meets the standard.

The cost of such a performance test should be minimal since the solvent inventory data would be part of normal operating equipment in the plant. If not, the estimated purchase cost of two accurate liquid weight meters is $1,400.

Because incinerators destroy the solvent rather than recover it, a different type of performance test is used. The proposed procedure measures the mass of VOC (as carbon) in the incinerator system vents (incinerator inlet, incinerator outlet, and fugitive emission vents), and determines the incinerator system's overall control efficiency. There are important differences between the carbon adsorber and incinerator test procedures that should be noted. The test procedure for the carbon adsorber system relates the original amount of solvent used at the coating head to the amount of solvent controlled, i.e. recovered, by the adsorber. It is possible to compare the two amounts because the same measurement method is used (liquid solvent used versus liquid solvent recovered). However, for incinerator systems, the amount of solvent used should not be directly related to the amount of solvent controlled, i.e. destroyed, because different measurement procedures are used. (liquid solvent used in the coating is measured as mass of solvent, while the gaseous emissions destroyed are measured as mass of carbon). Thus, for incinerators, the amount controlled or destroyed is determined by using the amount of solvent measured in the inlet vent versus the outlet vent. The overall incinerator system control efficiency is determined by relating the amount destroyed to all the potential emissions.

To make the incinerator test procedure equivalent to the carbon adsorber test procedure, one must be able to measure all the potential emissions, both fugitive emissions and oven emissions ducted into the incinerator. That is, all fugitive VOC emissions from the web coating area must be captured and vented through stacks suitable for testing. Prior to the performance test for incineration-controlled affected facilities, the owner or operator will be required to construct a temporary total enclosure around the coating line for the purpose of capturing fugitive VOC emissions. A total enclosure is defined as any structure or building around the coating applicator and flashoff area or the entire coating line for the purpose of confining and totally capturing fugitive VOC emissions. If a permanent total enclosure exists on the line prior to the performance test, and the enforcing agency is satisfied that the enclosure is totally capturing fugitive emissions; the construction of a temporary enclosure is not required.

The concentration of VOC (as carbon) in the incinerator vent system is measured by Reference Method 25, "Determination of Total Gaseous Nonmethane Organic Emissions as Carbon (TGNMO)." The results of this method combined with the results of Reference Methods 1 through 4 yields the mass of VOC (as carbon) in the vent.

Three one-hour runs of Reference Method 25 are required for a complete test, with Reference Methods 2, 3 and 4 being performed at least twice during that period. Measurements at the inlet, outlet and fugitive emission vents should be performed simultaneously. The total time required for one complete performance test is estimated at 8 hours, with an estimated overall cost $4,000, plus $2,000 for each fugitive vent measured.

The TGNMO method (Reference Method 25) was selected to measure the VOC concentration in incinerators for certain reasons. It is simple to use, especially in explosive atmospheres or when sampling high-temperature, moist streams. Also because the detector used in Reference Method 25 measures all the non-methane organics as methane, all carbon atoms give an equivalent instrument response. Therefore, the problem of varying response ratios for different organic compounds (typical of all flame ionization units) is avoided.

The decision to propose two different performance test methods was made after considering several factors. It is usually preferable to have the same performance test method regardless of the type of control device. In this case, the stack sampling procedure described for incinerators is also applicable to carbon adsorbers. However, the solvent inventory method is a far more practical and accurate procedure. It is very inexpensive, requires no special technical sampling and analytical procedures, and has a test period of one month, so that a representative variety of coatings can be tested. Unfortunately, an inventory-type method cannot be applied to incinerators. The one-day TGNMO inlet and outlet stack test procedure is the best method for testing incinerators, but this method would become exorbitantly expensive and impractical if a longer test period were required. The advantages of the solvent inventory-type test for carbon adsorbers outweigh the disadvantages of having two different performance test methods.

Reports Impact Analysis

The reporting requirements necessitated by the proposed standard are authorized in Section 114 of the Clean Air Act. The proposed standard would require the preparation of three types of reports. First, the general provisons (Subpart A of 40 CFR Part 60) would require notification reports which inform the agency of facilities subject to new source performance standards (NSPS). These reports include notification of construction, anticipated start-up, acutal start-up, and physical or operational changes. Second, reports of performance test results and performance evaluations of the continuous monitoring systems would be required. These reports show whether a facility is initially meeting the level of the standard. Third, monthly reports explaining whether an affected facility is in or out of compliance with the standard would be required

The respondent group to the reporting requirements of the proposed standard would be the pressure sensitive tapes and labels (PSTL) industry. It is estimated that through the fifth year of standard applicability, approximately 290 new PSTL sources will have been established which would have to comply with the reporting requirements of the proposed standard. This number of sources includes adhesive, release, and precoat coating facilities. To implement the reporting requirements of the proposed standard, through the first five years of applicability, the PSTL industry would incur a manpower demand of about 12 man-years. Comments are invited on any of the reporting requirements of the proposed standard.

Section 60.447 of the proposed standard explains specific reporting requirements in further detail.

Public Hearing

A public hearing will be held to discuss the proposed standards in accordance with Section 307(d)(5) of the Clean Air Act. Persons wishing to make oral presentations should contact EPA at the address given in the ADDRESSES section of this preamble. Oral presentations will be limited to 15 minutes each. Any member of the public may file a written statement before, during, or within 30 days after the hearing. Written statements should be addressed to the Central Docket Section address given in the ADDRESSES section of this preamble.

A verbatim transcript of the hearing and written statements will be available for public inspection and copying during normal working hours at EPA's Central Docket Section in Washington, D.C. (see ADDRESSES section of this preamble).

Docket

The docket is an organized and complete file of all the information submitted to or otherwise considered in the development of this proposed rulemaking. The principal purposes of the docket are (1) to allow interested parties to readily identify and locate documents so that they can intelligently and effectively participate in the rulemaking process, and (2) to serve as the record in case of judicial review.

Miscellaneous

As prescribed by Section 111, establishment of standards of performance for the manufacture of pressure sensitive tapes and labels was preceded by the Administrator's determination (40 CFR 60.16, 44 FR 49222, dated August 21, 1979) that these sources contribute significantly to air pollution which may reasonably be anticipated to endanger public health or welfare. In accordance with Section 117 of the Act, publication of this proposal was preceded by consultation with appropriate advisory committees, independent experts, and Federal departments and agencies. The Administrator will welcome comments on all aspects of the proposed regulation, including economic and technological issues, and on the proposed test methods.

Comments are specifically invited from small PSTL companies on the definition of the affected facility. Larger companies in this industry have objected to the present definition. They feel the affected facility should be defined as a coating line from initial unwind to final wind. Any comments submitted to the Administrator on this issue should contain specific information and data pertinent to an evaluation of the affected facility definition. Alternative courses of action should be suggested.

It should be noted that standards of performance for new sources established under Section 111 of the Clean Air Act reflect:

> * * * application of the best technological system of continuous emission reduction which [taking into consideration the cost of achieving such emission reduction, any nonair quality health and environmental impact and energy requirements] the Administrator determines has been adequately demonstrated [Section 111(a)(1)].

Although there may be emission control available that can reduce emissions below those levels required to comply with standards of performance, this technology might not be selected as the basis of standards of performance due to costs associated with its use. Accordingly, standards of performance should not be viewed as the ultimate in achievable emissions control. In fact, the Act requires (or has the potential for requiring) the imposition of a more stringent emission standard in several situations.

For example, applicable costs do not necessarily play as prominent a role in determining the "lowest achievable emission rate" for new or modified sources located in nonattainment areas, i.e., those areas where statutorily-mandated health and welfare standards are being violated. In this respect, Section 173 of the Act requires that new or modified sources constructed in an area which exceeds the National Ambient Air Quality Standard (NAAQS) must reduce emissions to the level which reflects the "lowest achievable emission rate" (LAER), as defined in Section 171(3) for such category of source. The statute defines LAER as that rate of emissions based on the following, whichever is more stringent:

> (A) The most stringent emission limitation which is contained in the implementation plan of any State for such class of category of source, unless the owner of operator of the proposed source demonstrates that such limitations are not achievable, or
>
> (B) The most stringent emission limitation which is achieved in practice by such class of category of source.

In no event can the emission rate exceed any applicable new source performance standard (Section 171(3)).

A similar situation may arise under the prevention of significant deterioration of air quality provisions of the Act (Part C). These provisions require that certain sources (referred to in Section 169(1)) employ "best available control technology" (BACT) as defined in Section 169(3) for all pollutants regulated under the Act. Best available control technology must be determined on a case-by-case basis, taking energy, environmental and economic impacts and other costs into account. In no event may the application of BACT result in emissions of any pollutants which will exceed the emissions allowed by an applicable standard established pursuant to Section 111 (or 112) of the Act.

In all events, State Implementation Plans (SIP's) approved or promulgated under Section 110 of the Act must provide for the attainment and maintenance of NAAQS designed to protect public health and welfare. For this purpose, SIP's must in some cases require greater emission reduction than those required by standards of performance for new sources.

Finally, States are free under Section 116 of the Act to establish even more stringent emission limits than those established under Section 111 or those necessary to attain or maintain the NAAQS under Section 110. Accordingly, new sources may in some cases be subject to limitations more stringent than standards of performance under Section 111, and prospective owners and operators of new sources should be aware of this possibility in planning for such facilities.

This regulation will be reviewed four years from the date of promulgated. This review will include an assessment of such factors as the need for integration with other programs, the existence of alternative methods, enforceability, and improvements in emission control technology, and reporting requirements. The reporting requirements in this regulation will be reviewed as required under EPA's sunset policy for reporting requirements in regulations.

Section 317 of the Clean Air Act requires the Administrator to prepare an economic impact assessment for any new source standard of performance under Section 111(b) of the Act. An economic impact assessment was prepared for the proposed regulations and for other regulatory alternatives. All aspects of the assessment were considered in the formulation of the proposed standards to insure that the proposed standards would represent the best system of emission reduction considering costs. The economic impact assessment is included in the Background Information Document.

Dated: December 22, 1980.

Douglas M. Costle,

Administrator.

It is proposed that 40 CFR Part 60 be amended by adding a new Subpart RR as follows:

Subpart RR—Standards of Performance for Pressure Sensitive Tape and Label Surface Coating Operations

Sec.

Authority: Sec. 111, 301(a) of the Clean Air act as amended (42 U.S.C. 7411, 7601(a)), and additional authority as noted below.

Subpart RR—Standards of Performance for Pressure Sensitive Tape and Label Surface Coating Operations

§ 60.440 Applicability and designation of affected facility.

(a) The affected facility to which the provisions of this subpart apply is each pressure sensitive adhesive coating line, each release coating line, and each precoat coating line used in the manufacture of pressure sensitive materials.

(b) This subpart applies to any affected facility which begins construction, modification, or reconstruction after [—— date of publication in **Federal Register**].

§ 60.441 Definitions and symbols.

(a) Except as otherwise required by the context, terms used in this subpart are defined in the Act, in Subpart A of this part, or in this section as follows:

"Coating applicator" means an apparatus used to apply a surface coating to a continuous web.

"Coating line" means a coating applicator, flashoff area, and oven.

"Coating solids applied" means the solids content of the coated adhesive, release, or precoat as defined by Reference Method 24.

"Flashoff area" means the portion of a coating line after the coating applicator and usually before the oven entrance.

"Fugitive volatile organic compounds" means any volatile organic compounds which are emitted from the coating applicator and flashoff areas and are not emitted in the oven.

"Hood or enclosure" means any device used to capture fugitive volatile organic compounds.

"Oven" means a chamber which uses heat or irradiation to bake cure, polymerize, or dry a surface coating.

"Precoat" means a coating operation in which a primer, lacquer, or tackifying coating (or their equivalent) is applied to a surface as a precursor to the production of a pressure sensitive or release product.

"Pressure sensitive tape and label surface coating operation" means any coating line which coats a continuous web with either pressure sensitive adhesive, release or precoat coatings associated with pressure sensitive products.

"Solvent applied in the coating" means all organic solvent contained in the adhesive, release, and precoat formulations that is metered into the coating applicator from the formulation area.

"Total enclosure" means a structure or building around the coating applicator and flashoff area or the entire coating line for the purpose of confining and totally capturing fugitive VOC emissions.

"Volatile organic compound (VOC)" means any organic compound which is measured by Reference Methods 24 or 25.

(b) All symbols used in this subpart not defined below are given meaning in the Act or in Subpart A of this part.

"a" means the gas stream vents exiting the emission control device.

"b" means the gas stream vents entering the emission control device.

"C_{aj}" means the concentration of VOC (carbon equivalent) in each gas stream (j) exiting the emission control device, in parts per million by volume.

"C_{bi}" means the concentration of VOC (carbon equivalent) in each gas stream (i) entering the emission control device, in parts per million by volume.

"C_{fk}" means the concentration of VOC (carbon equivalent) in each gas stream (k) emitted directly to the atmosphere, in parts per million by volume.

"G" means the calculated weighted average mass (kg) of VOC per mass (kg) of coating solids applied each calendar month.

"M_{oi} means the mass (kg) of VOC per mass (kg) of coating solids applied in each coating (i) used in the calendar month.

"M_r" means the total mass (kg) of solvent recovered for a calendar month.

"M_{si}" means the mass (kg) of coating solids applied in each coating (i) used in the calendar month as measured by the reference method specified in § 60.446(a) or by the coating manufacturer's formulation data.

"Q_{aj}" means the volumetric flow rate of each effluent gas stream (j) exiting the emission control device, in dry standard cubic meters per second.

"Q_{bi}" means the volumetric flow rate of each effluent gas stream (i) entering the emission control device, in dry standard cubic meters per second.

"Q_{fk}" means the volumetric flow rate of each effluent gas stream (k) emitted to the atmosphere, in dry standard cubic meters per second.

"R" means the overall VOC emission reduction achieved for a calendar month (in percent).

"R_q" means the required overall VOC emission reduction (in percent).

§ 60.442 Standard for volatile organic compounds.

(a) On and after the date on which the performance test required by § 60.8 has been completed each owner or operator subject to this subpart shall—

(1) Cause the discharge into the atmosphere from an affected facility not more than 0.20 kg VOC/kg of coating solids applied as calculated on a weighted average basis for one calendar month; or

(2) Demonstrate for each affected facility;

(i) A 90 percent overall VOC emission reduction as calculated over a calendar month; or

(ii) The percent overall VOC emission reduction specified in § 0.443(b) as calculated over a calendar month.

(b) Any coating line which causes the discharge into the atmosphere of not more than 125 kilograms of VOC per day and 15 megagrams of VOC per year is not considered an affected facility and is not therefore subject to the emission limits of § 60.442(a). If either the 125 kilogram per day limit or the 15 megagram per year limit are exceeded, the coating line shall become an affected facility and will be subject to § 60.442(a) and all its associated subparts.

§ 60.443 Compliance provisions.

(a) To determine compliance with § 60.442(1), the owner or operator of the affected facility shall calculate a weighted average of the mass of solvent used per mass of coating solids applied for a one calendar month period according to the following procedures:

(1) Measure the VOC content (kg VOC/kg coating solids applied) of all coatings applied using the reference method specified in § 60.446(a) of this subpart or by using the coating manufacturer's formulation data.

(2) Compute the weighted average by the following equation:

$$G = \frac{\sum_{i=1}^{n} (M_{oi} \times M_{si})}{\sum_{i=1}^{n} M_{si}}$$

(3) For each affected facility where the value of G is less than or equal to 0.20 kg VOC per kg of coating solids applied, the affected facility is in compliance with § 60.442(a)(1).

(b) To determine compliance with § 60.442(a)(2), the owner or operator shall calculate the required overall VOC emission reduction according to the following equation:

$$R_q = \left(\frac{G - 0.20}{G} \right) \times 100$$

If R_q is less than or equal to 90 percent, then the required overall VOC emission reduction is R_q. If R_q is greater than 90 percent, than the required overall VOC emission reduction is 90 percent.

(c) Where compliance with the emission limits specified in § 60.442(a)(2) is achieved through the use of a solvent recovery system, the owner or operator shall determine the overall VOC emission reduction for a one calendar month period by the following equation:

$$R = \left[\frac{M_r}{\sum_{i=1}^{n} (M_{oi} \times M_{si})} \right] \times 100$$

If the R value is equal to or greater than the R_q value specified in § 60.443(b), then compliance with § 60.442(a)(2) is demonstrated.

(d) Where compliance with the emission limit specified in § 60.442(a)(2) is achieved through the use of a solvent destruction device, the owner or operator shall determine calendar monthly compliance by comparing the monthly required overall VOC emission reduction specified in § 60.443(b) to the overall VOC emission reduction demonstrated in the most recent performance test which complied with § 60.442(a)(2). If the monthly required overall VOC emission reduction is less than or equal to the overall VOC reduction of the most recent performance test, the affected facility is in compliance with § 60.442(a)(2).

(e) Where compliance with § 60.442(a)(2) is achieved through the use of a solvent destruction device, the owner or operator shall continuously record the destruction device combustion temperature during coating operations for thermal incineration destruction devices or the gas temperature upstream and downstream of the incinerator catalyst bed during coating operations for catalytic incineration destruction devices. For thermal incineration destruction devices the owner or operator shall report all three hour periods (during actual coating operations) during which the average temperature of the device is more than 28C° (50F°) below the average temperature of the device during the most recent performance test complying with § 60.442(a)(2). For catalytic incineration destruction devices, the owner or operator shall report all three hour periods (during actual coating operations) during which the average temperature of the device immediately before the catalyst bed is more than 28C°(50F°) below the average temprature of the device during the most recent performance test complying with § 60.442(a)(2), and all three hour periods (during actual coating operations) during which the average temperature difference across the catalyst bed is less than 80 percent of the average temperature difference of the device during the most recent performance test complying with § 60.442(a)(2).

(f) After the initial performance test required for all affected facilities under § 60.8, compliance with the VOC emission limitation and percentage reduction requirements under § 60.442 is based on the average emission reduction for one calendar month. A separate performance test is completed at the end of each calendar month after the initial performance test, and a new calendar month's average VOC emission reduction is calculated to show compliance with the standard.

(g) If a common emission control device is used to recover or destruct solvent from more than one affected facility, the performance of that control device is assumed to be equal for each of the affected facilities. Compliance with § 60.442(a)(2) is determined by the methods specified in § 60.443(c) and § 60.443(e) and is performed simultaneously on all affected facilities.

(h) If a common emission control device is used to recover solvent from an existing facility (or facilities) as well as from an affected facility (or facilities), the overall VOC emission reduction for the affected facility (or facilities), for the purpose of compliance, shall be determined by the following procedures:

(1) The owner or operator of the existing facility (or facilities) shall determine the mass of solvent recovered for a calendar month period from the existing facility (or facilities) prior to the connection of the affected facility (or facilities) to the emission control device.

(2) The affected facility (or facilities) shall then be connected to the emission control device.

(3) The owner or operator shall determine the total mass of solvent recovered from both the existing and affected facilities over a calendar month period. The mass of solvent determined in paragraph (h) (1) of this section from the existing facility shall be subtracted from the total mass of recovered solvent to obtain the mass of solvent recovered from the affected facility (or facilities). The overall VOC emission reduction of the affected facility (or facilities) can then be determined as specified in § 60.443(c).

(i) If a common emission control device is used to destruct solvent from an existing facility (or facilities) as well as from an affected facility (or facilities), the overall VOC emission reduction for the affected facility (or facilities), for the purpose of compliance, shall be determined by the following procedures:

(1) The owner or operator shall operate the emission control device with both the existing and affected facilities connected.

(2) The concentration of VOC (in parts per million by volume) after the common emission control device shall be determined as specified in § 60.444(c). This concentration is used in the calculation of compliance for both the existing and affected facilities.

(3) The volumetric flow out of the common control device attributable to the affected facility (or facilities) shall be calculated as a weighted average of the volumetric flows into the control device from the affected facility (or facilities) and the existing facility (or facilities). Compliance is determined by the use of the equation specified in § 60.444(c).

§ 60.444 Performance test procedures.

(a) The performance test for affected facilities complying with § 60.442(a) without the use of add-on controls shall be identical to the procedures specified in 60.443(a).

(b) The performance test for affected facilities controlled by a solvent recovery device shall be conducted as follows:

(1) The performance test will consist of one calendar month run and not the average of three runs as specified in § 60.8(f).

(2) The weighted average mass of VOC per mass of coating solids applied for a one calendar month period shall be determined as specified in § 60.443(a)(1) and § 60.443(a)(2).

(3) Calculate the required overall VOC emission reduction as specified in § 60.443(b).

(4) Inventory solvent usage and solvent recovery for a one calendar month period.

(5) Determine the performance of the solvent recovery device as specified in § 60.443(c).

(c) The performance test for affected facilities controlled by a solvent destruction device shall be conducted as follows:

(1) The weighted average mass of VOC per mass of coating solids applied for a one calendar month period shall be determined as specified in § 60.443(a)(1) and § 60.443(a)(2).

(2) Calculate the requried overall VOC emission reduction as specified in § 60.443(b).

(3) Determine the performance of the solvent destruction device by the following procedures:

$$R = \left[\frac{\sum_{i=1}^{n} (Q_{bi} \times C_{bi}) - \sum_{j=1}^{m} (Q_{aj} \times C_{aj})}{\sum_{i=1}^{n} (Q_{bi} \times C_{bi}) + \sum_{k=1}^{} (Q_{fk} \times C_{fk})} \right] \times 100$$

(i) The owner or operator of the affected facility shall construct the overall VOC emission reduction system so that all volumetric flow rates and total VOC emissions can be accurately determined by the applicable test methods and procedures specified in § 60.446(b).

(ii) The owner or operator of an affected facility shall construct a temporary total enclosure around the coating line applicator and flashoff area during the performance test for the purpose of capturing fugitive VOC emissions. If a permanent total enclosure exists in the affected facility prior to the performance test and the Administrator is satisfied that the enclosure is totally capturing fugitive VOC emissions, then no additional total enclosure will be required for the performance test.

(iii) For each affected facility where the value of R is greater than or equal to the value of R_a calculated in § 60.443(b), compliance with § 60.442(a)(2) is demonstrated.

(iv) The performance of the solvent destruction device shall be determined by averaging the results of three runs as specified in § 60.8(f).

(Sec. 114 of the Clean Air Act as amended (42 U.S.C. 7414))

§ 60.445 Monitoring of operations and recordkeeping.

(a) The owner or operator of an affected facility subject to this subpart shall maintain a calendar month record of all coatings used and the results of the reference test method specified in § 60.446(a) or the manufacturer's formulation data used for determining the VOC content of those coatings.

(b) The owner or operator of an affected facility controlled by a solvent recovery device shall maintain a calendar month record of the amount of solvent applied in the coating at each affected facility.

(c) The owner or operator of an affected facility controled by a solvent recovery device shall install, calibrate, maintain, and operate a monitoring device for indicating the cumulative amount of solvent recovered by the device over a calendar month period. The monitoring device shall be accurate within ±2.0 percent. The owner or operator shall maintain a calendar month record of the amount of solvent recovered by the device.

(d) The owner or operator of a coating line operating at the conditions specified in § 60.442(b) shall maintain a daily and yearly record of the amount of solvent applied in the coating at the facility.

(e) The owner or operator of an affected facility controlled by a thermal incineration solvent destruction device shall install, calibrate, maintain, and operate a monitoring device which continuously indicates and records the temperature of the solvent destruction device's exhaust gases. The monitoring device shall have an accuracy of the greater of ±0.75 percent of the temperature being measured expressed in degrees Celsius or ±2.5°C.

(f) The owner or operator of an affected facility controlled by a catalytic incineration solvent destruction device shall install, calibrate, maintain, and operate a monitoring device which continuously indicates and records the gas temperature both upstream and downstream of the catalyst bed.

(g) The owner or operator of an affected facility controlled by a solvent destruction device which uses a hood or enclosure to capture fugitive VOC emissions shall install, calibrate, maintain, and operate a monitoring device which continuously indicates that the hood or enclosure is operating. No continuous monitor shall be required if the owner or operator can demonstrate that the hood or enclosure system is interlocked with the affected facility's oven recirculation air system.

(Sec. 114 of the Clean Air Act as amended (42 U.S.C. 7414))

§ 60.446 Test methods and procedures.

(a) The VOC content per unit of coating solids applied and compliance with § 60.442(a)(1) shall be measured by either Reference Method 24 or manufacturers' formulation data. In the event of any inconsistency between a Method 24 test and manufacturers' formulation data, the Method 24 test will govern. The Administrator may require an owner or operator to perform Method 24 tests during such months as he deems appropriate.

(1) For Reference Method 24, the coating sample must be a one liter sample taken at a point which will be representative of the coating applied to the web substrate. The one liter sample is to be divided into three aliquots for triplicate analyses.

(b) Reference Method 25 shall be used to determine the VOC concentration, in parts per million by volume, of each effluent gas stream entering and exiting the solvent destruction device or its equivalent, and each effluent gas stream emitted directly to the atmosphere. Reference Methods 1, 2, 3, and 4 shall be used to determine the sampling location, volumetric flow rate, molecular weight, and moisture of all sampled gas streams. For Reference Method 25, the sampling time for each of three runs must be at least one hour. The minimum sampling volume must be 0.003 dscm except that shorter sampling times or smaller volumes, when necessitated by process variables or other factors, may be approved by the Administrator.

(c) If the owner or operator can demonstrate to the Administrator's satisfaction that testing of representative stacks yields results comparable to those that would be obtained by testing all stacks, the Administrator will approve testing of representative stacks on a case-by-case basis.

(Sec. 114 of the Clean Air Act as amended (42 U.S.C. 7414))

§ 60.447 Reporting requirements.

(a) For all affected facilities, the performance test data from the initial performance test are submitted to the Administrator.

(b) The owner or operator of a coating line operated at the conditions specified in § 60.442(b) shall report the total amount of the solvent applied in the coating for each operating day. Every fourth quarter the yearly amount of solvent applied in the coating shall be reported.

(c) For affected facilities complying with § 60.442 without solvent recovery or solvent destruction devices the weighted average VOC content for each calendar month as specified in § 60.443(a)(2) shall be reported to the Administrator.

(d) For all affected facilities complying with § 60.442 by using a solvent recovery device, the following information shall be reported to the Administrator for each calendar month.

(1) The required overall emission reduction specified in § 60.443(b).

(2) The demonstrated overall emission reduction as specified in § 60.443(c).

(e) For all affected facilities complying with § 60.442 by using a solvent destruction device, the following information shall be reported to the Administrator for each calendar month.

(1) The required overall emission reduction specified in § 60.443(b).

(2) The overall emission reduction demonstrated during the most recent performance test which complied with § 60.442.

(3) All periods of temperature drop as defined under § 60.443(f).

(f) The owner or operator of an affected facility shall submit the written reports required under paragraphs (a) and (b) of this section to the Administrator for every calendar quarter. All quarterly reports shall be postmarked by the 30th day following the end of each calendar quarter.

(g) The owner or operator of an affected facility shall submit the written reports required under paragraphs (c), (d), and (e) of this section to the Administrator within ten days following the end of the calendar month being reported only if:

(1) The emissions limits of § 60.442 were exceeded during the calendar month; or

(2) Temperature drops as defined under § 60.443(f) occurred during the calendar month.

(Sec. 114 of the Clean Air Act as amended (42 U.S.C. 7414))

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federal register

Tuesday
December 30, 1980

Part IX

Department of Education

Office of the Secretary

Nomenclature and Technical Amendments

DEPARTMENT OF EDUCATION

Office of the Secretary

34 CFR Subtitle A and Subtitle B, Chapters I–VII

Nomenclature and Technical Amendments

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: This document makes nomenclature and technical amendments in regulations transferred to Title 34 of the Code of Federal Regulations. These changes are necessary to update the Code of Federal Regulations to reflect the shift of responsibility for these programs to the Department of Education.

EFFECTIVE DATE: December 30, 1980.

FOR FURTHER INFORMATION CONTACT: A. Neal Shedd, Director, Division of Regulations Management, 400 Maryland Avenue, S.W., Room 2129, Washington, D.C. 20202. Telephone: (202) 245–7091.

SUPPLEMENTARY INFORMATION: The Department of Education (ED) published on November 21, 1980, at 45 FR 77368, a final rule for the transfer and redesignation of ED regulations in Title 34 of the Code of Federal Regulations.

This final rule makes the specific and general nomenclature and technical amendments necessary in the regulations redesignated on November 21, 1980, as well as specific amendments correcting Part 106, published on May 9, 1980 at 45 FR 30955. Specific changes are listed before general changes. All changes are made in the order that they appear in the list. Unless otherwise specified, general changes apply to 34 CFR Parts 75 through 796 inclusive.

The publication of this document as a proposed rule for public comment is unnecessary because it contains only the nomenclature and technical amendments described above. No substantive changes are made in the regulations.

(Department of Education Organization Act, Pub. L. 96–88, Oct. 17, 1979, 93 Stat. 668 (20 U.S.C. 3401 *et. seq.*))

(Catalog of Federal Domestic Assistance Number not applicable.)

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

Accordingly, 34 CFR Parts 75 through 796 inclusive are amended as follows:

1. Title 34 CFR, Subtitle A is amended by adding the following note after each of the following sections: 75.734, 75.741, 76.101, 76.103, 76,301, 76,401, 76.705, 76.706, 76.734, 76.741, 76.783, and 99.1: (Note: This section is based on a provision in the General Education Provisions Act (GEPA). Section 427 of the Department of Education Organization Act (DEOA), 20 U.S.C. 3487, provides that except to the extent inconsistent with the DEOA, the GEPA "shall apply to functions transferred by this Act to the extent applicable on the day preceding the effective date of this Act." Although standardized nomenclature is used in this section to reflect the creation of the Department of Education, there is no intent to extent the coverage of the GEPA beyond that authorized under Section 427 or other applicable law.)

1a. The undesignated introductory material preceding Part 75 is removed.

2. Wherever they appear in 34 CFR Part 75, the following terms are changed to "the Secretary" in the order listed:

Old nomenclature—New nomenclature

Each appropriate official of the Education Division—the Secretary
The Appropriate official of the Education Division—the Secretary
The Appropriate official—the Secretary
The official—the Secretary.

2a. The following table lists the part number for Title 34 of the Code of Federal Regulations, the prior Catalog of Federal Domestic Assistance (CFDA) number, and the new CFDA number effective on September 15, 1980. The part numbers are listed in order by the ED Staff Offices. Parts 75 and 76 are amended by changing all references to the old CFDA numbers in accordance with the table.

Office of Elementary and Secondary Education

34 CFR Part	Old CFDA No.	New CFDA No.
200	13.428	84.009
201	13.430	84.012
203	13.431	84.013
204	13.429	84.011
208	13.486	84.043
211	13.577	84.092

Office of Elementary and Secondary Education—Continued

34 CFR Part	Old CFDA No.	New CFDA No.
215	13.433	84.014
218	13.477	84.040
219	13.477	84.040
220	13.478	84.041
221	13.477	84.040
222	13.478	84.041
240	13.410	84.006
241	13.591	84.103
250	13.534	84.060
251	13.534	84.060
252	13.551	84.072
253	13.535	84.061
254	13.536	84.062
255	13.551	84.072
256	13.535	84.061
257	13.535	84.061
258	13.551	84.072
259	13.535	84.061
260	13.536	84.062
261	13.536	84.062
262	13.536	84.062
263	13.569	84.087
270	13.405	84.004
280	13.531	84.143
	13.532	84.057
	13.685	84.106
	13.686	84.107
	13.687	84.108
	13.689	84.110
296	13.554	84.074

Office of Special Education and Rehabilitative Services

34 CFR Part	Old CFDA No.	New CFDA No.
300	13.449	84.027
301	13.449	84.027
302	13.427	84.012
305	13.450	84.028
307	13.445	84.025
309	13.444	84.024
315	13.567	84.086
318	13.451	84.029
320	13.446	84.026
324	13.443	84.023
338	13.560	84.078
330	13.446	84.026
331	13.446	84.026
332	13.446	84.026
333	13.446	84.026
345	13.562	84.080
346	13.562	84.080
347	13.562	84.080
361	13.624	84.126
362	13.626	84.128
	13.629	84.129

Office of Vocational and Adult Education

34 CFR Part	Old CFDA No.	New CFDA No.
400	13.493	84.048
	13.494	84.049
	13.495	84.050
	13.499	84.052
406	13.498	84.051
	13.588	84.101
425	13.400	84.002
426	13.400	84.002
431	.....	84.118
432	13.692	84.113

Office of Vocational and Adult Education—Continued

34 CFR Part	Old CFDA No.	New CFDA No.
432	13.579	84.093
	.....	84.093
440	13.563	84.081
441	13.563	84.081
442	13.563	84.081
443	13.563	84.081
444	13.563	84.081

Office of Bilingual Education and Minority Languages Affairs

34 CFR Part	Old CFDA No.	New CFDA No.
500	13.403	84.003
501	13.403	84.003
502	13.403	84.003
503	13.403	84.003
504	13.403	84.003
505	13.403	84.003
510	13.403	84.003
514	13.403	84.003
515	13.403	84.003
520	13.403	84.003
525	13.558	84.077
526	13.586	84.099
527	13.587	84.100
537	13.545	84.068

Office of Postsecondary Education

34 CFR Part	Old CFDA No.	New CFDA No.
605	13.550	84.071
606	13.585	84.098
610	13.491	84.046
614	.....	84.142
617	13.457	.....
	13.458	.....
	13.459	.....
	13.593	.....
	13.594	.....
621	13.453	84.135
624	13.454	84.031
629	13.540	84.064
631	13.510	84.055
639	.....	84.097
643	13.488	84.044
644	13.543	84.066
645	13.492	84.047
646	13.582	84.096
647	13.691	84.112
648	13.580	84.094
649	13.555	84.075
650	13.567	84.085
655	13.436	84.017
662	13.438	84.019
	13.439	84.020
	13.440	84.021
	13.441	84.022
667	13.581	84.095
674	13.470	84.037
	13.471	84.038
675	13.463	84.033
676	13.418	84.007
682	13.460	84.032
686	13.548	84.069
690	13.539	84.063
692	13.539	84.063
695	13.582	84.096

Office of Educational Research and Improvement

34 CFR Part	Old CFDA No.	New CFDA No.
700	.....	84.117
701	.....	84.117
702	.....	84.117
703	13.950	84.117
705	.....	84.117
708	13.950	84.117
710	13.950	84.117
714	13.950	84.117
716	13.950	84.117

Office of Educational Research and Improvement—Continued

34 CFR Part	Old CFDA No.	New CFDA No.
718	13.950	84.117
720	13.950	84.117
726	13.922	84.114
730	13.925	84.116
740	13.420	84.008
745	13.565	84.083
752	13.561	84.079
753	13.568	84.084
755	13.564	84.082
757	13.693	84.123
758	13.522	.....
765	13.544	84.067
766	13.599	84.105
767	13.599	84.105
768	13.599	84.105
769	13.549	84.070
770	13.464	84.034
	13.465	84.035
773	13.406	84.005
774	13.570	84.088
	13.571	84.084
	.....	84.089
776	13.468	84.036
777	13.475	84.039
778	13.576	84.091
790	.....	84.124
793	13.489	84.045
795	13.950	84.117
796	13.553	84.073

PART 75—DIRECT PROTECT GRANT AND CONTRACT PROGRAMS

§ 75.100 [Amended]

3. Section 75.100 is amended by removing the note following the citation of authority for the section.

4. Section 75.220 is amended by revising paragraph (b)(3) to read as follows:

§ 75.220 Procedures the Department uses under § 75.219(a).

* * * * *

(b) * * *

(3) A Department employee who is not a program officer of the program but who is qualified to evaluate the application.

* * * * *

5. Section 75.221 is amended by revising paragraph (b)(1)(iii) to read as follows:

§ 75.221 Procedures the Department uses under § 75.219(b).

* * * * *

(b) * * *

(1) * * *

(iii) A Department employee who is not a program officer for any of the programs under which the applicant wants funds but who is qualified to review the application.

* * * * *

6. Section 75.59 is revised to read as follows:

§ 75.591 Federal evaluation—cooperation by a grantee.

A grantee shall cooperate in any evaluation of the program by the Secretary.

(20 U.S.C. 1226c, 1231a)

7. Section 75.620 is amended by revising paragraph (b) to read as follows:

§ 75.620 General conditions on publication.

* * * * *

(b) *Required Statement.* The grantee shall ensure that any publication that contains project materials also contains the following statements:

"The contents of this (insert type of publication; e.g., book, report, film) were developed under a grant from the Department of Education. However, those contents do not necessarily represent the policy of the Department of Education, and you should not assume endorsement by the Federal Government."

(20 U.S.C. 3474)

8. Section 75.626 is amended by revising paragraph (a) to read as follows:

§ 75.626 Show Federal support; give papers to vest title.

(a) Any patent application filed by a grantee for an invention made under a grant must include the following statement in the first paragraph:

"The invention described in this application was made under a grant from the Department of Education."

* * * * *

9. Section 75.720 is amended by revising paragraph (b) to read as follows:

§ 75.720 Financial and performance reports.

* * * * *

(b) A grantee shall submit these reports annually, unless the Secretary allows less frequent reporting. However, the Secretary may require a grantee of the National Institute of Education to submit performance reports more often than annually.

* * * * *

10. Section 75.901 is amended by removing and reserving paragraph (a), removing paragraph (c), and revising paragraph (b) to read as follows:

§ 75.901 Suspension and termination.

(a) [Reserved]

(b) The Secretary may use the Education Appeal Board to resolve disputes that are not subject to other procedures. Cross-reference: See the following sections in Part 74:

(1) Section 74.113 (Violation of terms).
(2) Section 74.114 (Suspension).
(3) Section 74.115 (Termination).
(4) The last sentence of § 74.73(c) (Financial reporting after a termination).
(5) Section 74.112 (Amounts payable to the Federal Government).

(20 U.S.C. 1221e-3(a)(1))

§ 75.902 [Removed]

11. Section 75.902 is removed.

12. Section 75.903 is amended by revising paragraph (c) to read as follows:

§ 75.903 Effective date of termination.

* * * * *

(c) The date of a final decision of the Secretary under Part 78 of this title.

(20 U.S.C. 3474)

PART 76—STATE-ADMINISTERED PROGRAMS

13. Section 76.591 is revised to read as follows:

§ 76.591 Federal evaluation—cooperation by a grantee.

A State and subgrantee shall cooperate in any evaluation of a program by the Secretary.

(20 U.S.C. 1226c, 1231a, 3474)

14. Section 76.600 is amended by revising paragraph (b) to read as follows:

§ 76.600 Where to find construction regulations.

* * * * *

(b) The State shall perform the functions that the Secretary performs under §§ 75.602 (Preservation of historic sites) and 75.605 (Approval of drawings and specifications) of this title.

* * * * *

15. The title of Part 77 is revised to read as follows:

PART 77—DEFINITIONS THAT APPLY TO DEPARTMENT REGULATIONS

16. Section 77.1 is amended by removing and reserving paragraph (a), removing the definition of "HEW" from paragraph (b) and the definitions of "Appropriate official of the Education Division," "Assistant Secretary," "Commissioner," and "Education Division" from paragraph (c), and revising the introductory text and indicated terms in paragraphs (b) and (c) to read as follows:

§ 77.1 Definitions that apply to all Department programs.

(a) [Reserved]

(b) Unless a statute or regulation provides otherwise, the following definitions in Part 74 of this title apply to the regulations in Title 34 of the Code of Federal Regulations. The section of Part 74 that contains the definition is given in parentheses.

* * * * *

(c) Unless a statute or regulation provides otherwise, the following definitions also apply to the regulations in this title:

* * * * *

"Department" means the U.S. Department of Education.

* * * * *

"ED" means the U.S. Department of Education.

"EDGAR" means the Education Department General Administrative Regulations (34 CFR Parts 74, 75, 76, 77, and 78).

* * * * *

"Secretary" means the Secretary of the Department of Education or an official or employee of the Department acting for the Secretary under a delegation of authority.

* * * * *

§ 77.2 [Removed]

17. Section 77.2 is removed.

PART 106—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION PROGRAMS AND ACTIVITIES RECEIVING OR BENEFITING FROM FEDERAL FINANCIAL ASSISTANCE

§ 106.4 [Amended]

(a) In § 106.4 paragraph (a) is revised by changing the reference "§86.3(a)" to read "§ 106.3(a)".

18. Section 106.11 is revised to read as follows:

§ 106.11 Application.

Except as provided in this subpart, this Part 106 applies to every recipient and to each education program or activity operated by such recipient which receives or benefits from Federal financial assistance.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

19. Section 106.15 is amended by revising paragraph (b) to read as follows:

§ 106.15 Admissions.

* * * * *

(b) *Administratively separate units.* For the purposes only of this section, §§ 106.16 and 106.17, and Subpart C, each administratively separate unit shall be deemed to be an educational institution.

* * * * *

20. Section 200.1 is amended by revising paragraph (b) to read as follows:

PART 200—FINANCIAL ASSISTANCE TO LOCAL EDUCATIONAL AGENCIES AND STATE AGENCIES TO MEET THE SPECIAL EDUCATIONAL NEEDS OF EDUCATIONALLY DEPRIVED, HANDICAPPED, MIGRANT, AND NEGLECTED AND DELINQUENT CHILDREN—GENERAL PROVISIONS

§ 200.1 Applicability.

* * * * *

(b) *Education Department General Administrative Regulations.* Assistance provided under this part is subject to Parts 76 and 77 of this title.

* * * * *

§ 200.2 [Amended]

21. In § 200.2 paragraph (b) is amended by removing the word "Commissioner" from the list of terms.

22. Section 201.1 is amended by revising paragraph (b) to read as follows:

PART 201—FINANCIAL ASSISTANCE TO LOCAL EDUCATIONAL AGENCIES TO MEET THE SPECIAL EDUCATIONAL NEEDS OF EDUCATIONALLY DEPRIVED AND NEGLECTED AND DELINQUENT CHILDREN

§ 201.1 Applicability.

* * * * *

(b) Assistance under this part is subject to the Educational Department General Administrative Regulations in Parts 76 and 77 of this title.

* * * * *

PART 204—GRANTS TO STATE EDUCATIONAL AGENCIES TO MEET THE SPECIAL EDUCATIONAL NEEDS OF MIGRATORY CHILDREN

23. Section 204.12 is amended by revising paragraph (b)(12) to read as follows:

§ 204.12 What provisions are required in a State's annual program plan?

* * * * *

(b) * * *

(12) *Monitoring and enforcement.* An SEA shall include in its plan a monitoring and enforcement plan (in the format prescribed by the Secretary) or an appropriate reference to a currently approved plan on file with the Secretary.

* * * * *

24. In § 208.4 paragraph (b) is amended by removing "Commissioner" from the list of defined terms.

25. Section 208.10 is amended by revising paragraph (e) to read as follows:

PART 208—STRENGTHENING STATE EDUCATIONAL AGENCY MANAGEMENT

§ 208.10 State plan.

* * * * *

(e) The SEA may submit amendments to its title V–B State plan so long as they conform to the requirements for amendments in Parts 75 or 76 of this title, whichever is applicable.

(20 U.S.C. 3162 and 30984 (a)(12))

PART 209—ADMINISTRATION OF EDUCATION PROGRAMS AND DUTIES OF THE STATE EDUCATIONAL AGENCY

26. In § 209.4 paragraph (b) is amended by removing "Commissioner" from the list of defined terms.

27. Section 219.1 is amended by revising paragraph (c) to read as follows:

PART 219—SCHOOL CONSTRUCTION ASSISTANCE IN CASES OF CERTAIN DISASTERS

§ 219.1 Definitions.

* * * * *

(c) "Disaster review team" means a group comprised of representatives of the Department, Office of Facilities Engineering and Property Management, the State educational agency (when available), and local educational agencies.

(20 U.S.C. 646)

* * * * *

PART 220—ASSISTANCE FOR CURRENT SCHOOL EXPENDITURES IN CASES OF CERTAIN DISASTERS

27a. Section 220.1 is amended by revising paragraph (d) to read as follows:

§ 220.1 Definitions.

* * * * *

(d) "Disaster review team" means a group comprised of representatives of the Department, Office of Facilities Engineering and Property Management, the State educational agency (when available), and local educational agencies.

(20 U.S.C. 2141–1(a))

* * * * *

PART 221—ASSISTANCE FOR SCHOOL CONSTRUCTION IN AREAS AFFECTED BY FEDERAL ACTIVITIES

28. Section 221.64 is amended by revising paragraph (b) to read as follows:

§ 221.64 Disposal of federally owned temporary school facilities provided under section 9.

* * * * *

(b) The Secretary may, as appropriate, declare temporary school facilities surplus to the needs of the local educational agency and may dispose of the facilities.

(20 U.S.C. 639)

29. Part 221, Appendix A, paragraph (a)(1) of section 2.7 is amended by removing the words "of the Department of Health, Education, and Welfare".

PART 222—ASSISTANCE FOR LOCAL EDUCATIONAL AGENCIES IN AREAS AFFECTED BY FEDERAL ACTIVITIES AND ARRANGEMENTS FOR EDUCATION OF CHILDREN WHERE LOCAL EDUCATIONAL AGENCIES CANNOT PROVIDE SUITABLE FREE PUBLIC EDUCATION

§ 222.70 [Amended]

29a. Section 222.70 is amended by revising the references in paragraph (a) as follows:
Change "45 CFR Part 84 ff" to "34 CFR Part 104 ff".
Change "45 CFR Part 121 ff" to "34 CFR Part 300 ff".
Change "45 CFR Part 116" to "34 CFR Part 200".

30. Section 222.83 is amended by revising paragaph (c) to read as follows:

§ 222.83 Monitoring.

* * * * *

(c) If the Department has already audited an applicant's section 5(e) program or project, it is not expected that the State educational agency would audit the same program or project.

* * * * *

31. In Parts 361, 362, 369, and 370 the phrase "Rehabilitation Services Administration" is changed to "Department", *except* in sections 361.86(c)(2) and 370.2(a).

PART 361—THE STATE VOCATIONAL REHABILITATION PROGRAM

§ 361.1 [Amended]

32. Section 361.1 is amended by removing paragraphs (e), (v), and (hh).

§ 361.15 [Amended]

33. Section 361.15(b) is amended by changing the references to "Part 70 of this title" to "45 CFR Part 70" and "§ 70.4 of this title" to "45 CFR 70.4".

§ 361.151 [Amended]

34. Section 361.151(f) is amended by changing the reference to "Part 46 of this title" to "45 CFR Part 46".

PART 362—PROJECT GRANTS AND OTHER ASSISTANCE IN VOCATIONAL REHABILITATION

§ 362.1 [Amended]

35. In § 362.1 paragraph (a) is amended by removing "Commissioner", "Department", and "Secretary" from the list of defined terms.

§ 362.14 [Removed]

36. Section 362.14 is removed.

§ 362.19 [Amended]

37. Section 362.19 is amended by changing "Assistant Secretary for Health, Department of Health, Education, and Welfare" to "Secretary."

§ 362.24 [Amended]

38. Section 362.24 is amended by changing the reference to "Part 46 of this title" to "45 CFR Part 46."

PART 369—VENDING FACILITY PROGRAM FOR THE BLIND ON FEDERAL AND OTHER PROPERTY

§ 369.1 [Amended]

39. Section 369.1 is amended by removing and reserving paragraphs (e) and (r).

40. Section 526.612 is amended by revising paragraph (b) to read as follows:

§ 526.612 Eligible programs.

* * * * *

(b) In-service and developmental programs designed to enable instructional and ancillary personnel to continue to improve their qualifications while participating in bilingual vocational training programs; fellowships or traineeships for persons engaged in activities described in paragraphs (a) and (b) of this section are an allowable cost. A fellowship is an award to an individual student made by the Department. A traineeship is an award to an institution for student support (stipends or allowances) and for institutional support (either in a predetermined amount or based on actual costs).

(Secs. 186, 187; 20 U.S.C. 2416, 2417)

PART 537—INDOCHINA REFUGEE CHILDREN ASSISTANCE

§ 537.3 [Amended]

41. In § 537.3 paragraph (b) is amended by removing "Commissioner" from the list of defined terms.

42. Section 537.4 is amended by revising paragraph (b) to read as follows:

§ 537.4 How does a State apply for funds?

* * * * *

(b) A State application, as required by section 205(a) of the Act and by Part 76 of this title.

(20 U.S.C. 1232d)

43. Section 603.4 is revised to read as follows:

PART 603—COMMISSIONER'S RECOGNITION PROCEDURES FOR NATIONAL ACCREDITING BODIES AND STATE AGENCIES

§ 603.4 Inclusion on list.

Any accrediting agency or association which desires to be listed by the Secretary as meeting the criteria set forth in § 603.6 should apply in writing to the Director, Division of Eligibility and Agency Evaluation, Office of Postsecondary Education, Department of Education, Washington, D.C. 20202.

(20 U.S.C. 1141(a))

44. Section 603.22 is revised to read as follows:

§ 603.22 Inclusion on list.

Any State agency which desires to be listed by the Secretary as meeting the criteria set forth in § 603.24 should apply in writing to the Director, Division of Eligibility and Agency Evaluation, Office of Postsecondary Education, Department of Education, Washington, D.C. 20202.

(20 U.S.C. 1087-1(b))

PART 614—COLLEGE HOUSING PROGRAMS ADMINISTERED BY THE DEPARTMENT OF EDUCATION

§ 614.1 [Amended]

45. Section 614.1 is amended by removing paragraph (g) and redesignating paragraph (h) as paragraph (g).

46. Section 614.4 is amended by revising paragraph (a) to read as follows:

§ 614.4 Applications.

(a) Applications will be received periodically and considered concurrently for both the direct loan and grant subsidy programs. In order to maintain flexibility in the allocation of available funds, ED reserves the option to approve either a direct loan or a grant to a particular applicant.

* * * * *

§ 614.60 [Amended]

47. Section 614.60 is amended by removing the definition of "Field Office".

§ 614.62 [Amended]

48. Section 614.62 is amended by changing "the appropriate HUD Field Office" and "the appropriate Field Office" to "ED" wherever they appear.

49. Part 614 is amended by removing and reserving Subparts B and C, reserving Subpart D, and by changing "HUD" to "ED" wherever it appears in Subparts A, E, and F.

50. Part 655, Appendix, Chapter II, paragraph (a) of section 1.2 is amended by changing the words "Office" to "Department" and "Bureau" to "Office".

PART 655—MODERN FOREIGN LANGUAGE AND AREA STUDIES

51. Part 655, Appendix, Chapter V, section 1.1 is amended by changing the reference to "41 CFR 3–4.5202–1(b)" to "41 CFR 34–4.5202–1(b)".

PART 675—COLLEGE WORK-STUDY AND JOB LOCATION AND DEVELOPMENT PROGRAM

52. Part 675, Appendix B is amended by changing "Department of Health, Education, and Welfare" to "Department of Education" wherever it appears.

PART 682—GUARANTEED STUDENT LOAN PROGRAM

§ 682.200 [Amended]

53. Section 682.200 is amended by removing the definitions of "Commissioner", "Nonprofit institution", and "State".

54. Section 682.600 is amended by revising paragraph (a)(1) to read as follows:

§ 682.600 Participation agreement between an eligible school and the Secretary.

(a) * * *

(1) Establish its basic eligibility as an institution of higher education or vocational school, as defined in § 682.200, through certification by the Division of Eligibility and Agency Evaluation, Office of Postsecondary Education, Department of Education; and

* * * * *

55. Section 695.8 is revised to read as follows:

PART 695—INCENTIVE GRANTS FOR STATE STUDENT FINANCIAL ASSISTANCE TRAINING PROGRAM

§ 695.8 State matching requirements.

The Federal funds expended under this part must be matched by an equal amount of State funds. In satisfying this matching requirement, the State is subject to Part 74 of this title. The matching must be from non-federal sources and may be cash or in kind. The State shall maintain supporting records to indicate the amount and sources of such matching.

(20 U.S.C. 1088b–3)

PART 700—GENERAL

§ 700.1 [Amended]

56. Section 700.1 is amended by removing the definitions of "Director" and "Institute".

57. Section 700.2 is amended by revising paragraph (a)(2) to read as follows:

§ 700.2 Regulations that apply to programs of the National Institute of Education.

(a) * * *

(2) The regulations in this Chapter VII.

* * * * *

58. Section 726.03 is amended by removing the definition of "Administrator."

59. Part 726 is amended by changing the term "Administrator" to "Secretary" wherever it appears.

60. Section 730.1 is revised to read as follows:

PART 730—SUPPORT FOR IMPROVEMENT OF POSTSECONDARY EDUCATION

§ 730.1 Purpose.

The purpose of the regulations in this part is to implement the provisions of Title X of the Higher Education Act of 1965, which provides for grants to, and contracts with, institutions of postsecondary education and other public and private educational institutions and agencies to improve postsecondary educational opportunities. The program is administered by the Fund for the Improvement of Postsecondary Education, a unit within the Office of the Assistant Secretary for Educational Research and Improvement of the Department of Education, with the advice of a Board of Advisors.

(20 U.S.C. 1135)

PART 770—LIBRARY SERVICES, PUBLIC LIBRARY CONSTRUCTION, AND INTERLIBRARY COOPERATION

§ 770.3 [Amended]

60a. Section 770.3 is amended by removing "Commissioner" from the list of defined terms.

61. Section 795.1 is amended by revising paragraph (a)(2) to read as follows:

PART 795—STATE DISSEMINATION GRANTS PROGRAM

§ 795.1 Regulations that apply to the State Dissemination Grants Program.

(a) * * *

(2) The general provisions for NIE grants in 34 CFR Parts 700–702.

* * * * *

62. Section 795.5 is amended by revising paragraphs (a)(7) and (b)(2) to read as follows:

§ 795.5 Types of awards; funding requirements.

(a) * * *

(7) Each application must show an SEA contribution, in funds or in kind, to be included from the commencement of the project, in accordance with 34 CFR Part 74.

(b) * * *

(2) Salary cost of regular SEA staff properly attributable to the carrying out of the project will be considered an in kind SEA contribution to the project, in accordance with Part 74 of this title.

* * * * *

63. Wherever they appear in the Parts 75 through 796 inclusive, excluding Parts 99, 100, 101, 104, and 106, the terms listed are changed as follows:

Old nomenclature	*New nomenclature*
U.S. Office of Education	Department
U.S.O.E.	ED
OE	ED
O.E.	ED
An Education Division	a Department
An Office of Education	a Department
Education Division General Administrative Regulations	Education Department General Administrative Regulations
Education Division	Department
Secretary of Health, Education, and Welfare	Secretary
Secretary of the Department of Health, Education, and Welfare	Secretary
Assistant Secretary for Education	Secretary
U.S. Commissioner of Education	Secretary
United States Commissioner of Education	Secretary
41 CFR Chapters 1 and 3	41 CFR Chapters 1 and 34.

64. Wherever they appear in 34 CFR Parts 700, 701, 702, 703, 705, 708, 710, 714, 716, 718, 720, and 795 the terms listed are changed as follows:

Old nomenclature	*New nomenclature*
Director	Secretary
Institute	Department
NIE	ED
National Institute of Education	Department.

65. Wherever it appears in Parts 75 through 796 inclusive, excluding Parts 99, 100, 101, 104, and 106, the term "Office of Education" is changed to "Department," except in: the *Comment* following § 300.303, § 662.12(d), § 662.22(d), § 662.32(c), § 662.42(c), Appendix D to Part 674, and the Appendix to Part 793.

66. Wherever it appears in Parts 75 through 796 inclusive, excluding Parts 99, 100, 101, 104, and 106, the term "Commissioner" is changed to "Secretary", except in the Appendix to Part 793.

67. Wherever it appears in Parts 75 through 796 inclusive, excluding Parts 99, 100, 101, 104, and 106, the term "HEW" is changed to "ED", except in § 215.2 where it is changed to "HHS".

68. Wherever it appears in the Parts 75 through 796 inclusive, excluding Parts 99, 100, 101, 104, and 106, the term "Commissioner of Education" is changed to "Secretary", except in the *Comment* following § 300.307.

69. The sections in former 45 CFR Part 105 which were redesignated as 34 CFR Parts 408, 525, 526, and 527 at 45 FR 77368 (November 21, 1980) are renumbered as follows:

Old sections	*New sections*
105.1–105.504 (Appendices A, B)	408.1–408.504 (Appendices A, B)
105.601–105.607	525.601–525.607
105.611–105.617	526.611–526.617
105.621–105.627	527.621–527.627.

70. An authority citation for 34 CFR Parts 525, 526, and 527 is added to read as follows:

Authority: Secs. 101–195 of Title II of Pub. L. 94–482 as further amended by Pub. L. 95–40 (20 U.S.C. 2301 to 2461), unless otherwise noted.

PART 525—BILINGUAL VOCATIONAL TRAINING PROGRAM

71. Section 525.601 is revised to read as follows:

§ 525.601 Purpose.

The purpose of the bilingual vocational training program is to prepare persons of limited English-speaking ability to perform adequately in an environment requiring English language skills and to fill the critical need for more and better trained persons in occupational categories vital to both the persons and the economy. Funds available to the Secretary pursuant to section 183 of Part B of Title I of the Vocational Education Act of 1963, as amended by section 202 of Title II of the Education Amendments of 1976, Pub. L. 94–482 (referred to as "the Act") may be used for making grants or contracts for bilingual vocational training programs.

(Sec. 181; 20 U.S.C. 2411; Conf. Rept. No. 94–1701, p. 228)

72. Section 526.611 is revised to read as follows:

PART 526—BILINGUAL VOCATIONAL INSTRUCTOR TRAINING PROGRAM

§ 526.611 Purpose.

The purpose of the bilingual vocational instructor training program is to provide training programs to meet the critical shortage of instructors possessing both the job knowledge and skills and the dual language capabilities required for adequate instruction of persons handicapped by their limited English-speaking ability. Funds available to the Secretary pursuant to section 183 of Part B of Title I of the Vocational Education Act of 1963, as amended by section 202 of Title II of the Education Amendments of 1976, Pub. L. 94–482 (referred to as "the Act") may be used for making grants or contracts for bilingual vocational instructor training programs.

(Sec. 186; 20 U.S.C. 2416)

73. Section 527.621 is revised to read as follows:

PART 527—BILINGUAL VOCATIONAL INSTRUCTIONAL MATERIALS, METHODS, AND TECHNIQUES PROGRAM

§ 527.621 Purpose.

The purpose of the bilingual vocational instructional materials, methods, and techniques program is to develop instructional materials and encourage research programs and demonstration projects to meet the critical shortage of such instructional materials suitable for bilingual vocational training programs. Funds available to the Secretary pursuant to section 183 of Part B of Title I of the Vocational Educational Act of 1963, as amended by section 202 of Title II of the Education Amendments of 1976, Pub. L. 94–482 (referred to as "the Act") may be used for making grants or contracts for bilingual vocational instructional materials, methods, and techniques.

[FR Doc. 80-40420 Filed 12-29-80; 8:45 am]

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December 30, 1980

Part X

Department of Education

Educational Programs; Proposed Regulations

DEPARTMENT OF EDUCATION

34 CFR Part 692

State Student Incentive Grant Program

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: These regulations simplify existing rules for the State Student Incentive Grant Program and incorporate statutory changes made by the Education Amendments of 1980.

DATES: All comments must be received on or before February 13, 1981.

ADDRESSES: Any comments on these proposed regulations should be addressed to Lanora G. Smith, Acting Chief, State Student Incentive Grant Program, Regional Office Building 3, Room 4004, 7th and D Streets, S.W., Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Lanora G. Smith, telephone (202) 472–4265.

SUPPLEMENTARY INFORMATION: On September 14, 1977, final regulations for the State Student Incentive Grant Program were published in the **Federal Register** (45 CFR Part 192). The regulations were amended April 3, 1980 (45 FR 22542). On November 21, 1980, 45 CFR Part 192 was redesignated as 34 CFR Part 692. The Department proposes to simplify the language and requirements of the existing regulations, telescope initial and continuation awards into a single program, and otherwise conform the regulations to changes made by the Education Amendments of 1980 (Pub. L. 96–374). The following table shows where the existing regulations have been incorporated into the proposed regulations.

Existing Regulations	Proposed Regulations
(34 CFR Part 692—Formerly 45 CFR Part 192).	
§ 692.1.	692.1, 692.10.
692.1–1.	692.3.
692.2 (Definitions of "continuation award", "cost of education", "dependent student", "expected family contribution of a dependent student", "expected family contribution of an independent or self-supporting student", "half-time student", "independent student", "initial award", "National of the United States", "undergraduate student")	Deleted.
692.2 (All other definitions).	692.4.
692.3.	Deleted (covered by the statute).
692.4(a)–(c), (e)–(h), (j).	692.21.
692.4(d).	692.40.
692.4(i).	Deleted (covered by section 1203 of the Act).
692.5.	692.20(b).
692.6.	692.40.
692.7.	Deleted—See proposed 692.41.
692.8.	Deleted.
692.9.	692.21(h).
692.10.	692.21(g).

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding the proposed regulations. Written comments and recommendations may be sent to the address given at the beginning of this document. In developing final regulations for this program, the Department will consider all comments received on or before the 45th day after publication of this document.

All written comments submitted in response to the proposed regulations will be available for inspection, both during and after the comment period, in Room 4004, Regional Office Building 3, 7th and D Streets, S.W., Washington, D.C., between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Saturdays, Sundays, and Federal holidays.

Assessment of Educational Impact

The Department particularly requests comments on whether the proposed regulations in this document would require transmission of information that is already being gathered by or is available from any other agency or authority of the United States.

Citation of Legal Authority

The reader will find a citation of statutory or other legal authority in parentheses on the line following each substantive provision.

Dated: December 22, 1980.

(Catalog of Federal Domestic Assistance Number 84.069: State Student Incentive Grant Program)

Shirley M. Hufstedler,

Secretary of Education.

The Secretary proposes to revise Part 692 of Title 34 of the Code of Federal Regulations to read as follows:

PART 692—STATE STUDENT INCENTIVE GRANT PROGRAM

Subpart A—General

Sec.

Subpart B—What Does the Department Assist Under This Program?

Subpart C—How Does a State Apply to Participate in This Program?

Subpart D [Reserved]

Subpart E—How Does a State Select Students for Grants?

AUTHORITY: Secs. 415A–415D of Title IV of the Higher Education Act of 1965, as amended, 86 Stat. 255, 90 Stat. 2094, 91 Stat. 218, 94 State. 1406–1407 (20 U.S.C. 1070c–1070c–3), unless otherwise noted.

Subpart A—General

§ 692.1 What is the State Student Incentive Grant Program?

The State Student Incentive Grant Program assists States that provide grants to eligible students who attend institutions of higher education and have substantial financial need.

(20 U.S.C. 1070c–1070c–3)

§ 692.2 Who is eligible to participate in the State Student Incentive Grant Program?

(a) *State participation.* A State that meets the requirements in §§ 692.20–692.21 is eligible to receive payments under this program.

(b) *Student participation.* A student who meets the requirements of § 692.40 is eligible to receive a grant from a State under this program.

(20 U.S.C. 1070c–1)

§ 692.3 What regulations apply to the State Student Incentive Grant Program?

The following regulations apply to the State Student Incentive Grant Program:

(a) The Education Department General Administrative Regulations (EDGAR) in Part 76 (State-Administered Programs) and Part 77 (Definitions).

(b) The regulations in Part 604 that implement section 1203 of the Act (Federal-State Agreement).

(c) The regulations in this Part 692.

(20 U.S.C. 1070c)

§ 692.4 What definitions apply to the State Student Incentive Grant Program?

The following definitions apply to the regulations in this part:

(a) *Definitions in EDGAR.* The following terms used in this part are defined in Part 77:

Nonprofit
Secretary
State

(b) *Definition in Part 668.* The following definition in Part 668 of this title applies to the regulations in this part:

Institution of higher education (§ 668.1(a)(2)(i))

(c) *Other definitions that apply to this part.* The following additional definitions apply to this part:

"Academic year" means a period of time during which a full-time student is expected to complete the equivalent of one of the following:

(1) Two semesters.

(2) Two trimesters.

(3) Three quarters.

(4) Nine hundred clock hours of instruction.

"Act" means the Higher Education Act of 1965, as amended. "Clock hour" means a period of time that is equivalent to—

(1) A 50- to 60-minute class, lecture, or recitation; or

(2) A 50- to 60-minute faculty-supervised laboratory, ship training, or internship.

"Full-time student" means a student carrying a full-time academic workload—other than by correspondence—as measured by both of the following:

(1) Coursework or other required activities, as determined by the institution that the student attends or by the State.

(2) The tuition and fees normally charged for full-time study by that institution.

(20 U.S.C. 1070c-1070c-3, 1088)

Subpart B—What Does the Department Assist Under This Program?

§ 692.10 For what purposes may a State use its payments under this program?

A State may use its payments under the State Student Incentive Grant Program to—

(a) Make grants to students under new student grant programs; or

(b) Expand grants under existing student grant programs by—

(1) Making grants to additional eligible students; or

(2) Increasing the size of grants.

(20 U.S.C. 1070c)

Subpart C—How Does a State Apply to Participate in This Program?

§ 692.20 What agreement must a State have with the Secretary?

To participate in the State Student Incentive Grant Program, a State must—

(a) Enter into an agreement with the Secretary under section 1203 of the Act (Federal-State Agreement); and

(b) For each fiscal year that it wishes to participate, submit an application that contains information that shows that the State's student grant program meets the requirements in § 692.21.

(20 U.S.C. 1070c-2(a))

(Cross-reference: See 34 CFR Part 604, Federal-State Agreements.)

§ 692.21 What requirements must be met by a State program?

To receive a payment under this program for any fiscal year, a State must have a program that—

(a) Is administered by a single State agency in accordance with the Federal-State Agreement under section 1203 of the Act;

(b) Awards grants only to students who meet the eligibility requirements in § 692.40;

(c) Provides that a grant to a full-time student will not be more than $2,000 for each academic year;

(d) Provides for the selection of students to receive grants on the basis of substantial financial need determined annually by the State on the basis of standards that the State establishes and the Secretary approves. Cross-reference: See § 692.41.

(e) Provides that all nonprofit institutions of higher education in the State are eligible to participate unless that participation is in violation of—

(1) The constitution of the State; or

(2) A State statute that was enacted before October 1, 1978.

(f) Provides that, with the approval of the State agency, an institution of higher education may use any proportion of the payments under this program for grants to students who are not carrying or planning to carry at least one-half the normal full-time workload;

(g) Provides that—

(1) The State will pay at least 50 percent of each grant; and

(2) The amount that the State expends during a fiscal year for grants under this program represents an additional amount for grants to students attending institutions of higher education over the amount expended by the State for that purpose during the second fiscal year before the fiscal year in which the State first received funds under this program;

(h) Provides for State expenditures under the State program of an amount that is not less than—

(1) The average annual aggregate expenditures for the preceding three fiscal years; or

(2) The average annual expenditure per full-time equivalent student for those years; and

(i) Provides for reports to the Secretary that are necessary to carry out the Secretary's functions under this part.

(20 U.S.C. 1070c-2)

Subpart D—[Reserved]

Subpart E—How Does a State Select Students for Grants?

§ 692.40 What are the requirements for student eligibility?

(a) To be eligible for a grant and to receive payments under the grant, a student must—

(1)(i) Be a United States citizen or National;

(ii) Be a permanent resident of the United States;

(iii) Provides evidence from the Immigration and Naturalization Service that the student is in the United States for other than a temporary purpose with the intention of becoming a permanent resident of the United States; or

(iv) Be a permanent resident of the Trust Territory of the Pacific Islands or of the Northern Mariana Islands;

(2) Be enrolled or accepted for enrollment at an institution of higher education;

(3) Have substantial financial need as determined annually in accordance with the State's criteria approved by the Secretary;

(4) In accordance with the standards and practices of the institution at which the student is enrolled, maintain satisfactory progress in a course of study;

(5)(i) Not owe a refund on a grant received for attendance at that institution under the Pell Grant, Supplemental Educational Opportunity Grant, or State Student Incentive Grant programs;

(ii) Not be in default on a loan made by the institution under the National Defense Student Loan or National Direct Student Loan programs unless the student has made arrangements, satisfactory to the institution, to repay the loan; and

(iii) Not be in default on a loan insured under the Guaranteed Student Loan or the Parent Loans for Undergraduate Students (PLUS) program unless the Secretary (for a

federally insured loan) or a guarantee agency (for a loan insured by that guarantee agency) determines that the student has made satisfactory arrangements to repay the loan; and

(6) File with the institution (or with the lender, in the case of a loan or a loan guarantee) a statement that the money attributable to the grant, loan, or loan guarantee will be used solely for expenses related to attendance or continued attendance at the institution.

(b) The Secretary does not consider a National Defense Student Loan, a National Direct Student Loan, or a Guaranteed Student Loan that is discharged in bankruptcy to be in default for purposes of this section.

(20 U.S.C. 1070c–2, 1091)

§ 692.41 What standards may a State use to determine substantial financial need?

A State may determine substantial financial need by using—

(a) The State's own needs analysis system, if approved by the Secretary;

(b) The criteria and standards for determining need promulgated by the Secretary under section 482 of the Act; or

(c) A combination of these systems.

(20 U.S.C. 1070c–2, 1089)

[FR Doc. 80–40413 Filed 12–29–80; 8:45 am]
BILLING CODE 4000–01–M

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34 CFR Parts 201 and 774

Title I and Title IV of the Elementary and Secondary Education Act—Financial Assistance to Local Educational Agencies for Children With Special Educational Needs (Title I) and Grants to State Educational Agencies for Educational Improvement, Resources, and Support (Title IV)

AGENCY: Department of Education.

ACTION: Proposed regulations.

SUMMARY: The Secretary issues proposed regulations for Title I and Title IV of the Elementary and Secondary Education Act (ESEA). These proposed regulations contain procedures for the submission of written objections and show cause hearings, when the Secretary proposes to implement a by-pass to provide equitable services for private school children. These proposed regulations contain specific timelines and procedures to ensure that an expeditious and fair decision is made on whether a by-pass is implemented.

DATE: All comments on these proposed regulations must be received on or before March 2, 1981.

ADDRESS: Comments should be addressed to Mr. Stephen Freid, Office of General Counsel, Department of Education, 400 Maryland Avenue, SW., Room 4091, Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Freid. Telephone (202) 426–6300.

SUPPLEMENTARY INFORMATION: Under Title I and Title IV of ESEA, local educational agencies (LEAs) are required to provide equitable services and programs for children attending private schools (20 U.S.C. 2740, 3086). The specific requirements relating to the services and programs that must be provided for private school children are contained in the Title I and Title IV statutes, and the regulations that have been issued to implement these statutes (34 CFR Parts 201, 774).

The Education Division General Administrative Regulations (EDGAR), which were published in the **Federal Register** in final form on April 3, 1980 (45 FR 22494–22631), contain additional requirements on the participation of private school children that are applicable to the Title I program, but not to the Title IV program.

In some instances LEAs have been unable or unwilling to provide the required services and programs for private school children. This situation occurs sometimes as a result of State laws that limit the types of services that LEAs can provide for private school children.

Because LEAs may be unable or unwilling to provide equitable services and programs for private school children under Title I or Title IV, the Secretary is authorized to provide these services through a by-pass. Under a by-pass, the Secretary waives the LEA's responsibility for providing services for private school children under the affected program, and arranges for the provision of equitable services for the private school children. The Secretary normally hires a contractor to provide these services for the private school children and pays for the services from the appropriate allocations of the affected LEA and State educational agency (SEA). Title I and Title IV by-passes are presently in operation in number of States and LEAs.

Before a by-pass can be implemented under Title I or Title IV, the Secretary must provide both the affected LEA and SEA an opportunity to submit written objections and an opportunity to appear before the Secretary, or the Secretary's designee, to show cause why the by-pass should not be implemented. Presently, the Title I and Title IV regulations do not contain any provisions governing the submission of written objections or the show cause hearing.

These proposed regulations contain specific procedures and timelines so that the submission of written objections and the show cause hearing are handled in a fair and expeditious manner. Opportunity is provided to all concerned parties—the LEA, the SEA, and representatives of the private school children—to present their views on whether the by-pass should be implemented.

In addition, the proposed regulations for Title IV contain a section on the procedures the Secretary uses in making the initial decision to implement a by-pass (§ 774.83). The notice of proposed rulemaking for Title I that was published in the **Federal Register** on June 11, 1980 (45 FR 39712) already contains these procedures in § 116a.95. Those procedures are not repeated in these proposed regulations for Title I, but are cross-referenced as § 201.91 rather than § 116a.95 to correspond to the numbering system that will be used in the final Title I regulations.

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding the proposed regulations. Written comments and recommendations may be sent to the address given at the beginning of this preamble. All comments received on or before the 60th day after publication of this document will be considered in the development of the final regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 4091, 400 Maryland Avenue, SW., Washington, D.C. between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Citation of Legal Authority

A citation of statutory or other legal authority is placed in parentheses on the line following each substantive provision of these proposed regulations.

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

(Catalog of Federal Domestic Assistance Nos. 84.010, Educationally Deprived Children—Local Educational Agencies; 84.068, Instructional Materials and School Library Resources;

The Secretary amends Parts 201 and 774 of Title 34 of the Code of Federal Regulations to read as follows:

PART 201—FINANCIAL ASSISTANCE TO LOCAL EDUCATIONAL AGENCIES TO MEET THE SPECIAL EDUCATIONAL NEEDS OF EDUCATIONALLY DEPRIVED AND NEGLECTED AND DELINQUENT CHILDREN

(1) The following sections are added to the table of contents under Subpart F of Part 201:

Subpart F—Evaluation

Authority: Sec. 130 of Title I of the Elementary and Secondary Act, as amended by Pub. L. 95–561 (20 U.S.C. 2740; 92 Stat. 2171–2172).

(2) The following two sections are added to Subpart F of Part 201:

§ 201.92 Submission of written objections to the proposed by-pass.

(a) If an LEA or SEA submits written objections to the proposed by-pass in accordance with § 201.91(a)(2)(i), the Secretary—

(1) Sends a copy of the written objections to appropriate representatives of the private school children in the affected LEA; and

(2) Allows the representatives of the private school children 30 days to submit written comments on whether a by-pass should be implemented in the affected LEA.

(b) After the close of the 30 day period for the submission of written comments by the represenatives of the private school children, the Secretary—

(1) Makes a final decision concerning whether a by-pass should be implemented; or

(2) Determines that further proceedings should be conducted under § 201.93.

(Sec. 130(b)(4)(A); 20 U.S.C. 2740(b)(4)(A))

§ 201.93 Show cause hearing.

(a) If an LEA or SEA requests an opportunity for a hearing to show cause why a proposed by-pass should not be implemented in accordance with § 201.91(a)(2)(ii), or if the Secretary determines that further proceedings should be conducted under § 201.92(b)(2), the Secretary—

(1) Notifies appropriate representatives of the private school children in the affected LEA that a show cause hearing will be held, and that they may participate in the hearing; and

(2) Designates a hearing officer.

(b) The Secretary may combine show cause hearings that involve similar legal or factual issues.

(c) The hearing officer notifies the LEA, SEA, and the representatives of the private school children of the time and place of the hearing.

(d) The LEA, SEA, and the representatives of the private school children each may be represented by legal counsel.

(e) The hearing officer does not have authority to—

(1) Issue subpoenas;

(2) Require or conduct discovery; or

(3) Rule on the validity of any statute or regulation, including these procedures.

(f) At the show cause hearing—

(1) A transcript is taken; and

(2) The LEA, SEA, and representatives of the private school children each may submit oral or written evidence and arguments.

(g) At the close of the hearing, or within 10 days thereafter, the hearing officer—

(1) Requests further information from the LEA, SEA, representatives of the private school children or appropriate Department of Education officials, to be filed within 30 days; or

(2) Indicates that a decision will be issued on the basis of the existing record.

(h) After the hearing, the hearing officer—

(1) Issues a written decision on whether the LEA and SEA have demonstrated that the proposed by-pass should not be implemented; and

(2) Sends copies of the decision to the LEA, SEA, representatives of the private school children, and the Secretary.

(i) The LEA, SEA, and representatives of the private school children have 10 days from receipt of the hearing officer's decision to submit written comments on the decision to the Secretary.

(j) The Secretary adopts, reverses, or modifies the hearing officer's decision within 45 days of the close of the comment period stated in paragraph (i) of this section.

(Sec. 130(b)(4)(A); 20 U.S.C. 2740(b)(4)(A))

PART 774—GRANTS TO STATE EDUCATIONAL AGENCIES FOR EDUCATIONAL IMPROVEMENT, RESOURCES, AND SUPPORT

(1) The following sections are added to the table of contents under Subpart I of Part 774:

Subpart I—Section 406 Compliance Procedures

Authority: Sec. 406 of Title IV of the Elementary and Secondary Education Act, as amended by Pub. L. 95–561 (20 U.S.C. 3086; 92 Stat. 2234–2236).

(2) The following three sections are added to Part 774:

§ 774.83 Secretary's procedures for by-pass actions.

Before taking any final by-pass action under § 774.81 and § 774.82, the Secretary provides the LEA and SEA with—

(a) Written notice of the Secretary's intent to by-pass the LEA. This notice—

(1) Indicates the reasons for the by-pass;

(2) Advises the LEA and SEA that, within 45 days, they may—

(i) Submit written objections to the proposed by-pass; and

(ii) Request in writing the opportunity for a hearing to show cause why the by-pass should not be implemented; and

(3) Is sent by certified mail with a return receipt requested; and

(b) An opportunity to appear at a hearing before the Secretary, or the Secretary's designee, to show cause why the by-pass should not be implemented.

(Sec. 406(h); 20 U.S.C. 3086(h))

§ 774.84 Submission of written objections to the proposed by-pass.

(a) If an LEA or SEA submits written objections to the proposed by-pass in accordance with § 774.83(a)(2)(i), the Secretary—

(1) Sends a copy of the written objections to appropriate representatives of the private school children in the affected LEA; and

(2) Allows the representatives of the private school children 30 days to submit written comments on whether a by-pass should be implemented in the affected LEA.

(b) After the close of the 30 day period for the submission of written comments by the representatives of the private school children, the Secretary—

(1) Makes a final decision concerning whether a by-pass should be implemented; or

(2) Determines that further proceedings should be conducted under § 774.85.

(Sec. 406(h); 20 U.S.C. 3086(h))

§ 774.85 Show cause hearing.

(a) If an LEA or SEA requests an opportunity for a hearing to show cause why a proposed by-pass should not be implemented in accordance with § 774.83(a)(2)(ii), or if the Secretary determines that further proceedings should be conducted under § 774.84(b)(2), the Secretary—

(1) Notifies appropriate representatives of the private school children in the affected LEA that a show cause hearing will be held, and that they may participate in the hearing; and

(2) Designates a hearing officer.

(b) The Secretary may combine show cause hearings that involve similar legal or factual issues.

(c) The hearing officer notifies the LEA, SEA, and the representatives of the private school children of the time and place of the hearing.

(d) The LEA, SEA, and the representatives of the private school children each may be represented by legal counsel.

(e) The hearing officer does not have authority to—

(1) Issue subpoenas;

(2) Require or conduct discovery; or

(3) Rule on the validity of any statute or regulation, including these procedures.

(f) At the show cause hearing—

(1) A transcript is taken; and

(2) The LEA, SEA, and representatives of the private school children each may submit oral or written evidence and arguments.

(g) At the close of the hearing, or within 10 days thereafter, the hearing officer—

(1) Requests further information from the LEA, SEA, representatives of the private school children, or appropriate Department of Education officials, to be filed within 30 days; or

(2) Indicates that a decision will be issued on the basis of the existing record.

(h) After the hearing, the hearing officer—

(1) Issues a written decision on whether the LEA and SEA have demonstrated that the proposed by-pass should not be implemented; and

(2) Sends copies of the decision to the LEA, SEA, representatives of the private school children, and the Secretary.

(i) The LEA, SEA, and representatives of the private school children have 10 days from receipt of the hearing officer's decision to submit written comments on the decision to the Secretary.

(j) The Secretary adopts, reverses, or modifies the hearing officer's decision within 45 days of the close of the comment period stated in paragraph (i) of this section.

(Sec. 406(h); 20 U.S.C. 3086(h))

[FR Doc. 80-40414 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

34 CFR Part 605

Continuing Education Outreach—State-Administered Program

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary is issuing proposed regulations for the Continuing Education Outreach—State-Administered Program. The proposed regulations are being issued to reflect the statutory changes resulting from the Education Amendments of 1980. Activities previously carried out under the Community Service and Continuing Education Program, the Education Information Centers Program, and the State Planning Commissions Program have been consolidated into a single program and revised. The proposed regulations will govern a comprehensive program of planning, information services, and continuing education projects. Institutions of higher education, public and private organizations, community based educational institutions, business, industry, and labor are eligible to receive subgrants and contracts.

DATES: Comments must be received on or before March 2, 1981.

Public meetings are planned to take comments on these proposed regulations. A notice giving the city, time, and location will be published later in the **Federal Register.**

ADDRESSES: Comments should be addressed to Mr. Charles I. Griffith, Office of Postsecondary Education, U.S. Department of Education, (Room 3717, ROB-3), 400 Maryland Avenue, SW., Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Mr. John E. Donahue, Office of Postsecondary Education, U.S. Department of Education, (Room 3717, ROB-3), 400 Maryland Avenue, SW., Washington, D.C. 20202. Telephone (202) 245-9868.

SUPPLEMENTARY INFORMATION:

Assessment of Educational Impact

The Department particularly requests comments on whether the proposed regulations in this document would require transmission of information that is already being gathered by or is available from any other agency or authority of the United States.

Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding the proposed regulations. Written comments and recommendations may be sent to the address given in this preamble. All comments received on or before the 60th day after publication of this document will be considered in the development of the final regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 3717, ROB-3, 7th and D Streets, SW., Washington, D.C. between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Citation of Legal Authority

A citation of statutory of other legal authority is placed in parentheses on the line following each substantive provision of these proposed regulations.

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number not yet assigned)

PART 610—[REMOVED]

The Secretary proposes to (1) remove Part 610, and (2) revise Part 605 of Title 34 of the Code of Federal Regulations to read as follows:

PART 605—CONTINUING EDUCATION OUTREACH—STATE-ADMINISTERED PROGRAM

Subpart A—General

Sec.

Subpart B—[Reserved]

Subpart C—How Does the Secretary Make a Grant to a State?

Subpart D [Reserved]

Subpart E [Reserved]

Subpart F—What Conditions Must be Met by a State?

Subpart G—What Are the Administrative Responsibilities of a State and Its Subgrantees and Contractors?

Authority: Sections 111 through 115 of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1011-1015).

Subpart A—General

§ 605.1 Continuing Education Outreach—State-Administered Program.

(a) *General description.* The Continuing Education Outreach—State-Administered Program provides Federal financial assistance primarily to increase access to programs of continuing education for adults whose educational needs have been inadequately served. Recipients shall use this assistance to help traditional and non-traditional learners through—

(1) Comprehensive statewide planning;

(2) Information services; and

(3) Continuing education.

(20 U.S.C. 1011-1015)

(b) *Comprehensive statewide planning.* (1) Each State shall use the funds available for comprehensive statewide planning to support planning, and related studies, designed to achieve—

(i) Improved access to programs of postsecondary education for traditional and non-traditional learners;

(ii) Improved retention of traditional and non-traditional learners in programs of postsecondary education;

(iii) Effective coordination of educational occupational information and counseling services for youths and adults; and

(iv) More effective use of resources available for continuing education.

(2) Comprehensive statewide planning funds may also be used to prepare the annual report described in § 605.60.

(20 U.S.C. 1013(a))

(c) *Information services.* Each State shall use the funds available for information services to develop and coordinate new and existing—

(1) Postsecondary education information and counseling services for traditional and non-traditional learners; and

(2) Occupational information and counseling services for youth and adults. (20 U.S.C. 1014(a)).

(d) *Continuing education.* (1) Each State shall use the funds available for continuing education to make subgrants and award contracts for—

(i) Promoting access to and retention in postsecondary educational programs for adults whose educational needs have been inadequately served;

(ii) Expanding and improving postsecondary educational programs that help adults develop their occupational potential and prepare for transitions between education and work;

(iii) Eliminating barriers—posed by previous education or training, age, sex, race, handicap, national origin, rural isolation, or economic circumstance—that may place adults at a disadvantage in seeking postsecondary educational opportunities;

(iv) Strengthening statewide and other mechanisms of information, counseling, and referral that provide access to postsecondary education and serve the special needs of adults; and

(v) Developing strategies to promote the financial self-sufficiency of postsecondary educational programs initiated under this part.

(2) Eligible continuing education projects include such activities as:

(i) Creation or expansion of labor education, training, and technical assistance programs;

(ii) Development of cooperative relationships between State and local labor organizations and institutions and agencies that provide opportunities for continuing education;

(iii) Removal of barriers to continuing education caused by rural isolation or other rural-related factors;

(iv) Preretirement continuing education programs related to legal, vocational, and health services available to older adults;

(v) Promotion of sharing resources for innovative uses of technology on an inter-state or intra-state basis, including telecommunications, to overcome barriers to postsecondary educational opportunities;

(vi) Educational and occupational information and counseling services designed to meet the special needs of adult women, particularly homemakers, and to assist their entry or re-entry into postsecondary education and the labor force;

(vii) Collection and dissemination of information, including the creation of data banks, on sources of student financial assistance and information designed to assist individuals to make choices among postsecondary institutions, programs, and other educational opportunities;

(viii) Community education activities, consistent with the purposes of this part, for adults in rural areas;

(ix) Postsecondary educational programs suited to individuals whose educational needs have been inadequately served, especially the handicapped, older individuals, migrant and seasonal farm workers, individuals who can participate in programs only on a part-time basis, and individuals who otherwise would be unlikely to continue their education beyond high school;

(x) Child care services to assist individuals desiring to participate in continuing education programs in order to enter or re-enter the field of postsecondary education and the labor force; and

(xi) Promotion or delivery of postsecondary education services to women at the places of their employment or in conjunction with their employment.

(20 U.S.C. 1015)

§ 605.2 Eligible parties.

(a) States that have entered into a Federal-State relationship agreement with the Secretary as specified in 34 CFR Part 604 are eligible to receive grants for Statewide planning, information services, and continuing education.

(20 U.S.C. 1012-1015, 1143)

(b) Institutions of higher education and public and private organizations—including business, industry, labor, and community based educational institution—are eligible to receive subgrants and contracts from the States for information and counseling services and continuing education projects.

(20 U.S.C. 1014(c), 1015(b))

§ 605.3 Regulations that apply to the Continuing Education Outreach—State-Administered Program.

The following regulations apply to the Continuing Education Outreach—State-Administered Program:

(a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 76 (State-Administered Programs) and 34 CFR 77 (General);

(b) The regulations in this part 605; and

(c) The regulations in 34 CFR Part 604.

§ 605.4 Definitions that apply to the Continuing Education Outreach—State-Administered Program.

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR Part 77:

Contract
Fiscal year
Grant
Private
Project
Public
Secretary
State
Subgrant
Subgrantee

(b) *Definitions that apply to this part.* The following definitions apply to this part.

"Adults whose educational needs have been inadequately served" means individuals 18 years of age or older who—because of circumstances of age, sex, low income, handicap, minority status, rural isolation, status of employment or underemployment, lack of education, or other significant barriers—have been discouraged from obtaining equal educational opportunities.

"Continuing education" means postsecondary instruction and support services designed to meet the educational needs of adults, including the expansion of available learning opportunities for adults whose educational needs are inadequately served by current educational offerings in their communities.

"Act" means the Higher Education Act of 1965, as amended.

"Adult population" means the population eighteen years of age and older.

"Youth" means an individual between 16 and 18 years of age who is seeking, or considering seeking, employment.

"Planning for continuing education" means planning to improve access to programs of postsecondary education for adults in a State, particularly those who have been inadequately served, and to promote more effective and efficient use of available resources, including efforts to ensure equal treatment of applicants in the evaluation of subgrant proposals.

(20 U.S.C. 1013(c); 1018)

Subpart B (Reserved)

Subpart C—How Does the Secretary Make a Grant to a State?

§ 605.20 How does the Secretary initially allot program funds?

The Secretary makes the initial allotment of programs funds after a State has consummated an agreement with the Secretary as required in 34 CFR Part 604. The allotment is made according to the formula in section 112 (a)(1) of the Act.

(20 U.S.C. 1012)

§ 605.21 What are the requirements for subsequent allotments?

The Secretary makes an allotment to a State in subsequent fiscal years after the Secretary receives a satisfactory annual report as provided for in § 605.60.

(20 U.S.C. 1012, 1013)

§ 605.22 How does a State determine the amount of funds to be used for comprehensive statewide planning?

(a) The amount of funds available for planning depends on the amount of the total annual appropriation for the Continuing Education Outreach Program.

(1) In a fiscal year in which the appropriation is less than $18,500,000, the State shall use at least 15 percent but not more than 20 percent of its allotment for comprehensive statewide planning.

(2) In a fiscal year in which the appropriation is at least $18,500,000 but not more than $23,999,999, the State may use from ten to fifteen percent of its allotment for comprehensive statewide planning.

(3) In a fiscal year in which the appropriation is $24,000,000 or more, the State shall use up to 10 percent of its allotment for comprehensive statewide planning.

(b) If the State does not wish to receive comprehensive planning funds in a particular fiscal year, the State must so notify the Secretary of this prior to the beginning of that fiscal year, so that funds can be reallocated to the other States.

(c) A State may use up to 50 percent of the funds available to it for comprehensive statewide planning for the purpose of supporting continuing education projects.

(d) A State shall use 50 percent of the funds remaining for comprehensive statewide planning—after implementing the set-aside in paragraph (c), if any—for planning for continuing education, unless a waiver is granted.

(e) On application from a State, the Secretary grants a waiver of the requirement in paragraph (d) if the State satisfactorily demonstrates that—

(1) Planning for postsecondary continuing education has been an integral part of its existing planning process;

(2) It regularly collects data related to adult learners, including those who are being inadequately served;

(3) It periodically assesses the statewide postsecondary educational needs of adults; and

(4) It consults with public advisory groups composed of persons knowledgeable about the postsecondary educational needs of adults.

(20 U.S.C. 1013(a)(c); S. Rept. 96–733 at 8)

§ 605.23 How does a State determine the amount of funds to be used for information services?

A State shall use not less than $50,000 nor more than 12 percent of its allotment, whichever is greater, to provide information services.

(20 U.S.C. 1014(a))

§ 605.24 How does a State determine the amount of funds to be used for continuing education?

A State shall use the funds remaining from its allotments—after reserving the amounts required for comprehensive statewide planning and information services—for subgrants and contracts for continuing education projects.

(20 U.S.C. 1015)

Subpart D [Reserved]

Subpart E [Reserved]

Subpart F—What Conditions Must Be Met by a State?

§ 605.50 Coordination

A State shall coordinate its comprehensive statewide planning and information services activities to the maximum extent feasible with Federal, State, and local planning and information services being done under the following programs:

(a) Subpart 4 of Part A of Title IV of the Higher Education Act (Special Programs for Students from Disadvantaged Backgrounds).

(b) Part B of Title IV of the Higher Education Act (Guaranteed and Insured Student Loans).

(c) Section 485 of the Higher Education Act (Institutional and Financial Assistance Information for Students).

(d) The Vocational Education Act.

(e) The Comprehensive Employment and Training Act.

(f) The Older Americans Act of 1965.

(g) The Rehabilitation Act of 1973.

(h) The Career Education Incentive Act.

(i) The Adult Education Act.

(j) The Veterans Readjustment Assistance Act.

(k) Other Federal, State, and local programs that provide educational outreach, guidance, counseling, and information.

(20 U.S.C. 1013(d), 1014(b))

§ 605.51 Limitation on payments to the States.

(a) The Secretary does not make payments to the States in excess of two-thirds of the total costs of the State's program under this part.

(b) The State may not use funds from other Federal programs for matching.

(20 U.S.C. 1019)

Subpart G—What Are the Administrative Responsibilities of a State and Its Subgrantees and Contractors?

§ 605.60 Annual report.

(a) In addition to the requirements of EDGAR, 34 CFR 76.720, a State that receives funds under this program shall submit to the Secretary at the end of each fiscal year a report on each aspect of its Continuing Education Outreach Program. This report shall include the following:

(1) A list of each activity supported, including the amount of Federal and non-Federal funds allocated to planning, information services, and continuing education programs.

(2) A description of each activity supported.

(3) A detailed analysis of the relationship between the activities carried out and the priorities established by the comprehensive statewide planning process. This shall include:

(i) An evaluation of the fiscal year's activities; and

(ii) A projection of the types of activities the State plans to support in the next fiscal year.

(b)(1) The State entity responsible for comprehensive planning under this part shall be responsible for submission of the annual report.

(2) If a State does not receive funds for statewide planning, the State shall designate the State entity that shall be responsible for the report.

(20 U.S.C. 1013(b))

§ 605.61 Child care project restrictions.

A State may not award grants or contracts for the provision of child care services for the benefit of persons participating in continuing education projects unless—

(a) The State entity responsible for comprehensive statewide postsecondary education planning has established a cooperative agreement with the State agency responsible for coordinating child care services; and

(b) The grantee or contractor is licensed by the State to provide child care services, or is in the process of renewing its license and is likely to have that renewal approved.

(20 U.S.C. 1015(c))

§ 605.62 Administrative funds.

A State may use up to five percent of the funds available for continuing education, or $40,000, whichever is greater, for the administration of continuing education activities or the direct operation of continuing education projects.

(20 U.S.C. 1015(d))

[FR Doc. 80-40415 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

Office of Elementary and Secondary Education

34 CFR Part 222

School Assistance in Federally Affected Areas—Special Impact Aid Program for Refugees

AGENCY: Department of Education.

ACTION: Notice of proposed regulations.

SUMMARY: The Secretary of Education proposes regulations to implement the Special Impact Aid Program for Refugees under the authority of the Education Amendments of 1980. This program authorizes Federal financial assistance to local educational agencies (LEAs) which experience in any school year an enrollment increase of at least 20 students who have fled from Cambodia, Vietnam, Laos, Cuba, or Haiti.

DATES: Comments on these proposed regulations must be received (on or before 60 days after publication in the Federal Register).

ADDRESSES: Written comments should be addressed to Mr. Carrol U. Dexter, Department of Education, 300 Independence Avenue, S.W., Room G660, Washington, D.C. 20201. Telephone (202) 472-4014.

FOR INFORMATION CONTACT: Carroll U. Dexter. Telephone: (202) 472-4014

SUPPLEMENTARY INFORMATION:

Background

This program is designed to provide Federal financial assistance to local educational agencies (LEAs) which experience an enrollment increase of at least twenty students from Cambodia, Vietnam, Laos, Cuba, or Haiti.

An eligible LEA is authorized to receive for FY 1981 an amount equal to the product of the number of eligible children in excess of 20 in average daily attendance in the LEA multiplied by the current local expenditure rate per pupil of that LEA, plus $200 for each eligible child in excess of 20.

For example, if the LEA had an increase of 23 eligible children and a local expenditure rate of $1,000 per child, the entitlement would be calculated as follows: the number of eligible children in excess of 20 multiplied by the local expenditure rate ($3 \times \$1,000$) plus $200 for each eligible child in excess of 20 (3×200). This LEA would be entitled to $3,600.

Invitation to Comment

Interested parties are invited to submit comments and recommendations on these proposed regulations. Written comments may be sent to Mr. Carroll U. Dexter, 300 Independence Avenue, S.W., Room G660, Washington, D.C. 20202. All comments received on or before 60 days after publication of these proposed regulations will be considered in the development of the final regulations.

Comments submitted in response to these proposed regulations will be available for public inspection during and after the comment period in Room G660, 300 Independence Avenue, S.W., Washington, D.C., between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Information Requirements

The Department particularly requests comments on whether the program requirements in this document would require transmission of information that is already being gathered by or is available for any other agency or Department of the United States.

Citation of Legal Authority

The reader will find a citation of statutory or other legal authority in parentheses on the line following each substantive section of these proposed regulations.

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number 84.041, School Assistance in Federally Affected Areas—Maintenance and Operation)

The Secretary amends 34 CFR Part 222 to add a new Subpart K to read as follows:

PART 222—ASSISTANCE FOR LOCAL EDUCATIONAL AGENCIES IN AREAS AFFECTED BY FEDERAL ACTIVITIES AND ARRANGEMENT FOR EDUCATION OF CHILDREN WHERE LOCAL EDUCATION AGENCIES CANNOT PROVIDE SUITABLE FREE PUBLIC EDUCATION

* * * * *

Subpart K—Special Impact Aid Program for Refugees

Sec.

Sec.

Authority: Education Amendments of 1980, Pub. L. 96-374, 20 U.S.C. 239a.

Subpart K—Special Impact Aid Program for Refugees

§ 222.130 What is the special impact aid program for refugees?

This program authorizes Federal financial assistance to any local educational agency (LEA) which experiences in any school year an enrollment increase of at least 20 eligible students who either—

(a) Fled from Cambodia, Vietnam, or Laos and were admitted into the United States on or after January 1, 1979; or

(b) Fled from Cuba or Haiti and were admitted into the United States on or after November 1, 1979.

(20 U.S.C. 239a)

§ 222.131 What regulations apply to the special impact aid program for refugees?

The following regulations apply to the Special Impact Aid Program for Refugees:

(a) The regulations in this Part 222.

(b) The definitions in the Education Division General Administrative Regulations (EDGAR) in 34 CFR Part 77 (General).

(20 U.S.C. 239a, 1221e-3(2)(1))

§ 222.132 What definitions apply to the special impact aid program for refugees?

(a) The following terms used in this part are defined in EDGAR (34 CFR Part 77):

Applicant
Application

(20 U.S.C. 239a, 1221e-3(a)(1))

(b) *Definitions that apply to this part.* The following definitions apply specifically to this part:

"Act" means the Education Amendments of 1980 (Pub. L. 96-374).

"Eligible children" means—

(l) Aliens who fled from Cambodia, Vietnam, or Laos, and who, on or after January 1, 1979—

(i) Were admitted into the United States as refugees under section 207 of the Immigration and Nationality Act;

(ii) Are applicants for asylum or have been granted asylum in the United States; or

(iii) Were paroled into the United States as refugees under section 212(d)(5) of the Immigration and Nationality Act; or

(2) Aliens who fled from Cuba or Haiti and who, on or after November 1, 1979—

(i) Were admitted into the United States as refugees under section 207 of the Immigration and Nationality Act;

(ii) Are applicants for asylum or have been granted asylum in the United States;

(iii) Are paroled into the United States as refugees under section 212(d)(5) of the Immigration and Nationality Act; or

(iv) Are Cuban or Haitian entrants (status pending) who entered the United States on or after that date.

(20 U.S.C. 239a)

§ 222.133 What documents must an LEA submit to receive a grant?

(a) To apply for assistance under the Act, the applicant LEA shall file an application with the Secretary which includes—

(1) An accurate count of the total number of eligible children;

(2) The current local expenditure rate of the applicant LEA stated in § 222.135.

(3) An assurance that no eligible child counted for purposes of this section shall be counted for payments made under any other provision of Pub. L. 81-874.

(4) Any other information and assurances the Secretary considers as necessary to make appropriate decisions and ensure that the applicant complies with the Act and regulations.

(20 U.S.C. 239a)

§ 222.134 How does the LEA count eligible children?

The applicant LEA shall conduct a survey to determine the number of eligible children in average daily attendance (ADA). For each eligible child the LEA shall establish in its survey—

(a) The country from which the child migrated to the United States;

(b) The date of the child's entry into the United States;

(c) That the child is in the United States under one of the provisions referred to in paragraphs (1) (i), (ii) or (iii), or (2) (i), (ii), (iii) or (iv) of the definition of "eligible children" in § 222.132(b); and

(d) The date that the child originally enrolled in the applicant LEA.

§ 222.135 How does the LEA compute the current local expenditure rate?

(a) The current local expenditure rate is the amount of funds per child that the applicant derives and expends from State and local sources of revenue for free public education.

(b) The current local expenditure rate does not include amounts of funds made available to the applicant by the Federal Government.

(c) The current local expenditure rate shall be based upon the most recent year for which the applicant LEA has data.

(20 U.S.C. 239a)

§ 222.136 How does the Secretary determine the size of a grant to an LEA?

(a) To determine the size of a grant, the Secretary multiplies the number of eligible children in excess of 20 in the applicant LEA by the current local expenditure rate of the LEA, and adds $200 for each eligible child in excess of 20.

(b) In the event that the appropriation is not large enough to fully fund all eligible LEAs in accordance with paragraph (a) of this section, the Secretary proportionately reduces the entitlement for each eligible LEA.

(20 U.S.C. 239a)

§ 222.137 What records must a grantee maintain?

The grantee shall maintain, and make available to the Secretary upon request, adequate written records to substantiate its entitlement to funds under the Special Impact Aid Program for Refugees.

(20 U.S.C. 239a)

[FR Doc. 80-40422 Filed 12-29-80; 8:45 am]
BILLING CODE 4000-01-M

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34 CFR Part 777

Library Research and Demonstration Program (Title II-B HEA)

AGENCY: Department of Education.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Secretary proposes to amend the regulations for the Library Research and Demonstration Program. The regulations are being amended to reflect the statutory changes contained in the Education Amendments of 1980, to incorporate the general selection criteria in the Education Division General Administrative Regulations (EDGAR), and to reflect administrative experience.

DATES: Comments must be received on or before January 29, 1981.

ADDRESSES: Comments should be addressed to Mr. Henry Drennan, Library Research and Demonstration Branch, U.S. Department of Education, Room 3319-A, ROB-3, 400 Maryland Avenue, S.W., Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Library Research and Demonstration Branch, U.S. Department of Education, Room 3319-A, ROB-3, 400 Maryland

Avenue, S.W., Washington, D.C. 20202. Telephone No. (202) 245–2993.

SUPPLEMENTARY INFORMATION: The Library Research and Demonstration Program awards and administers grants and contracts for research and demonstration projects to improve libraries, including the promotion of economical and efficient information delivery, cooperative efforts related to librarianship, and developmental projects; to improve training in librarianship; to improve information technology; and to disseminate information that is derived from Library Research and Demonstration Program projects.

The revisions to these regulations reflect: The Education Amendments of 1980, Pub. L. 96–374, the Education Division General Administrative Regulations (EDGAR), and administrative experience.

The most signficant revisions to the proposed regulations are the following:

(a) The selection criteria for judging applications is changed to place more emphasis on the plan of operation, quality of key personnel, and significance of the proposed project.

(b) The purpose of the program has been expanded to include the promotion of economical and efficient information delivery, the promotion of cooperative efforts related to librarianship, the support of developmental projects, and the improvement of information technology.

(c) Eligibility for grants and contracts is expanded to include profit making organizations, agencies, and institutions.

These regulations will be codified in Title 34 of the Code of Federal Regulations along with other Department of Education programs.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding the proposed regulations. The Department particularly requests comments on whether the proposed regulations in this document would require transmission of information that is already being gathered by or is available from any other agency or authority of the United States. Written comments and recommendations may be sent to the address given at the beginning of this preamble. All comments received on or before the 30th day after publication of this document will be considered in the development of the final regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 3319–A, ROB–3, 7th and D Streets, S.W., Washington, D.C. between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Citation of Legal Authority

A citation of statutory or other legal authority is placed in parentheses on the line following each substantive provision of these proposed regulations.

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

(Catalog of Federal Domestic Assistance No. 84.039, Library Research and Demonstration Program. Part I of OMB Circular A–95 does not apply to this program)

The Secretary proposes to amend Part 777 of 34 CFR to read as follows:

PART 777—LIBRARY RESEARCH AND DEMONSTRATION PROGRAM

Subpart A—General

Sec.

Subpart B—Kinds of Projects for Which Grants and Contracts are Made

Subpart C—How to Apply for a Grant

Subpart D—How a Grant is Made

Subpart E—Conditions that Must be Met by a Grantee

Subpart F—The Administrative Responsibilities of a Grantee

Authority: Part B of Title II of the Higher Education Act of 1965, as amended by Section 201 of the Education Amendments of 1980, 94 Stat. 1383 (20 U.S.C. 1021 et seq.).

Subpart A—General

§ 777.1 Description of the Library Research and Demonstration Program.

The purpose of the Library Research and Demonstration Program is to encourage research and development relating to—

(a) The improvement of libraries, including:

(1) the promotion of economical and efficient information delivery,

(2) cooperative efforts related to librarianship, and

(3) developmental projects;

(b) Training in librarianship; and

(c) The improvement of information technology.

(Section 201, 223 of the Act; 20 U.S.C. 1021, 1033)

§ 777.2 Eligible parties.

Applications for grants and contracts may be submitted by—

(a) An institution of higher education; or

(b) A public or private agency, institution or organization.

(Section 223 of the Act; 20 U.S.C. 1033)

§ 777.3 Regulations that apply to grants.

The following regulations apply to grants under the Library Research and Demonstration Program:

(a) The Education Division General Administration Regulations (EDGAR) 34 CFR 75 and 34 CFR 77.

(b) The regulations in this Part 777.

(20 U.S.C. 3474)

§ 777.4 Regulations that apply to contracts.

The regulations in this part do not govern the award of contracts under the Library Research and Demonstration Program. Contracts under this part are governed by—

(a) Federal and Department procurement regulations in 41 CFR Chapters 1 and 34; and

(b) The requests for proposals for the procurement, if any, referenced in the Commerce Business Daily.

(20 U.S.C. 3474)

§ 777.5 Definitions that apply to the Library Research and Demonstration Program.

(a) Definitions in EDGAR. The following terms used in this part are defined in 34 CFR Part 77:

Applicant	Grant
Application	Grantee
Award	Nonprofit
Budget	Private
Contract	Project
Department	Public
Equipment	Secretary
Facilities	Supplies

(b) Definitions that apply to this Part. The following definitions apply to this Part:

"Act" means the Higher Education Act of 1965, as amended.

"Institution of higher education" means such an institution as defined by Section 1201 of the Act.

"Librarianship" means the principles and practices of the library and information science, including the acquisition, organization, storage, retrieval and dissemination of information, and reference and research

use of library and other information resources.

(20 U.S.C. 3474)

Subpart B—Kinds of Projects for Which Grants and Contracts are Made

§ 777.10 Authorized activities.

(a) The Secretary may award a grant or contract to support a research and demonstration project that will

(1) Improve—

(i) Libraries;

(ii) Training in librarianship; or

(iii) Information technology; and

(2) Disseminate information that is derived from a project funded under this Part.

(b) A project that includes any one or more of the activities described in § 777.10(a) may be supported under this Part.

(Section 201, 223 of the Act; 20 U.S.C. 1021 and 1033)

Subpart C—How to Apply for a Grant

§ 777.20 Application requirements.

An applicant must demonstrate, on the application form furnished by the Secretary, that the proposed project meets the requirements of the Act and all applicable regulations. The applicant must address each of the Selection Criteria for Evaluating Applications in Subpart D.

(Section 223 of the Act; 20 U.S.C. 1033)

Subpart D—How a Grant is Made

§ 777.30 How the Secretary judges applications.

(a) The Secretary evaluates an application on the basis of the criteria in § 777.31 and awards up to 100 points for these criteria.

(b) The maximum possible score for each complete criterion is indicated in parentheses next to the heading of that criterion.

(20 U.S.C. 3474)

§ 777.31 Selection criteria for evaluating applications.

(a) *Plan of operation* (25 points)

(1) The Secretary reviews each application for information that shows the quality of the plan of operation for the project.

(2) The Secretary looks for information that shows—

(i) High quality in the design of the project;

(ii) An effective plan of management that ensures proper and efficient administration of the project;

(iii) A clear description of how the objectives of the project relate to the purpose of the program;

(iv) The way the applicant plans to use its resources and personnel to achieve each objective;

(v) A clear description of how the applicant will provide equal access and treatment for eligible project participants who are members of groups that have been traditionally underrepresented, such as—

(i) Members of racial or ethnic minority groups;

(ii) Women;

(iii) Handicapped persons; and

(iv) The elderly.

(b) *Quality of key personnel* (15 points)

(1) The Secretary reviews each application for information that shows the qualifications of the key personnel the applicant plans to use on the project.

(2) The Secretary looks for information that shows—

(i) The qualifications of the project director (if one is to be used);

(ii) The qualifications of each of the other key personnel to be used in the project;

(iii) The time that each person referred to in paragraphs (b)(1) and (2) of this section will commit to the project; and

(iv) The extent to which the applicant, as part of its nondiscriminatory employment practices, encourages applications for employment from persons who are members of groups that have been traditionally underrepresented, such as, members of racial or ethnic minority groups, women, handicapped persons, and the elderly.

(3) To determine personnel qualifications, the Secretary considers experience and training, in fields related to the objectives of the project, as well as other information that the applicant provides.

(c) *Budget and cost effectiveness* (10 points)

(1) The Secretary reviews each application for information that shows that the project has an adequate budget and is cost effective.

(2) The Secretary looks for information that shows—

(i) The budget for the project is adequate to support the project activities; and

(ii) Costs are reasonable in relation to the objectives of the project.

(d) *Evaluation plan* (10 points)

(1) The Secretary reviews each application for information that shows the quality of the evaluation plan for the project.

(2) The Secretary looks for information that shows methods of evaluation that are appropriate for the project, and, to the extent possible, are objective and produce data that are quantifiable.

(e) *Adequacy of resources* (5 points)

(1) The Secretary reviews each application for information that shows that the applicant plans to devote adequate resources to the project.

(2) The Secretary looks for information that shows—

(i) The facilities that the applicant plans to use are adequate; and

(ii) The equipment and supplies that the applicant plans to use are adequate.

(f) *Significance of proposed project* (30 points)

The Secretary reviews each application for information that shows the extent to which—

(1) The proposed project—

(i) Addresses an important library or information problem;

(ii) Is likely to improve operations or service in a significant number of libraries; or

(iii) Is likely to fulfill unmet informational, educational or cultural needs related to libraries and information science.

(2) The applicant demonstrates and understanding of the nature and magnitude of the needs to be addressed as well as the success or failure of related research and development actvity, and

(3) The proposed project addresses any priorities established for this program.

(g) *Dissemination* (5 points)

The Secretary reviews each application for information that shows—

(i) Results of the project will be adequately disseminated, and

(ii) To the extent possible, the project will be continued or replicated after the termination of Federal funding.

(Section 223 of the Act; 20 U.S.C. 1033)

Subpart E—Conditions That Must be Met by a Grantee

§777.40 Coordination with other groups.

Each institution of higher education that receives a grant under this part shall annually inform the State agency, designated under Section 1203 of the Act, of its project activities.

(Section 202 of the Act; 20 U.S.C. 1022)

Subpart F—The Administrative Responsibilities of a Grantee

§ 777.50 Performance reports.

The grantee shall submit the performance report required under 34 CFR Part 74, Subpart J, on a quarterly basis.

(Section 223 of the Act; 20 U.S.C. 1033)

[FR Doc. 80-40423 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

34 CFR Parts 385, 386, 387, 388, 389, and 390

Rehabilitation Training Program

AGENCY: Department of Education.

ACTION: Notice of Proposed Rulemaking: Cross-reference.

SUMMARY: The Secretary proposes regulations for the Rehabilitation Training Program in Title 34 of the Code of Federal Regulations:

(a) Rehabilitation Training—General (Part 385)

(b) Rehabilitation Long-Term Training (Part 386)

(c) Experimental and Innovative Training (Part 387)

(d) State Vocational Rehabilitation Unit In-Service Training (Part 388).

(e) Rehabilitation Continuing Education Programs (Part 389).

(f) Rehabilitation Short-Term Training (Part 390).

The Secretary invites comments on these proposed regulations.

The texts of the regulations on which the Secretary invites comments are published in the Rules and Regulations section of this issue of the Federal Register. They have been adopted as final regulations and will govern these programs until the Secretary issues new regulations based on public comment.

DATES: All comments, suggestions, or objections must be received on or before.

ADDRESSES: Comments should be addressed to: Mr. Harold F. Shay, Director, Division of Manpower Development, Rehabilitation Services Administration, Office of Special Education and Rehabilitative Services, Room 3321, Mary E. Switzer Building, 330 C Street, S.W., Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: Mr. Harold F. Shay, Telephone: (202) 245-0079.

INVITATION TO COMMENT: For additional details on how to comment, see the Preamble of the final regulations for these programs published in this issue of the Federal Register.

(Catalog of Federal Domestic Assistance Number 84.129, Rehabilitation Training)

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

[FR Doc. 80-40424 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

34 CFR Part 606

Continuing Education Outreach—Special Projects

AGENCY: Department of Education.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Secretary proposes regulations for the Continuing Education Outreach—Special Projects program for the first time. The regulations are proposed to reflect statutory changes in the Education Amendments of 1980. The proposed regulations will govern the administration of a program primarily designed to demonstrate the effectiveness of alternative providers and approaches which serve the postsecondary education needs of underserved adults. The proposed regulations will ensure that a wide range of applicants, including institutions of higher education, public and private organizations, States, business, industry, and labor, will be eligible to participate in the program.

DATES: Comments must be received on or before March 2, 1981. Public meetings are planned to take coments on these proposed regulations. A notice giving the city, time, and location will be published later in the Federal Register.

ADDRESSES: Comments should be addressed to Mr. Charles I. Griffith, Office of Postsecondary Education, U.S. Department of Education, (Room 3717, ROB-3), 400 Maryland Avenue, S.W., Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Mr. John E. Donahue, Office of Postsecondary Education, U.S. Department of Education, (Room 3717, ROB-3), 400 Maryland Avenue, S.W., Washington, D.C. 20202. Telephone (202) 245-9868.

SUPPLEMENTARY INFORMATION: The Continuing Education Outreach—Special Projects Program is the successor to the Community Service and Continuing Education—Special Projects program. The primary focus has been changed from assisting in the solution of national and regional problems to expanding access to continuing educational opportunities for underserved adults. Eligibility for grants has been expanded to include institutions of higher education, public and private organization community-based educational institutions, States, business, industry, and labor.

Invitation To Comment: Interested persons are invited to submit comments and recommendations regarding these proposed regulations. Written comments and recommendations may be sent to the address given earlier in this preamble. All comments received on or before March 2, 1981, will be considered in the development of the final regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 3717, ROB-3, 7th and D Streets, S.W., Washington, D.C. between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

The Department particularly requests comments on whether the proposed regulations in this document would require transmission of information that is already being gathered by or is available from any other agency or authority of the United States.

Citation of Legal Authority: A citation of statutory or other legal authority is placed in parentheses on the line following each substantive provision of these proposed regulations.

(Catalog of Federal Domestic Assistance Number not yet assigned)

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

The Secretary proposes to amend Part 606 of Title 34 of the Code of Federal Regulations to read as follows:

PART 606—CONTINUING EDUCATION OUTREACH—SPECIAL PROJECTS PROGRAM

Subpart A—General

Sec.

606.1 Continuing Education Outreach—Special Projects Program.

606.2 Eligible grantees.

606.3 Regulations that apply to the Continuing Education Outreach—Special Projects Program.

606.4 Definitions that apply to the Continuing Education Outreach—Special Projects Program.

Subpart B—What Kinds of Projects Does the Secretary Assist Under This Program?

606.10 Eligible activities.

606.11 Funding priorities.

Subpart C—How Does One Apply for a Grant?

606.20 How to apply for funds.

Subpart D—How Does the Secretary Make a Grant?

606.30 Procedures for evaluating applications.

606.31 Criteria for evaluating applications.

606.32 Project length.

Subpart E—What Condition Must Be Met by a Grantee?

606.40 Matching requirement.

Authority: Title I of the Higher Education Act of 1965, as amended by Pub. L. 96-374 (20 U.S.C. 1016), unless otherwise noted.

Subpart A—General

§ 606.1 Continuing Education Outreach—Special Projects.

The Continuing Education Outreach—Special Projects program provides Federal financial assistance for projects designed to demonstrate the effectiveness of alternative providers and approaches in increasing access to postsecondary continuing educational opportunities for underserved adult learners.

(20 U.S.C. 1016)

§ 606.2 Eligible grantees.

The following parties are eligible to receive grants under this program:

(a) Institutions of higher education.

(b) Public and private institutions and organizations, including business, industrial, and labor organizations.

(c) States.

(d) Any combination of these institutions, organizations, or States.

(20 U.S.C. 1016)

§ 606.3 Regulations that apply to the Continuing Education Outreach—Special Projects Program.

The following regulations apply to Continuing Education Outreach—Special Projects:

(a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 75 (Direct Grant Programs) and 34 CFR Part 77 (General).

(b) The regulations in this Part 606.

(20 U.S.C. 1016; 20 U.S.C. 1221e-3(a)(1))

§ 606.4 Applicable definitions that apply to the Continuing Education Outreach—Special Projects Program.

(a) *Definitions in EDGAR.* The following terms used in this part as defined in 34 CFR Part 77:

Applicant	Private
Application	Project
Budget period	Project period
Contract	Public
Fiscal year	Secretary
Grant	State
Grantee	

(b) *Definitions that apply to this part.* The following definitions apply to this part:

"Act" means Title XII of the Higher Education Act of 1965, as amended.

"Adults whose educational needs have been inadequately served" means individuals 18 years of age or older who—because of circumstances of age, sex, low income, handicap, minority status, rural isolation, status of unemployment, lack of education, or other significant barriers—have been discouraged from obtaining equal educational opportunities.

"Continuing education" means postsecondary instruction and support services designed to meet the educational needs of adults, including the expansion of available learning opportunities for adults whose educational needs are inadequately served by current educational offerings in their communities.

(20 U.S.C. 1018)

Subpart B—What Kinds of Projects Does the Secretary Assist Under This Program?

§ 606.10 Eligible activities.

The Secretary makes grants for projects that:

(a) Develop and evaluate innovative delivery systems, particularly those involving alternative providers, that increase access to postsecondary education for adults;

(b) Expand the range of educational and community resources that meet the needs of underserved adults for continuing education;

(c) Promote the development of interstate educational delivery systems, cooperative and consortial arrangements, and programs—including telecommunications—that more effectively address regional needs for continuing education;

(d) Stimulate and evaluate creative approaches to the problems of access for adults inadequately served by existing educational offerings;

(e) Develop statewide, regional, or national programs to coordinate educational and occupational information, including information on student financial assistance, through creation and expansion of data banks for the more effective coordination and dissemination of such information;

(f) Assist States to perform more effectively their functions of accrediting institutions of higher education in their State;

(g) Provide preservice and inservice training to personnel involved in child-care, including the recruitment and training of low-income parents for positions in childcare;

(h) Provide specialized training in early childhood education;

(i) Develop improved teacher certification criteria for child-care programs.

(20 U.S.C. 1016)

§ 606.11 Funding priorities.

(a) For any fiscal year the Secretary establishes priorities for the funding of proposed projects. The priorities shall be consistent with the objectives listed in § 606.10 and shall be announced in the Federal Register.

(b) To be eligible for funding a proposed project must respond to one of the priorities established by the Secretary.

(20 U.S.C. 1016)

Subpart C—How Does One Apply For a Grant?

§ 606.20 How to apply for funds.

(a) An applicant requesting funds under this part shall use the following procedures:

(1) The procedures contained in EDGAR (34 CFR Part 75, Subpart C); and

(2) The following special application procedures;

(i) On or before the deadline date for submitting its application to the Secretary, the applicant shall submit a copy of its application, with a letter asking for comment, to the State agency responsible for comprehensive postsecondary education planning under section 1203 of the Act (Federal-State agreements).

(ii) The applicant shall attach to its application to the Secretary a copy of its letter requesting the State agency to comment on the application.

(b) An applicant shall apply for a grant that extends from 18 to 30 months in duration.

(20 U.S.C. 1016)

Subpart D—How Does the Secretary Make a Grant?

§ 606.30 Procedure for evaluating applications.

(a) The Secretary evaluates an application on the basis of the criteria in § 606.31.

(b) The Secretary awards up to 100 points for these criteria.

(c) The maximum score for each criterion is indicated in parentheses.

(d) The Secretary considers the rank order of applications in selecting projects to be awarded grants.

(20 U.S.C. 1016)

§ 606.31 Criteria for evaluating applications.

(a) *Plan of Operation.* (10 points)

(1) The Secretary reviews each application for information that shows the quality of the plan of operation for the project.

(2) The Secretary looks for information that shows—

(i) High quality in the design of the projects;

(ii) An effective plan of management that insures proper and efficient administration of the project;

(iii) A clear description of how the objectives of the project relate to the purpose of the program;

(iv) The way the applicant plans to use its resources and personnel to achieve each objective;

(v) A clear description of how the applicant will provide equal access and treatment for eligible project participants who are members of groups that have been traditionally underrepresented, such as—

(A) Members of racial or ethnic minority groups;

(B) Women;

(C) Handicapped persons; and

(D) The elderly.

(b) *Quality of key personnel.* (7 points)

(1) The Secretary reviews each application for information that shows the quality of the key personnel the applicant plans to use on the project.

(2) The Secretary looks for information that shows—

(i) The qualifications of the project director (if one is to be used);

(ii) The qualification of each of the other key personnel to be used in the project;

(iii) The time that each person referred to in paragraphs (b)(2)(i) and (ii) of this section plans to commit to the project; and

(iv) The extent to which the applicant, as part of its nondiscriminatory employment practices, encourages applications for employment from persons who are members of racial or ethnic minority groups, women, handicapped persons, and the elderly.

(3) To determine the qualifications of a person, the Secretary considers evidence of past experience and training in fields related to the objectives of the project, as well as other information that the applicant provides.

(c) *Budget and cost effectiveness.* (5 points)

(1) The Secretary reviews each application for information that shows that the project has an adequate budget and is cost effective.

(2) The Secretary looks for information that shows—

(i) The budget for the project is adequate to support the project activities; and

(ii) Costs are reasonable in relation to the objectives of the projects.

(d) *Evaluation plan.* (12 points)

(1) The Secretary reviews each application for information that shows the quality of the evaluation plan for the project. (See 34 CFR 75.590—Evaluation by the grantee.)

(2) The Secretary looks for information that shows methods of evaluation that are appropriate for the project and, to the extent possible, are objective and produce data that are quantifiable.

(e) *Adequacy of resources.* (3 points)

The Secretary looks for information that shows—

(1) The facilities that the applicant plans to use are adequate; and

(2) The equipment and supplies that the applicant plans to use are adequate.

(f) *Innovation.* (10 points)

The Secretary reviews each application to determine the extent to which the proposed project duplicates current or past projects in the field of postsecondary continuing education.

(g) *Responsiveness to priorities.* (14 points)

The Secretary reviews each application to determine the extent to which the proposed project is responsive to one of the priorities established under § 606.11 for the fiscal year in which the application is submitted.

(h) *Replicability.* (12 points)

The Secretary reviews each application for information that describes the methods the applicant plans to use to disseminate the results of the proposed project to the general public and to professionals in the field of continuing education.

(i) *Dissemination.* (12 points)

The Secretary reviews each application for information that describes the methods the applicant plans to use to disseminate the results of the project to the general public and to professionals in the field of continuing education.

(j) *Value to the field of continuing education.* (15 points)

The Secretary reviews each application to assess the degree to which the proposed project would employ, or result in the development of, new approaches, methods, or materials of value in increasing the effectiveness of continuing education programs.

(20 U.S.C. 1016)

§ 606.32 Project length.

(a) The Secretary funds projects that are designed to be from eighteen to thirty months in length.

(1) The Secretary may issue a grant for a budget period of up to 12 months.

(2) The grantee may apply for a continuation grant on a noncompetitive basis contingent upon satisfactory performance and the availability of funds.

(20 U.S.C. 1016)

Subpart E—What Condition Must Be Met by a Grantee?

§ 606.40 Matching requirement

A grantee shall pay from non-federal funds at least one-third of the cost of its project funded under this part.

(20 U.S.C. 1019)

[FR Doc 80-40425 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

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34 CFR Parts 350, 351, 352, 353, 354, 355, and 356

National Institute of Handicapped Research

AGENCY: Department of Education.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Secretary is proposing regulations to implement the new and revised research authorities contained in Title II of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Public Law 95-602). These include revisions to existing grant authorities under which the scope of permissible research activity and the class of eligible applicants has been broadened. The regulations also cover a number of new special purpose grants and other assistance programs, a new research fellowship program, and requirements governing the peer review of all applications for grant assistance, all authorized by the 1978 Amendments.

DATE: Interested persons are invited to submit comments or suggestions regarding the proposed regulations on or before March 2, 1981.

ADDRESS: All written comments and suggestions should be sent to Nathan Ed Acree, National Institute of Handicapped Research, Department of Education, Switzer Office Building 3511, Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Nathan Ed Acree, National Institute of Handicapped Research, Room 3428, Switzer Office Building, 330 C Street, S.W., Washington, D.C. 20202, Area Code (202) 472-5248 or TTY (202) 245-0591.

SUPPLEMENTARY INFORMATION: The Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 located within a single title, Title II, all of the rehabilitation research authorities and established a National Institute of Handicapped Research within the Department of Health, Education, and Welfare to administer these programs. All functions of the National Institute of Handicapped Research were subsequently transferred to the

Department of Education under section 301(a)(4)(c) of the Department of Education Organization Act (Public Law 96–88).

Statutory Changes

The 1978 Amendments authorized a number of new Federal grant and other assistance programs to support the conducting of rehabilitation research. These include:

(1) A program under section 204(b)(6) of the Act to conduct research concerning the use of existing telecommunication systems which have the potential for substantially improving service delivery methods;

(2) A program under section 204(b)(7) of the Act to conduct joint projects with the National Institutes of Health, the Health Services Administration, the Administration on Aging, the National Science Foundation, the Veterans' Administration, the Office of Education, the National Aeronautics and Space Administration, other Federal agencies, and private industry in areas of joint interest involving rehabilitation;

(3) A program under section 204(b)(8) of the Act to conduct research related to the rehabilitation of handicapped children and of handicapped individuals who are aged sixty or older;

(4) A program under section 204(b)(9) of the Act to conduct research to develop and demonstrate innovative methods of attracting and retaining professionals to serve in rural areas;

(5) A model research and demonstration project under section 204(b)(10) of the Act to assess the feasibility of establishing a center for producing and distributing to deaf individuals captioned video cassettes providing a broad range of educational, cultural, scientific, and vocational programming;

(6) A model research and demonstration program under section 204(b)(11) of the Act to develop innovative methods of providing services to preschool age handicapped children;

(7) A model research and training program under section 204(b)(12) of the Act to establish model training centers to develop and use more advanced and effective methods of evaluating and developing the employment potential of handicapped individuals; and

(8) A fellowship program under section 202(d) of the Act to procure the assistance of highly qualified research fellows from the United States and foreign countries.

The 1978 Amendments also revised existing grant authorities by:

(1) Expanding the class of applicants eligible for grant assistance under all research programs to include private profitmaking agencies and organizations. Previously, eligibility was limited to States and public or nonprofit agencies and organizations;

(2) Broadening the scope of research activity under the general research and demonstrations authority of section 204(a) of the Act from a purely vocational or employment focus to encompass all rehabilitation problems encountered by handicapped individuals in their daily activities. Research under this authority now includes "basic research where related to rehabilitation techniques or services" and research related to psychiatric factors affecting rehabilitation; and

(3) Requiring Rehabilitation Research and Training Centers under section 204(b)(1) of the Act to conduct research based on the particular needs of handicapped individuals in the geographic area that the Center serves.

The 1978 Amendments also expanded, under certain of the new specialized research programs, the group of handicapped persons intended to benefit from research findings. Although the primary beneficiaries of the Institute's research programs continue to be State vocational rehabilitation agency clients, there are newly authorized grant programs that focus on the needs of preschool age handicapped children, other handicapped children, deaf persons, and handicapped individuals who are aged sixty or older.

Format and Content of the Proposed Regulations

Organizationally, the proposed regulations are divided into seven parts: a general part (Part 350) that contains provisions common to all of the research programs; five parts (Parts 351, 352, 353, 354, and 355) devoted to separate and distinct research grant programs; and a final part (Part 356) related to the research fellowship program.

Although section 204 of the Act contains 13 different authorities for making research grants, an administrative decision was made to organize these 13 authorities into five distinct research grant programs to correspond with the annual budget categories used by Congress in appropriating funds for these programs.

Part 350

Part 350, the general part, contains a statement of the purposes of the various rehabilitation research programs and a list of the various agencies and organizations eligible for grant assistance. It identifies the regulations and definitions that are applicable to these programs. Part 350 also contains grant application procedures, peer review, confidentiality, non-Federal matching requirements, and selection criteria to be used in reviewing and evaluating all applications for grant assistance.

The selection criteria proposed for the rehabilitation research programs are based primarily on the selection criteria set forth in the Education Division General Administrative Regulations (EDGAR) located in 34 CFR 75.202–206. Four additional selection criteria have been developed, however, that cover important elements of an effective research project that are not addressed by the EDGAR criteria. These are: project concept or national need (34 CFR 350.36(a)); research design (34 CFR 350.36(b)); research utilization plan (34 CFR 350.36(g)); and literature review (34 CFR 350.36(i)).

Specialized Research Grant Programs

Parts 351, 352, 353, 354, and 355 contain all of the specific requirements that apply to the direct grant programs established in section 204 of the Act.

Part 351, the Research and Demonstrations Projects Program, consists of all project activities except those related to technology and engineering, knowledge dissemination and utilization, and those activities specifically conducted by Research and Training Centers, Engineering Centers, and Model Training Centers. This includes a majority of the research activities authorized by section 204(a) of the Act as well as specialized projects under sections 204(b)(3), 204(b)(4), 204(b)(5), 204(b)(7), 204(b)(8), 204(b)(9), and 204(b)(11) of the Act.

Part 352 contains provisions related to the conduct of research and training activities by Rehabilitation Research and Training Centers authorized under section 204(b)(1) of the Act.

Part 353, the Rehabilitation Engineering Program, contains provisions related to research activities conducted by Rehabilitation Engineering Research Centers authorized by section 204(b)(2) of the Act. It also contains provisions related to specialized research activities that have an engineering focus under sections 204(b)(6) (telecommunications systems) and 204(b)(10) (video cassettes for deaf) of the Act.

Part 354 consists of regulations governing Model Training Centers authorized under section 204(b)(12) of the Act.

Part 355, the Knowledge Dissemination and Utilization Program, consists of project activities concerned with the development of practical applications for research findings,

statistical studies, and information dissemination. These activities are considered to be research "related activities which bear directly on the development of methods, procedures, and devices to assist in the provision of vocational and other rehabilitation services to handicapped individuals" authorized under section 204(a) of the Act. Projects supported under this part assist the Director of the National Institute of Handicapped Research in carrying out the knowledge dissemination functions mandated under 202(b) of the Act.

Research Fellowship Program

Part 356 contains requirements that apply to the Research Fellowship Program authorized by section 202(d) of the Act. Under this program assistance will be provided to individual researchers to engage in activities related to the solution of specific rehabilitation problems encountered by handicapped persons.

Assessment of Educational Impact

The Department particularly requests comments on whether the proposed regulations in this document would require transmission of information that is already being gathered by or is available from any other agency or authority of the United States.

Citation of Legal Authority

A citation of statutory authority is placed in parenthesis on the line following each substantive provision of the proposed regulations. The first citation is the appropriate section of the Rehabilitation Act of 1973, as amended, and it is followed by a citation to the same provision in the United States Code.

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number 84.133, National Institute of Handicapped Research)

The Secretary proposes to amend Title 34 of the Code of Federal Regulations by adding a new Part 350 to read as follows:

Part 350—HANDICAPPED RESEARCH: GENERAL PROVISIONS

Subpart A—General

Sec.

Authority: Title II of the Rehabilitation Act of 1973 (Public Law 93–112), as amended by Public Law 95–602 (29 U.S.C 760–762; 92 Stat. 2962–2966).

Subpart A—General

§ 350.1 Handicapped research.

(a) The Secretary provides financial assistance to—

(1) Support the conduct of research, demonstration projects and related activities for the rehabilitation of handicapped individuals, including programs designed to train persons who provide rehabilitation services and persons who conduct research;

(2) Facilitate the distribution of information concerning developments in rehabilitation procedures, methods, and devices;

(3) Improve the distribution of technological devices and equipment; and

(4) Increase the scientific and technological information presently available in the field of rehabilitation.

(b) The Secretary awards financial assistance through six types of programs—

(1) Research and demonstration projects (34 CFR Part 351);

(2) Research grants for establishment and operation or rehabilitation research and training centers (34 CFR Part 352);

(3) Research grants for establishment and operation of rehabilitation engineering programs (34 CFR Part 353);

(4) Research grants for establishment and operation of model training centers (34 CFR Part 354);

(5) Knowledge dissemination and research utilization projects (34 CFR Part 355); and

(6) Research fellowships (34 CFR Part 356).

(Section 200 and 204; 29 U.S.C. 760 and 762)

§ 350.2 Who is eligible for assistance under these programs?

The following agencies and organizations are eligible for grants or contracts as appropriate under these programs:

(a) State and public agencies or organizations;

(b) Private agencies or organizations; and

(c) Institutions of higher education.

(Section 204; 29 U.S.C. 762)

§ 350.3 What regulations apply to these programs?

The following regulations apply to grants under the Handicapped Research Programs—

(a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 75 (Direct Grant Programs).

(b) The EDGAR regulations in 34 CFR Part 77 (Definitions);

(c) The regulations in this Part, 34 CFR Part 350;

(d) The regulations in 34 CFR Parts 351, 352, 353, 354, 355, or 356, as appropriate; and

(e) 45 CFR Part 46 (Protection of Human Subjects).

(Sections 202 and 204; 29 U.S.C. 761a, 762)

§ 350.4 What definitions apply to these programs?

(a) The following definitions in 34 CFR Part 77 apply to the programs under Handicapped Research—

Applicant	Preschool
Application	Private
Award	Project
Budget Period	Project Period
Department	Public
Grant Period	Secretary
Nonprofit	State
Nonpublic	

(Section 202(i)(1); 29 U.S.C. 761a(i)(1)

(b) The following definitions also apply to programs under Handicapped Research.

"*Act*" means the Rehabilitation Act of 1973 (Public Law 93–112), as amended.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

"*Core area*" means a program of research in which the entire activity is planned so as to contribute in a sequential or complementary way to a centralized body of knowledge of manageable scope.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1)

"Demonstration" means the application of results derived from previous research, testing, or practice for purposes of establishing the reliability, furthering the validity, or determining the cost effectiveness of new rehabilitation procedures.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

"Development" means the systematic use of knowledge and understanding gained from research, directed toward creating useful materials, devices, systems, or methods, including design and development of prototypes and processes.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

"Director" means Director of the National Institute of Handicapped Research.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

"Fellowship" means a financial award to procure the assistance of highly qualified research fellows from the United States and foreign countries. It is not a grant.

(Section 202(d); 29 U.S.C. 761a(d))

"Handicapped individual" means any individual who (i) has a physical or mental disability which for such individual constitutes or results in a substantial handicap to employment; and (ii) can reasonably be expected to benefit in terms of employability from the provision of vocational rehabilitation services.

(Section 7(7)A; 29 U.S.C. 706(7)(A))

"Institute" means the National Institute of Handicapped Research.

(Section 202(a); 29 U.S.C. 761a(a))

"Project concept" means a statement of the purpose, scope, and objectives of a project.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

"Research" means intensive systematic study directed toward new or fuller scientific knowledge or understanding of the subject or problem studied. Research is classified as basic or applied.

(i) *"Basic research"* is research in which the investigator is concerned primarily with gaining new knowledge or understanding of the subject under study.

(ii) *"Applied research"* is research in which the investigator is primarily interested in a practical use of well established basic information for the purpose of meeting a recognized need.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

"Research utilization" means activities seeking to link research findings to practical applications in planning, policy-making, program administration, and service practice in the delivery of services to handicapped persons.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

"State rehabilitation agency" means the sole State agency designated to administer (or supervise local administration of) the State plan for vocational rehabilitation services. The term includes the State agency for the blind, if designated as the State agency with respect to that part of the plan relating to the vocational rehabilitation of blind individuals.

(Section 101(a)(1)(A); 29 U.S.C. 721(a)(1)(A))

"Target population" means the group of individuals, organizations, or other entities which would be affected by the results of research and to whom results would ordinarily be communicated. More than one target group may be involved since research results may affect those who receive services, provide services, or administer services.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

"Training" means a planned and systematic sequence of instruction under competent supervision which is designed to impart predetermined skills and knowledge.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

Subpart B—[Reserved]

Subpart C—How Does One Apply for a Grant?

§ 350.20 What are the application procedures for these programs?

An applicant for assistance under 34 CFR Parts 351, 352, 353, 354, or 355 shall submit a copy of the application to the State rehabilitation agency for comment in accordance with the procedures in EDGAR §§ 75.155–75.159.

(Sections 204c, 306(i); 29 U.S.C. 762(c), 776(i))

§ 350.21 How does an applicant inform the Secretary of its participation in the support of a project or center?

With the exception of 34 CFR Part 356 (Fellowships), an applicant shall identify in the application the financial contribution it proposes to make to support the proposed project or center.

(Section 204; 29 U.S.C. 762)

Subpart D—How Does the Secretary Make a Grant?

§ 350.30 To whom does the Secretary refer an application?

(a) The Secretary refers each application for a grant under the Handicapped Research Programs to a peer review panel established by the Secretary. The procedures for review by a group of experts under EDGAR § 75.217 (a) and (b) do not apply.

(b) The peer review panel reviews the application for the Secretary on the basis of the criteria described in § 350.36.

(Section 202(e); 29 U.S.C. 761a(e))

§ 350.31 What is the purpose of peer review?

The purpose of peer review is to insure that those activities supported by the Institute are of the highest scientific, administrative, or technical quality and that the results may be widely applied to appropriate population groups and situations.

(Section 202(e); 29 U.S.C. 761a(e))

§ 350.32 What is the composition of a peer review panel?

(a) The Secretary selects as members of a peer review panel non-Federal scientists and other experts qualified by training and experience in particular scientific, administrative, or technical fields to give expert advice on the scientific or technical merit of grant applications.

(b) In selecting an individual for membership on a peer review panel, the Secretary takes into account, among other factors, the following:

(1) The level of formal scientific or technical education completed by the individual;

(2) The extent to which the individual has engaged in scientific, technical, or administrative activities appropriate to the category of applications that the panel will consider, the role of the individual in those activities, and the quality of those activities; and

(3) The recognition received by the individual as reflected by awards and other honors from scientific and professional agencies and organizations outside the Department.

(Section 202(e); 29 U.S.C. 761a(e))

§ 350.35 How does the Secretary evaluate an application?

(a) The Secretary evaluates an application under 34 CFR Parts 351, 352, 353, 354, and 355 on the basis of the criteria in § 350.36, except as set forth in § 355.31(b).

(b) The Secretary awards up to 100 possible points for these criteria.

(c) The maximum possible score for each criterion is indicated in parentheses after the descriptive title of the criterion. For two of the criteria there is also a designation of the maximum score assigned to each of the component elements of those criteria.

(Section 202e; 29 U.S.C. 761a(e))

§ 350.36 What selection criteria does the Secretary use in reviewing a grant application?

(a) *Project concept or national need* (5 points).

(1) The Secretary reviews each application for information that shows the quality of the "project concept" or "national need" statement.

(2) The Secretary looks for information that shows—

(i) For any application that is addressing a specific project concept published by the Secretary in a Federal Register Application Notice, how well the project would contribute to its achievement.

(ii) For any application not addressed to a specific project concept (but responding to an Application Notice published in the Federal Register asking for field designed proposals), what national need the application will address, how clearly this need is described, how important the need is, and how well the project will meet the need.

(b) *Research design* (35 points).

(1) The Secretary reviews each application for information that shows the quality of the research design of the project.

(2) The Secretary looks for information that shows—

(i) Clearness and achievability of the project objectives (10 of the 35 points);

(ii) Soundness of the procedures to be utilized in achieving each objective (5 of the 35 points);

(iii) Precise definitions of terms where necessary (5 of the 35 points);

(iv) Description of subject population and appropriateness of sample size (5 of the 35 points);

(v) Appropriateness of statistical and other instruments to be used (5 of the 35 points); and

Adequacy of data analysis and basis for the conclusions reached (5 of the 35 points).

(c) *Plan of operation* (15 points).

(1) The Secretary reviews each application for information that shows the quality of the plan of operation for the project.

(2) The Secretary looks for information that shows—

(i) High quality in the operational design of the project (3 of the 15 points);

(ii) An effective plan of management that insures proper and efficient administration of the project (3 of the 15 points);

(iii) A clear description of how the objectives of the project relate to the purpose of the program (3 of the 15 points);

(iv) The way the applicant plans to use its resources and personnel to achieve each objective (3 of the 15 points);

(v) A clear description of how the applicant will provide equal access and treatment for eligible project participants who are members of groups that have been traditionally underrepresented, such as—

(A) Handicapped persons;

(B) The elderly;

(C) Women; and

(D) Members of racial or ethnic minority groups (3 of the 15 points).

(d) *Evaluation plan* (10 points).

(1) The Secretary reviews each application for information that shows the quality of the evaluation plan for the project.

(2) The Secretary looks for information that shows methods of evaluation that are appropriate for the project and, to the extent possible, are objective, and produce data that are quantifiable.

(e) *Quality of key personnel* (10 points).

(1) The Secretary reviews each application for information that shows the quality of key personnel proposed for the project.

(2) The Secretary looks for information that shows—

(i) The qualifications of the project director;

(ii) The qualifications of each of the other key personnel to be used in the project;

(iii) The time that each person referred to in paragraphs (2)(i) and (ii) of ths section will commit to the project; and

(iv) The extent to which the applicant as part of its nondiscriminatory employment practices, encourages applications for employment from persons who are members of groups that have been traditionally underrepresented such as—

(A) Handicapped persons;

(B) The elderly;

(C) Women; and

(D) Members of racial or ethnic minority groups.

(3) To determine personnel qualifications, the Secretary considers the experience and training, in fields related to the objectives of the project, as well as other information that the applicant provides.

(f) *Adequacy of resources* (5 Points).

(1) The Secretary reviews each application for information that shows that the applicant plans to devote adequate resources to the project.

(2) The Secretary looks for information that shows—

(i) The facilities that the applicant plans to use are adequate; and

(ii) The equipment and supplies that the applicant plans to use are adequate.

(q) *Research utilization plan* (10 points).

(1) The Secretary reviews each application for information that shows the quality of the research utilization plan.

(2) The Secretary looks for information that show—

(i) What will be delivered to the Department;

(ii) The format in which the results, products, or outcomes will be delivered to the Department;

(iii) The way in which results, products, or outcomes will be developed or provided for dissemination purposes to specified target populations; and

(iv) The procedures to be used in dissseminating the results, products, or outcomes at the local, State, or national levels.

(h) *Budget and cost effectiveness* (5 points).

(1) The Secretary reviews each application for information that shows that the project has an adequate budget and is cost effective.

(2) The Secretary looks for information that shows—

(i) The budget for the project is adequate to support the project activities; and

(ii) Costs are reasonable in relation to the objectives of the project.

(i) *Literature review* (5 Points).

(1) The Secretary reviews each application for information that shows the quality of the literature review.

(2) The Secretary looks for information that shows—

(i) A description of what has been done previously to alleviate the problem; and

(ii) An identification of the gaps that may be alleviated by the proposed project.

(34 CFR 75.201 through 75.206)

(Section 202(e) and 202(i)(1); 29 U.S.C. 761a(e) and 761a(i)(1))

Subpart E—What Conditions Apply to a Grantee?

§ 350.40 What are the matching requirements?

(a) Research and demonstration projects which bear directly on the development of procedures, methods, and devices to assist in the provision of vocational and other rehabilitation services can only be partially funded by the Secretary. It is expected that the grantee will participate in the costs of such projects. No specific percentage of

matching is required. Generally 10 percent is considered adequate.

(b) Grants may be made to pay for part or all of the costs or the following activities: Rehabilitation Research and Training Centers; Rehabilitation Engineering Centers; model training centers; and research projects on spinal cord injury, end-stage renal disease, telecommunications, joint projects with other Federal agencies and private industry, rehabilitation of handicapped children and handicapped individuals who are aged sixty or older, attraction and retention of professional workers in rural areas, captioned video cassetts for deaf individuals, and services for preschool handicapped children and their parents. The Secretary will determine at the time of the award whether the grantee must pay a portion of the project costs.

(Section 204; 29 U.S.C. 762)

Subpart F—What are the Administrative Responsibilities of a Grantee or Fellow?

§ 350.50 What are the requirements with respect to protection, use, and release of personal information?

(a) All personal information about individuals served or participating in any project under these parts, including lists of names, addresses, photographs, and records of evaluation, must be held confidential.

(b) The use of information and records concerning individuals must be limited only to purposes directly connected with the project, including project evaluation activities. This information may not be disclosed, directly or indirectly, other than in the administration of the project unless the consent of the agency providing the information and the consent of the individual to whom the information applies, or his or her representative, have been obtained in writing. The Secretary and other Federal or State officials responsible for enforcing legal requirements have access to this information without written consent being obtained. The final product of the project may not reveal any personal identifying information without written consent of the individual or his or her representative.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

The Secretary proposes to amend Title 34 of the Code of Federal Regulations by adding a new Part 351 to read as follows:

PART 351—HANDICAPPED RESEARCH: RESEARCH AND DEMONSTRATION PROJECTS

Subpart A—General

Sec.

Subpart B—What Kinds of Activities Does the Department Support Under This Program?

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

Subpart E—What Conditions Apply to a Grantee Under This Program?

Authority: Title II of the Rehabilitation Act of 1973 (Public Law 93-112) as amended by Public Law 95-602 (29 U.S.C. 760-762; 92 Stat. 2962-2966).

Subpart A—General

§ 351.1 What is the Research and Demonstration Projects Program?

A research project under this program is designed—

(a) To assist in the provision of vocational and other rehabilitation services to handicapped individuals, especially the most severely handicapped, through planning and conducting of research, demonstration, and specialized research activities;

(b) To cooperate with and assist in developing and sharing information found useful in other nations in the rehabilitation of handicapped individuals; or

(c) To assist in development of solutions to problems encountered by handicapped individuals in their daily activities, especially problems related to employment.

(Sections 202(g)(1); 204; 29 U.S.C. 761a(g)(1), 762)

§ 351.2 Who is eligible for assistance under this program?

Those agencies and organizations eligible to apply under this program are described in 34 CFR 350.2.

(Section 204; 29 U.S.C. 762)

§ 351.3 What regulations apply to this program?

The regulations referenced in 34 CFR 350.3 apply to this program.

(Sections 202 and 204; 29 U.S.C. 761a, 762)

§ 351.4 What definitions apply to this program?

The definitions listed in 34 CFR 350.4 apply to this program.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

Subpart B—What Kinds of Activities Does the Department Support Under This Program?

§ 351.10 What types of projects are authorized under this program?

The Research and Demonstration Projects Program provides financial assistance for the following types of projects—

(a) Medical and other scientific, technical, methodological, and other investigations into the nature of disability, methods of analyzing it, restorative techniques, including basic research where related to rehabilitation techniques or services; studies and analyses of industrial, vocational, social, psychiatric, psychological, economic and other factors affecting rehabilitation of handicapped individuals; special problems of homebound and institutionalized individuals; and other research related to problems encountered by handicapped individuals in their daily activities, especially problems related to employment.

(b) Specialized research activities as follows—

(1) Spinal cord injury research and demonstrations;

(2) End-state renal disease research and demonstrations;

(3) International research, demonstrations, training, and exchange of experts and technical assistance;

(4) Joint projects with other Federal agencies and private industry;

(5) Research related to handicapped children and handicapped individuals aged 60 years and older;

(6) Special research and demonstration projects designed to develop and demonstrate methods to attract and retain professionals to serve in rural areas in the rehabilitation of handicapped individuals; and

(7) Research and demonstration projects related to the provision of services to handicapped preschool children.

(Sections 204(a), 204(b)(3)-(5), 204(b)(7)-(9), 204(b)(11); 29 U.S.C. 762(a), 762(b)(3)-(5), 762(b)(7)-(9), 762(b)(11))

Subart C—Reserved

Subpart D—How Does the Secretary Make a Grant?

§ 351.30 How is peer review conducted under this program?

Peer review is conducted under this program in accordance with 34 CFR 350.30–350.32.

(Section 202(e); 29 U.S.C. 761a(e))

§ 351.31 What selection criteria are used under this program?

The selection criteria for this program are established and described in 34 CFR 350.36, with the weighted scores distributed as follows:

(a) Project concept or national need (5 Points).
(b) Research design (35 Points).
(c) Plan of operation (15 Points).
(d) Evaluation plan (10 Points).
(e) Quality of key personnel (10 Points).
(f) Adequacy of resources (5 Points).
(g) Research utilization (10 Points).
(h) Budget and cost effectiveness (5 Points).
(i) Literature review (5 Points).

(Sections 202(e) and 202(i)(1); 29 U.S.C. 761a(e) and 761a(i)(1))

§ 351.32 What are the priorities for funding under this program?

(a) The Secretary may from time to time reserve funds to support some or all of the types of projects listed in § 350.10.

(b) The Secretary advises the public of these priorities through an Application Notice published in the **Federal Register.**

(Sections 202(g), 204; 29 U.S.C. 761a(g), 762)

Subpart E—What Conditions Apply to a Grantee Under This Program?

§ 351.40 What are the allowable costs?

(a) In addition to those allowable costs set forth in EDGAR §§ 75.530–75.534, the following items are allowable under end-stage renal disease projects:

(1) Medical and technical expenses pursuant to treatment for end-stage renal disease;

(2) Purchase or rental or renal dialysis and other machines and supplies necessary for the treatment of end-stage renal disease, when such machines and supplies are not available under other Federal, State, or other program resources;

(3) Costs incident to the training of a patient with end-stage renal disease or members of the family in the use of renal dialysis and related equipment and in other aspects of end-stage renal disease care, including the use of home aides;

(4) Costs incident to necessary modification of a patient's living quarters;

(5) Hospital and related medical expenses for a donor of a kidney;

(6) Laboratory fees; and

(7) Tissue matching.

(b) If an individual selected to participate in an end-stage renal disease research project under this Part is eligible for and is receiving services for the treatment of end-stage renal disease under any other Federal, State, or other programs, the costs of these services shall not be attributed to a grant under this Part.

(Section 204(b)(4); 29 U.S.C. 762(b)(4))

The Secretary proposes to amend Title 34 of the code of Federal Regulations by adding a new Part 352 to read as follows:

PART 352—HANDICAPPED RESEARCH: REHABILITATION RESEARCH AND TRAINING CENTERS

Subpart A—General

Sec.
352.1 What is the Rehabilitation Research and Training Centers Program?
352.2 Who is eligible for assistance under this program?
352.3 What regulations apply to this program?
352.4 What definitions apply to this program?

Subpart B—What Kinds of Activities Does the Department Assist Under This Program?

352.10 What types of centers are authorized under this program?

Subpart C—Reserved

Subpart D—How Does the Secretary Make a Grant?

352.30 How is peer review conducted under this program?
352.31 What selection criteria are used under this program?
352.32 What are the priorities for funding under this program?

Authority: Title II of the Rehabilitation Act of 1973 (Public Law 93–112), as amended by Public Law 95–602 (29 U.S.C. 760–762; 92 Stat. 2962–2966).

Subpart A—General

§ 352.1 What is the Rehabilitation Research and Training Centers Program?

This program is designed to support—

(a) The conduct of coordinated and advanced programs of research in rehabilitation;

(b) The dissemination and active promotion of the utilization of findings resulting from such research; and

(c) The conduct of training programs (including graduate training) to assist individuals to more effectively provide rehabilitation services and to provide training (including graduate training) for rehabilitation research and other rehabilitation personnel.

(Section 204(b)(1); 29 U.S.C. 762(b)(1))

§ 352.2 Who is eligible for assistance under this program?

Those agencies and organizations eligible to apply under this program are described in 34 CFR 350.2

(Section 204; 29 U.S.C. 762)

§ 352.3 What regulations apply to this program?

The regulations referenced in 34 CFR 350.3 apply to this program.

(Sections 202 and 204; 29 U.S.C. 761a, 762)

§ 352.4 What definitions apply to this program?

The definitions listed in 34 CFR 350.4 apply to this program.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

Subpart B—What Kinds of Activities Does the Department Assist Under This Program?

§ 352.10 What types of centers are authorized under this program?

Rehabilitation reserarch and training centers are established and supported under this program. Within each center three types of activities are prescribed as follows:

(a) The research to be conducted at each center shall be determined on the basis of the particular needs of handicapped individuals by utilizing the geographic area served by the center as one source for identifying those problems which are national in scope. It may include basis research, where related to identifiable rehabilitation techniques or services, applied medical rehabilitation research, research regarding the psychological and social aspects of rehabilitation, and research related to vocational rehabilitation, independent living, and the rehabilitation of handicapped children and handicapped individuals aged 60 or older. The center shall develop practical applications for the findings of its research. Each separate study or investigation shall have a reasonable relationship to a central topic or research core area and shall contribute cumulatively to a coherent body of knowledge for the resolution of rehabilitation problems.

(b) Training programs at a center shall endeavor to: widely disseminate and actively promote utilization of new knowledge resulting from research; incorporate rehabilitation education into all rehabilitation related University undergraduate and graduate curricula;

and provide short-term, in-service and continuing education to improve the skills of professionals, paraprofessionals, consumers, parents, and other personnel involved in rehabilitation with respect to new knowledge generated through research findings.

(c) Service program components shall be developed to achieve the integration of services, research, and training necessary to—

(1) Provide direct knowledge and awareness of the needs of handicapped persons;

(2) Provide the linkage and structure to enable a center to more adequately and realistically assess these needs; and

(3) Provide a laboratory for the development, testing, implementation and demonstration of methods, techniques, procedures, and systems, to respond to these needs. Grants may include funds for services rendered by the center to handicapped individuals in connection with research and training activities.

(d) The three major activities—research, training, and services—are expected to be mutually supportive. Specifically, this concept calls for research needs to derive from service delivery problems; for research results to be assessed and applied in service delivery settings; and for research results to be disseminated through training.

(Section 204(b)(1); 29 U.S.C. 762(b)(1))

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

§ 352.30 How is peer review conducted under this program?

Peer review is conducted under this program in accordance with 34 CFR 350.30–350.32.

(Section 202(e); 29 U.S.C. 761a(e))

§ 352.31 What selection criteria are used under this program?

The selection criteria for this program are established and described in 34 CFR 350.36 with the weighted points distributed as follows:

(a) Project concept or national need (5 Points).

(b) Research design (35 Points).

(c) Plan of operation (15 Points).

(d) Evaluation plan (10 Points).

(e) Quality of key personnel (10 Points).

(f) Adequacy of resources (5 Points).

(g) Research utilization plan (10 Points).

(h) Budget and cost effectiveness (5 Points).

(i) Literature review (5 Points).

(Sections 202(e) and 202(i)(1); 29 U.S.C. 761a(e) and 761a(i)(1))

§ 352.32 What are the priorities for funding under this program?

(a) The Secretary may from time to time reserve funds to support some or all of the types of research projects listed in 34 CFR 352.10.

(b) The Secretary advises the public of these priorities through an Application Notice in the **Federal Register.**

(Sections 202(g) and 204; 29 U.S.C. 761a(g) and 762)

The Secretary proposes to amend Title 34 of the Code of Federal Regulations by adding a new Part 353 to read as follows:

PART 353—HANDICAPPED RESEARCH: REHABILITATION ENGINEERING PROGRAM

Subpart A—General

Sec.

Subpart B—What Kinds of Activities Does the Department Support Under This Program?

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

Authority: Title II of the Rehabilitation Act of 1973 (Public Law 93–112), as amended by Public Law 95–602 (29 U.S.C. 760–762; 92 Stat. 2962–2966).

Subpart A—General

§ 353.1 What is the Rehabilitation Engineering Program?

This program is designed to support—

(a) Development of innovative methods of applying advanced medical technology, scientific achievement, and psychiatric, psychological, and social knowledge to solve rehabilitation problems;

(b) Development of systems of technical and engineering information exchange and coordination; and

(c) Improvement in the distribution of technological devices and equipment to handicapped individuals.

(Sections 200(3), 204(b)(2); 29 U.S.C. 760(3), 762(b)(2))

§ 353.2 Who is eligible for assistance under this program?

Those agencies and organizations eligible to apply under this program are set forth in 34 CFR 350.2.

(Section 204; 29 U.S.C. 762)

§ 353.3 What regulations apply to this program?

The regulations referenced in 34 CFR 350.3 apply to this program.

(Sections 202 and 204; 29 U.S.C. 761a and 762)

§ 353.4 What definitions apply to this program?

The definitions listed in 34 CFR 350.4 apply to this program.

(Section 202(i)(1); 29 U.S.C. 761a(i)(1))

Subpart B—What Kinds of Activities Does the Department Support Under This Program?

§ 353.10 What types of projects are authorized under this program?

The Rehabilitation Engineering Research program provides financial assistance for—

(a) Rehabilitation Engineering Research Centers.

(i) Each Rehabilitation Engineering Research Center must be developed around one or more research core areas, each of which must be explored in depth to solve the problems in rehabilitation of handicapped individuals through the combined efforts of medical, engineering, and related sciences;

(ii) Each center must be located in a clinical rehabilitation setting which provides an environment for cooperative research and the transfer of research findings to rehabilitation practice at a reasonable cost.

(iii) Centers may emphasize the medical-technological management of disabling conditions, the adjustment to limitations of function of the individual and to the environment, service delivery systems, or other core areas, utilizing the application of new and innovative technology, and other areas as approved by the Secretary.

(iv) Centers must cooperate with State and other appropriate agencies in developing systems of information exchange and coordination to insure the prompt utilization of research findings.

(b) Research and demonstration projects as follows—

(i) Research and demonstration projects including basic research when related to rehabilitation techniques or services;

(ii) Studies, analyses, and demonstrations of architectural and

engineering design and reductions of environmental barriers adapted to meet the special needs of handicapped individuals;

(iii) Cooperative projects with public or private agencies and organizations;

(iv) Projects concerning existing telecommunication systems;

(v) International research, demonstrations, training and exchange of experts and technical assistance related to technology and engineering;

(vi) A project to assess the feasibility of establishing a center to produce and distribute captioned video cassettes to deaf individuals; and

(vii) Joint project with other Federal agencies and with private industry, including stimulation of private industry in the development and distribution of devices and systems to solve problems of handicapped individuals; and

(viii) Projects of manpower training in Rehabilitation Engineering.

(Sections 204(b)(2), 204(a), 204(b)(5)–(7), 204(b)(10); 29 U.S.C. 762(b)(2), 762(a), 762(b)(5)–(7), 762(b)(10))

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

§ 353.30 How is peer review conducted under this program?

Peer review is conducted under this program in accordance with 34 CFR 350.30–350.32.

(Section 202(e); 29 U.S.C. 761a(e))

§ 353.31 What selection criteria are used under this program?

The selection criteria for this program are established and described in 34 CFR 350.36 with the weighted points distributed as follows:

(a) Project concept or national need (5 Points).

(b) Research design (35 Points).

(c) Plan of operation (15 Points).

(d) Evaluation plan (10 Points).

(e) Quality of key personnel (10 Points).

(f) Adequacy of resources (5 Points).

(g) Research utilization plan (10 Points).

(h) Budget and cost effectiveness (5 Points).

(i) Literature review (5 Points).

(Sections 202(e) and 202(i)(1); 29 U.S.C. 761a(e) and 761a(i)(1))

§ 353.32 What are the priorities for funding under this program?

(a) The Secretary may from time to time reserve funds to support some or all of the types of research projects listed in 34 CFR 353.10.

(b) The Secretary advises the public of these priorities through an Application Notice published in the Federal Register.

(Section 202(g); U.S.C. 761a(g))

The Secretary proposes to amend Title 34 of the Code of Federal Regulations by adding a new Part 354 to read as follows:

PART 354—HANDICAPPED RESEARCH: MODEL RESEARCH AND TRAINING PROGRAM

Subpart A—General

Sec.

Subpart B—What Kinds of Activities Does the Department Support Under This Program?

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

Authority: Title II of the Rehabilitation Act of 1973 (Public Law 93–112), as amended by Public Law 95–602 (29 U.S.C. 760–762; 92 Stat. 2962–2966).

Subpart A—General

§ 354.1 What is the Model Research and Training Program?

This program is designed to develop and utilize more advanced and effective methods of evaluating and developing the employment potential of handicapped individuals.

(Section 204(b)(12); 29 U.S.C. 762(b)(12))

§ 354.2 Who is eligible for assistance under this program?

Those agencies and organizations eligible to apply under this program are set forth in 34 CFR 350.2.

(Section 204; 29 U.S.C. 762)

§ 354.3 What regulations apply to this program?

The regulations referenced in 34 CFR 350.3 apply to this program.

(Sections 202 and 204; 29 U.S.C. 761a and 762)

§ 354.4 What definitions apply to this program?

The definitions listed in 34 CFR 350.4 apply to this program.

(Sections 202(i)(1); 29 U.S.C. 761a(i)(1))

Subpart B—What Kinds of Activities Does the Department Support Under This Program?

§ 354.10 What types of centers are authorized under this program?

The model research and training program provides financial assistance for part or all of the costs of establishing and operating model training centers.

(a) Each model training center must be developed around one or more research core areas, each of which must be explored in depth. Each separate study or investigation within a core area shall contribute cumulatively to a coherent body of knowledge for the resolution of a rehabilitation problem. It must be undertaken on the basis of a predetermined plan that reflects what is already known about the topic. The development of a core area must involve a review of the literature; development of one or more hypotheses; selection or development of data gathering instruments; a series of demonstrations, experiments, surveys, or studies to test the hypotheses; the refinement of one or more hypotheses into a theory; and further validation studies and consultation with the prospective target population during the entire process.

(b) Each center must be located in a rehabilitation setting which provides an environment for cooperative research and the transfer of research findings to rehabilitation practice at a reasonable cost.

(c) The following categories of activities may be undertaken within model training centers;

(1) Training and continuing education for personnel involved with employment of handicapped individuals;

(2) Model procedures for testing and evaluating the employment potential of handicapped individuals;

(3) Model training programs to teach handicapped individuals skills which will lead to appropriate employment;

(4) New approaches for job placement of handicapped individuals, including new follow-up procedures relating to such placement; and

(5) Information services regarding education, training, employment and job placement for handicapped individuals.

(Section 204(b)(12); 29 U.S.C. 762(b)(12))

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

§ 354.30 How is peer review conducted under this program?

Peer review is conducted under this program in accordance with 34 CFR 350.30–350.32.

(Section 202(e); 29 U.S.C. 761a(e))

§ 354.31 What selection criteria are used under this program?

The selection criteria for this program are established and described in 34 CFR 350.36 with the weighted points distributed as follows:

(a) Project concept or national need (5 Points).

(b) Research design (35 Points).

(c) Plan of operation (15 Points).

(d) Evaluation plan (10 Points).

(e) Quality of key personnel (10 Points).

(f) Adequacy of resources (5 Points).

(g) Research utilization plan (10 Points).

(h) Budget and cost effectiveness (5 Points).

(i) Literature review (5 Points).

(Sections 202(e) and 202(i)(1); 29 U.S.C. 761a(e) and 761(i)(1))

§ 354.32 What are the priorities for funding under this program?

(a) The Secretary may from time to time reserve funds to support some or all of the types of research activities listed in 34 CFR 354.10(c).

(b) The Secretary advises the public of these priorities through an Application Notice published in the **Federal Register.**

(Section 202(g); 29 U.S.C. 761a(g))

The Secretary proposes to amend Title 34 of the Code of Federal Regulations by adding a new Part 355 to read as follows:

PART 355—HANDICAPPED RESEARCH: KNOWLEDGE DISSEMINATION AND UTILIZATION

Subpart A—General

Sec.

Subpart B—What Kinds of Activities Does the Department Support Under This Program?

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

Authority: Title II of the Rehabilitation Act of 1973 (Public Law 93–112), as amended by Public Law 95–602 (29 U.S.C. 760–762; 92 Stat. 2962–2966).

Subpart A—General

§ 355.1 What is the Knowledge Dissemination and Utilization Program?

This program is designed to assist in developing and implementing activities that will insure that rehabilitation knowledge generated from projects and centers funded by the Institute and from other sources is fully utilized to improve the lives of handicapped persons.

(Sections 202 and 204(a); 29 U.S.C. 761a and 762(a))

§ 355.2 Who is eligible for assistance under this program?

Those agencies and organizations eligible to apply under this program are described in 34 CFR 350.2

(Section 204; 29 U.S.C. 762)

§ 355.3 What regulations apply to this program?

The regulations referenced in 34 CFR 350.3 apply to this program.

(Sections 202 and 204; 29 U.S.C. 761a and 762)

§ 355.4 What definitions apply to this program?

The definitions listed in 34 CFR 350.4 apply to this program.

(Section 202(i)(1); 29 U.S.C. 761(i)(1))

Subpart B—What Kinds of Activities Does the Department Support Under This Program?

§ 355.10 What types of activities are authorized under this program?

The knowledge dissemination and utilization program provides financial assistance for the following types of projects—

(a) Research utilization;

(b) Research on the process of research utilization;

(c) Information dissemination activities;

(d) Building public awareness about ways of rehabilitating handicapped persons;

(e) Demographic studies of handicapped individuals.

(Sections 200(2), 202(b)(4)–(6)(8), 204(a), 204(b)(7); 29 U.S.C. 761a(b)(2), 761a(b)(4)–6)(8), 762(a), 762(b)(7))

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

§ 355.30 How is peer review conducted under this program?

Peer review is conducted under this program in accordance with 34 CFR 350.30–350.32.

(Section 202e; 29 U.S.C. 761a(e))

§ 355.31 What selection criteria are used under this program?

(a) The selection criteria for projects described in § 355.10(b) and (e) (research on the process of research utilization and demographic studies) are established in § 350.36 with the weighted points distributed as follows:

(1) Project concept or national need (5 Points).

(2) Research design (35 Points).

(3) Plan of operation (15 Points).

(4) Evaluation plan (10 Points).

(5) Quality of key personnel (10 Points).

(6) Adequacy of resources (5 Points).

(7) Research utilization plan (10 Points).

(8) Budget and cost effectiveness (5 Points).

(9) Literature review (5 Points).

(b) The selection criteria for projects described in § 355.10(a), (c) and (d) are:

(1) Project concept or national need (5 Points). See § 350.36(a).

(2) Project design (40 Points).

(i) The Secretary reviews each application for information that shows the quality of the project design.

(ii) The Secretary looks for information that shows—

(A) Description of linkage system to prospective target populations (10 of the 40 Points);

(B) Need assessment procedures (10 of the 40 Points);

(C) That rehabilitation knowledge or devices will be adapted or modified to facilitate greater understanding and use by the rehabilitation community (10 of the 40 Points); and

(D) Procedures for disseminating the rehabilitation knowledge or devices referred to in paragraph (C) (10 of the 40 Points).

(3) Plan of operation (15 Points). See § 350.36(c).

(4) Evaluation plan (15 Points). See § 350.36(d).

(5) Quality of key personnel (10 Points). See § 350.36(e).

(6) Adequacy of resources (5 Points). See § 350.36(f).

(7) Budget and cost effectiveness (5 Points). See § 350.36(h).

(8) Literature review (5 Points). See § 350.36(i).

(Section 202(e) and 202(i)(1); 29 U.S.C. 761a(e) and 761a(i))

§ 355.32 What are the priorities for funding under this program?

(a) The Secretary may from time to time reserve funds to support some or all of the types of projects listed in 34 CFR 355.10.

(b) The Secretary advises the public of these priorities through an Application Notice published in the **Federal Register.**

(Section 204; 29 U.S.C. 762)

The Secretary proposes to amend Title 34 of the Code of Federal Regulations by adding a new Part 356 to read as follows:

PART 356—HANDICAPPED RESEARCH: RESEARCH FELLOWSHIPS

Subpart A—General

Sec.
356.1 What is the Research Fellowship Program?
356.2 Who is eligible for assistance under this program?
356.3 What regulations apply to this program?
356.4 What definitions apply to this program?

Subpart B—What Kinds of Activities Does the Department Support Under This Program?

356.10 What types of activities are authorized?
356.11 What types of problems may be researched under the fellowship program?

Subpart C—How Does One Apply for Assistance Under This Program?

356.20 What are the application procedures under this Part?
356.21 What is the fellowship review process?

Subpart D—How Does the Secretary Select a Fellow?

356.30 What selection criteria are used for this program?

Subpart E—What Conditions Have to be Met by a Fellow?

356.40 What is the length of a fellowship award?
356.41 Employment during fellowship period.
356.42 What acknowledgement of support is required?

Subpart F—What are the Administrative Responsibilities of a Fellow?

356.50 What kinds of payments are allowed under this program?
356.51 What programmatic reports are required of fellows?

Subpart G—May Fellowships Be Terminated?

356.60 Termination of fellowships.

Authority: Title II of the Rehabilitation Act of 1973 (Public Law 93–112) as amended by Public Law 95–602 (29 U.S.C. 760–762; 92 Stat. 2962–2966).

Subpart A—General

§ 356.1 What is the Research Fellowships Program?

The purpose of this program is to procure the assistance of highly qualified individuals in the research program of the Institute.

(Sec. 202(d); 29 U.S.C. 761a(d))

§ 356.2 Who is eligible for assistance under this program?

Any person is eligible for assistance under this program who has training and experience that indicate a potential for engaging in scientific research related to the solution of rehabilitation problems of handicapped persons.

(Sec. 202(d); 29 U.S.C. 761a(d))

§ 356.3 What regulations apply to this program?

The following regulations apply to this program:

(a) The peer review and confidentiality requirements contained in 34 CFR 350.31–350.32 and 350.50.

(b) The regulations in this part—34 CFR Part 356; and

(c) 45 CFR Part 46 (Protection of Human Subjects).

(Sec. 202(d); 29 U.S.C. 761a(d))

§ 356.4 What definitions apply to this program?

The definitions listed in 34 CFR 350.4 apply to this program.

(Sec. 202(i)(1); 29 U.S.C. 761a(i)(1))

Subpart B—What Kinds of Activities Does the Department Support Under This Program?

§ 356.10 What type of activities are authorized?

Research fellowships provide awards of Federal assistance to enable individuals to carry out discrete research activities which have been identified in Application Notices published in the **Federal Register.**

(Sec. 202(d); 29 U.S.C. 761a(d))

§ 356.11 What types of problems may be researched under the fellowship program?

Problems encountered by handicapped persons in their daily lives that are due to the presence of a handicapping condition, problems associated with the provision of rehabilitation services to handicapped persons, and problems connected with the conduct of handicapped research may be addressed under this program.

(Sec. 202(d), 202(g)(1), 204; 29 U.S.C. 761a(d), 761a(g)(1), 762)

Subpart C—How Does One Apply for Assistance Under This Program?

§ 356.20 What are the application procedures under this Part?

From time to time the Secretary will publish in the **Federal Register** an Application Notice that announces the availability of fellowship assistance under this Part.

(Sec. 202(d); 29 U.S.C. 761a(d))

§ 356.21 What is the fellowship review process?

Fellowship applications will be reviewed in accordance with the peer review requirements governing grants in 34 CFR 350.30–350.32.

(Sec. 202(d); 29 U.S.C. 761a(d))

Subpart D—How Does the Secretary Select a Fellow?

§ 356.30 What selection criteria are used for this program?

Individuals applying for a research fellowship will be evaluated on the basis of—

(a) Quality and level of formal education received;

(b) Work experience;

(c) Recommendations of former or present supervisors or colleagues and other independent evidence that indicate an ability to work creatively in scientific research;

Sec. 202(d); 29 U.S.C. 761a(d))

Subpart E—What Conditions Have to be Met by a Fellow?

§ 356.40 What is the length of a fellowship award?

Fellowships may be approved for a maximum of 48 months. The initial award may be for any period not to exceed one year. Upon a finding of satisfactory progress toward accomplishment of the purposes of the fellowship the Secretary may make one or more continuation awards of 12 months in duration, not to exceed a total of 48 months support for any one fellowship.

(Sec. 202(d); 29 U.S.C. 761a(d))

§ 356.41 Employment during fellowship period.

Fellows are engaged fulltime in the activities authorized by the award and shall not engage in other employment, unless approved by the Secretary.

(Sec. 202(d); 29 U.S.C. 761a(d))

§ 356.42 What acknowledgement of support is required?

Publication, distribution, and disposition of all manuscripts and other materials resulting from a fellowship

awarded under this Part must acknowledge that assistance was received from the Department and the Institute. Three copies of these publications or other materials must be furnished to the Secretary.

(Sec. 202(d); 29 U.S.C. 761a(d))

Subpart F—What are the Administrative Responsibilities of a Fellow?

§ 356.50 What kinds of payments are allowed under this program?

(a) A *fellowship award* may include the following payments:

(1) A *stipend* in an amount authorized by the Secretary.

(2) A *health insurance allowance.*

(3) A *travel and transportation allowance.*

(i) Round trip travel, for the fellow only, from place of residence to the location of fellowship activity.

(ii) No allowance will be granted for shipping personal effects or household goods.

(iii) No allowance will be granted for transporting dependents, except as authorized by the Secretary for travel undertaken by dependents to join a fellow who is located during the period of fellowship activity in a coutry other than his or her country of residence. "Dependent" means the spouse or dependent children of a fellow.

(4) *Other allowances.*

The Secretary may authorize allowances for payment of the following expenses—tuition, fees, equipment, supplies, attendance at meetings required to carry out the purpose of the fellowship, or other related expenses of the fellowship.

(Sec. 202(d); 29 U.S.C. 761a(d))

§ 356.51 What programmatic reports are required?

Fellows are required to submit annual and final reports (along with work plans for the next fellowhsip period if applicable). Each report must contain as a minimum an analysis of the significance of the project and an assessment of the degree to which the objectives of the project have been achieved.

(Sec. 202(d); 29 U.S.C. 761a(d))

Subpart G—May Fellowships Be Terminated?

§ 356.60 Termination of fellowships.

(a) The Secretary may terminate a fellowship upon receipt from the fellow of a written request for termination. The Secretary shall terminate any fellowship prior to the date it would otherwise expire if it is determined that the fellow's performance is unsatisfactory or that the fellow is unable to carry out the purpose of the fellowship. The fellow shall be notified in writing of any termination.

(b) When a fellowship is terminated prior to the end of the fellowship period, all remaining unexpended funds must be returned to the Secretary.

(Sec. 202(d); 29 U.S.C. 761a(d))

[FR Doc. 80-40426 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

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34 CFR Part 629

Veterans' Cost-of-Instruction Payments Program

AGENCY: Department of Education.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Secretary proposes to amend the regulations for the Veterans' Cost-of-Instruction Payments (VCIP) Program. The regulations are being amended to reflect the statutory changes in the Education Amendments of 1980 and to reflect several administrative policy decisions. The proposed changes affect the eligibility criteria, the requirements of each grantee, and the payment process. The regulations have also been completely reorganized for the purposes of simplification and clarification.

DATES: Comments must be received on or before March 2, 1981.

ADDRESSES: Comments should be addressed to Stanley B. Patterson, Office of Postsecondary Education, Office of Institutional Support, U.S. Department of Education (Room 3514, ROB-3), 400 Maryland Avenue, S.W., Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Stanley B. Patterson. Telephone: (202) 245-2806.

SUPPLEMENTARY INFORMATION: The Veterans' Cost-of-Instruction Payments Program began in 1973 as a formula grant program which assists institutions of higher education in the provision of educational services to veterans. Grants support full-time offices of veterans' affairs which provide outreach, recruitment, counseling and tutorial services, and special programs for *educationally disadvantaged veterans.*

The proposed text of the revised regulations governing the VCIP program is printed following this preamble. The proposed changes in the regulations reflect the following administrative policy decisions:

(1) An amendment is proposed in Section 629.31(d) to give institutions their entire grant in one payment at the beginning of the academic year. The amount of the payment would be based on veteran enrollment on April 16. This single-payment system would replace the three-payment system now in use. This new system would ease the reporting requirements of grantees and enable an institution to plan its program activities more effectively.

(2) An amendment is proposed to delete as unnecessary the section entitled, Criteria for assessing the adequacy of veterans' programs, presently found in 34 CFR Section 629.16. Many of these criteria are already covered in Section 629.11 of the proposed regulations.

(3) An amendment is proposed to modify the definitions of "institution of higher education", "student", and "undergraduate" to bring the VCIP regulations into conformity with standard Education Department definitions.

The current regulations are also being amended to reflect the statutory changes in the Education Amendments of 1980. These revisions include:

(1) The eligibility criteria are amended so that a renewal applicant will no longer be eligible if it merely maintains its undergraduate veteran enrollment. It will be eligible, however, if its veteran enrollment increases by 10 percent, or if it meets the requirements of one of the other methods by which a renewal applicant can establish eligibility.

(2) An institution accepting a grant must now make an adequate effort to carry out outreach activities with a special emphasis on service-connected disabled veterans, other disabled or handicapped veterans, and incarcerated veterans in addition to educationally disadvantaged veterans.

(3) Institutions are required to make an adequate effort to coordinate their activities with the readjustment counseling program authorized under section 620 of title 38, and with the veterans employment and training initiatives authorized under the Comprehensive Employment and Training Act and under chapters 41 and 42 of title 38, in order to assist in serving the readjustment, rehabilitation, personal counseling and employment needs of veterans.

(4) The enrollment ceiling of 2500 undergraduate students below which an institution can enter a consortium arrangement is deleted. This deletion does not pertain to the ceiling of 2500 undergraduate students below which an institution need only maintain a full-time office of veterans's affairs and provide recruitment and counseling services.

(5) The second category of veterans for which an institution will receive a

payment is broadened to cover veterans who have a service-connected disability or who are disabled.

(6) The maximum grant to any institution is lowered from $135,000 to $75,000.

(7) The percentage of funds which an institution must use to carry out the required services of the program is increased from 75 percent to 90 percent.

Invitation To Comment:

Interested persons are invited to submit comments and recommendations regarding these proposed regulations. Written comments and recommendations may be sent to the address given at the beginning of this preamble. All comments received on or before March 2, 1981, will be considered in the development of the final regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 3514, ROB-3, 7th and D Streets, S.W., Washington, D.C. between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Assessment of Educational Impact

The Department particularly requests comments on whether the proposed regulations in this document would require transmission of information that is already being gathered by or is available from any other agency or authority of the United States.

Citation of Legal Authority

A citation of statutory or other legal authority is placed in parentheses on the line following each substantive provision of these proposed regulations.

(Catalog of Federal Domestic Assistance No. 84.540, Higher Education Veterans' Cost-of-Instruction Program (VCIP))

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

The Secretary amends Title 34 Part 629 of the Code of Federal Regulations to read as follows:

PART 629—VETERANS' COST-OF-INSTRUCTION PAYMENTS TO INSTITUTIONS OF HIGHER EDUCATION

Sec.

Authority: Section 420, Higher Education Act of 1965, as amended (20 U.S.C. 1070e-1), unless otherwise noted.

Subpart A—General

§ 629.1 Veterans' Cost-of-Instruction Payment program.

This program provides funds to institutions of higher education for the educational needs of veterans. Funds are used to establish and maintain a full-time Office of Veterans' Affairs which provides outreach and recruitment activities, counseling and tutorial services, and special programs for educationally disadvantaged veterans.

(20 U.S.C. 1070e-1)

§ 629.2 Eligible parties.

(a) *Criteria for initial eligibility.* An institution of higher education is eligible to receive payments under this part if the number of qualified undergraduate veteran students who are receiving benefits under chapter 31 or chapter 34 of title 38, United States Code (or who have received benefits under subchapter V or subchapter VI of chapter 34 while attending the institution during the academic year) equals at least 25 in number and at least one of the following:

(1) 110 percent of the number of such qualified undergraduate veteran students in attendance on April 16 of the preceding academic year.

(2) 10 percent of the total number of undergraduate students in attendance at the institution during the current academic year, if this number does not constitute a percentage of its undergraduate students which is less than the percentage for the preceding academic year.

(b) *Criteria for continuing eligibility.* An institution of higher education which is applying for assistance during an academic year following one during which it has received assistance under this part will be eligible to receive payments under this part if—

(1) The applicant meets the criteria for initial eligibility as defined in paragraph (a) of this section;

(2) The applicant has a percentage decline in the number of undergraduate veteran students receiving benefits under chapter 31 or chapter 34 of title 38, United States Code, no greater than the national percentage decline in the number of undergraduate veteran students enrolled in all institutions of higher education since the applicant's initial year of eligibility;

(3) The Secretary determines that the applicant is making a reasonable effort to recruit, enroll, and provide necessary services to veterans, taking into consideration the extent to which the number of persons referred to in paragraph (a) of this section falls short of meeting the ratio criteria set forth in that paragraph.

(c) *Criteria for renewed eligibility.* An applicant which has qualified for payment during any preceding fiscal year, but subsequently became ineligible, is eligible to receive payments under this part if—

(1) The applicant would have been eligible had paragraph (b) of this section been in effect when the applicant became ineligible;

(2) The applicant has had a full-time office of veterans' affairs since its last year of participation in the program; and

(3) The appropriations made available during the fiscal year in which the award would be made are in excess of—(i) $14,380,000, or (ii) the amount requested in the President's budget, whichever is greater, by an amount sufficient to make payments to all institutions meeting the requirements of paragraphs (c)(1) and (c)(2) of this section.

(20 U.S.C. 1070e-1)

§ 629.3 Ineligible parties.

School or departments of divinity and proprietary institutions are not eligible to receive assistance under this part.

(20 U.S.C. 1070e-1)

§ 629.4 Regulations that apply to the Veterans' Cost-of-Instruction Payments program.

The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 75 (Direct Grant Programs) and 34 CFR Part 77 (Definitions) and the regulations in this part 629 apply to the Veterans' Cost-of-Instruction Payments program.

(20 U.S.C. 1070e-1, 1088, 1141)

§ 629.5 Definitions that apply to the Veterans' Cost-of-Instruction Payments program.

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR Part 77:

Applicant
Application
Award
Department
Fiscal Year
Grant
Grant Period
Secretary
State

(b) *Definitions that apply to this part.* The following definitions apply to this part:

"Academic year" means a period beginning on July 1 and ending the following June 30.

"Cost-of-Instruction payment," or "payment," means an amount calculated with respect to an institution of higher education for an academic year on the basis of eligible undergraduate veteran student enrollment.

"Counseling" means professional assistance available to veterans for consultation on personal, family, educational, and career problems.

"Full-time" with respect to an Office of Veterans' Affairs, means that the Office of Veterans' Affairs: (1) is staffed by at least one person who is employed by an institution on a full-time basis and whose sole institutional responsibility is that of coordinating the activities of the office and (2) provides services at times and places convenient to the veterans being served. An institution described in §629.11(c) may employ part-time employees for this purpose who together assume the responsibility of at least one full-time employee.

"Institution of higher education" is defined in the Higher Education Act of 1965, as amended, Pub. L. 89–329, Section 1201(a).

"Instructional expenses in academically related programs" means the expenditures of instructional departments of an institution of higher education for salaries, office expenses, equipment and research.

"Outreach" means an extensive coordinated, community-wide program of reaching veterans, with special emphasis on educationally disadvantaged veterans, service-connected disabled veterans, other disabled or handicapped veterans, and incarcerated veterans within the institution's service area to determine their needs and to make appropriate referral and follow-up arrangements with relevant service agencies.

"Qualified undergraduate veteran student" means an undergraduate veteran student who is in attendance at the institution on April 16 of the academic year in which the institution is applying, or when this date falls between academic terms of the institution, the end of the previous academic term.

"Recruitment" means a concerted effort to interest veterans in taking advantage of opportunities for a wide variety of post-secondary training experiences at the institution or other agencies providing educational programs.

"School or department of divinity" is defined in the Higher Education Act of 1965, as amended, Pub. L. 89–329, Section 1201(l).

"Special education programs" means specially designed remedial, tutorial, and motivational programs designed to promote success in the postsecondary experience.

"Student" means a person in attendance as at least a half-time student at an institution of higher education. The term is further defined as follows:

(1) "Full-time student" means a student who is enrolled for the equivalent of not less than 12 semester hours and is being charged on the basis of the institution's full-time fee schedule.

(2) "Three-quarter-time student" means an enrolled student who is carrying a three-quarter-time academic work load as detetermined by the institution and which amounts to at least three-quarters of the course-load of a full-time student.

(3) "Half-time student" means an enrolled student who is carrying a half-time academic work load as determined by the institution and which amounts to at least one-half the course-load of a full-time student.

"Undergraduate student" means a student enrolled in an undergraduate course of study at an institution of higher education who (1) has not been awarded a baccalaureate or first professional degree, (2) is pursuing a program of studies at a two-year institution leading to a certificate, degree, or diploma, or (3) is receiving or has received educational assistance under subchapter V or subchapter VI of chapter 34 of title 38, United States Code.

"Veteran" means a person receiving benefits under chapter 31 or chapter 34 of title 38, United States Code, or who, if enrolled in an institution of higher education, would be eligible for such benefits.

(20 U.S.C. 1070e–1, 1088, 1141)

Subpart B—What Kinds of Activities Does the Department Assist Under This Program?

§ 629.11 Required activities.

(a) A grantee must maintain a full-time office of veterans' affairs which has responsibility for veterans' outreach, recruitment, and special education programs, and which provides educational, vocational, and personal counseling for veterans.

(b) A grantee must also make an adequate effort to—

(1) Provide programs designed to prepare educationally disadvantaged veterans for study at an institution of higher education (i) under subchapter V of chapter 34 of title 38, United States Code; and (ii) in the case of any institution located near a military installation, under subchapter VI of chapter 34 of title 38;

(2) Provide active outreach services with special emphasis on service-connected disabled veterans, handicapped veterans, incarcerated veterans, and educationally disadvantaged veterans, recruiting, and counseling activities through the use of funds available under federally assisted work/study programs (with special emphasis on the veterans-student services program under section 1685 of title 38, United States Code);

(3) Provide an active tutorial assistance program, including dissemination of information regarding such programs, in order to make maximum use of the benefits available under section 1692 of title 38, United States Code; and

(4) Coordinate activities provided under this part with the readjustment counseling program authorized under section 620 of title 38, United States Code, and with the veterans' employment and training initiatives authorized under the Comprehensive Employment and Training Act, and under chapters 41 and 42 of title 38, United States Code, in order to assist in serving the readjustment, rehabilitation, personal counseling and employment needs of veterans.

(c) A grantee with less than 2500 undergraduate students in attendance on April 16 of the academic year in which the institution applies (or, when this date falls between academic terms of the institution, the end of the previous academic term) need only maintain a full-time office of veterans' affairs which provides recruitment and counseling services.

(d) If a grantee cannot reasonably be expected to carry out all of the required functions by itself, the Secretary may permit one or more of the required

functions to be carried out under a consortium agreement between the institution and one or more such institutions located within a reasonable commuting distance.

(e) All services must be readily accessible to all veterans served by the project.

(20 U.S.C. 1070e–1)

Subpart C—How Does One Apply for a Grant?

§629.21 Application requirements.

(a) Each application must contain the following information:

(a) Data showing that the institution is eligible for assistance.

(b) Information that shows the amount of the payment to the applicant would be entitled.

(c) An assurance that the institution will expend during the award period for all academically-related programs of the institution, in terms of either total or per student expenditure, at least the average amount expended during the preceding three academic years.

(20 U.S.C. 1070e–1)

Subpart D—How Does the Secretary Make A Grant?

§ 629.31 Calculation of cost-of-instruction payments.

(a) The Secretary determines a grantee's cost-of-instruction payment based on the following institutional data:

(1) the number of qualified undergraduate veteran students who are receiving vocational rehabilitation subsistence under chapter 31 of title 38, United States Code, or educational assistance under chapter 34 of title 38, United States Code, and to whom services required under the terms of a grant will be reasonably accessible.

For students meeting this requirement, a grantee will receive the following payments:

(i) $300 per full-time student.

(ii) $225 per three-quarter-time student.

(iii) $150 per half-time student.

(2) The number of qualified undergraduate veteran students who have ever received educational assistance under subchapter V or subchapter VI of chapter 34 of title 38 or who have a service-connected disability as defined in Section 101(16) of title 38, United States Code, and to whom the services required under the terms of a grant will be reasonably accessible. For students meeting this requirement, a grantee will receive the following payments:

(i) $150 per full-time student.

(ii) $112.50 per three-quarter-time student.

(iii) $75 per half-time student.

(b) No payments will be made to grantees for students who are not full-time, three-quarter-time, or half-time students.

(c) The maximum payment in any fiscal year to any institution of higher education, or any branch thereof located in a different community is $75,000.

(d) Funds which become available as a result of the limitation on payments described in paragraph (b) of this section shall be apportioned so that all, instituions to which VCIP payments are to be made will receive a minimum of $9,000, and then in excess of $9,000, to the extent that funds remain available. No grantee shall receive funds in excess of the amounts calculated according to paragraph (a) of this section.

(e) Funds appropriated will be apportioned so that each grantee will receive one payment based on the grantee's enrollment data.

(f) Funds obligated to an individual institution which are later deobligated shall be reallocated proportionately to grantee institutions at a later date.

(20 U.S.C. 1070e–1)

Subpart E—What Conditions Must Be Met by a Grantee?

§ 629.41 Expenditure requirements.

(a) At least (1) 90 percent of the funds awarded to an institution or (2) the amount of funds needed to implement the required services, whichever is greater, shall be used by the institution to implement these services. Any remaining awarded funds must be used solely to defray instructional expenses in academically related programs.

(b) The grantee must engage in all activities listed in § 629.11, except as provided in § 629.11(c) and (d).

(c) VCIP funds may be used to pay for travel expenditures only if such expenditures are incurred by the grantee in connection with recruitment and outreach activities, attendance at Department-sponsored meetings providing technical assistance, and attendance at Department approved professional meetings.

(d) A proposed budget for the operation of the Office of Veterans' Affairs must be submitted to the Department within 90 days of receipt of the Notice of Award specifying the institution's share of funds in any fiscal year.

(20 U.S.C. 1070e–1)

[FR Doc. 80-40427 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

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34 CFR Part 651

Training in the Legal Profession

AGENCY: Department of Educations.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Secretary of Education issues proposed regulations for the Legal Profession Training Program. The proposed regulations authorize awards to assist individuals from disadvantaged backgrounds to undertake training for the legal profession. The proposed regulations cover eligible activities and costs under the program.

DATES: Interested persons are invited to submit comments, suggestions, or objections regarding the proposed regulations on or before March 2, 1981.

ADDRESSES: Written comments should be addressed to Donald Bigelow, Chief, Graduate Training Branch, U.S. Department of Education, 400 Maryland Avenue, S.W., (Room 3060, ROB–3), Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Donald M. Bigelow, Telephone: (202) 245–2347.

SUPPLEMENTARY INFORMATION: The Legal Profession Training Program is designed to help admit to accredited law schools disadvantaged students who, but for the program, would not have been admitted and to assist these students in obtaining a legal education and law degree. The program funds preliminary training to prepare students for law school, counseling and related services, and stipends to help support the students during both their preliminary and law school training.

Since its inception, the program has been carried out through a non-competitive award to the Council on Legal Educational Opportunity (CLEO), a non-profit private agency. With substantial funding from other sources, CLEO started the program before it was authorized in the Higher Education Act. The program has been popularly known as the "CLEO Program."

The proposed regulations authorize the Secretary to continue to carry out the program through an award to CLEO, consistent with the legislative history of the statute. (H.R. Rep. No. 96–520, 96th Cong. 1st Sess. 55 (1979); S. Rep. No. 96–733, 96th Cong. 2d Sess. 72 (1980)). As called for by the statute, the proposed regulations also supply criteria for identifying eligible individuals from disadvantaged backgrounds and provisions on eligibile activities.

Invitation to Comment:

Interested persons are invited to submit comments and recommendations regarding the proposed regulations. Written comments and recommendations may be sent to the address given at the beginning of this preamble. All comments received on or before (the 60th day after publication of this document) will be considered in the development of the final regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 3060 ROB–3, 7th Street, S.W., Washington, D.C. between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Assessment of Educational Impact:

The Department particularly requests comments on whether the proposed regulations in this document would require transmission of information that is already being gathered by or is available from any other agency or authority of the United States.

Citation of Legal Authority:

A citation of statutory or other legal authority is placed in parentheses on the line following each substantive provision of these regulations.

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

The Secretary of Education proposes to amend Title 34 by adding a new Part 651 to read as follows:

PART 651—TRAINING IN THE LEGAL PROFESSION

Subpart A—General

Sec.

Subpart B—What Kinds of Activites Does the Secretary Support Under This Program?

Subpart C—[Reserved]

Subpart D—How Is an Award Made?

Subpart E—What Conditions Must Be Met by an Award Recipient?

Authority: Part D of Title IX of the Higher Education Act of 1965, as amended by Sec. 904 of Pub. L. 96–374, 94 Stat. 1486–87 (20 U.S.C. 1134l).

Subpart A—General

§ 651.1 Training in the Legal Profession.

(a) The Legal Profession Training Program assists individuals from disadvantaged backgrounds to undertake training for the legal profession.

(b) The program is designed to help admit to accredited law schools disadvantaged students who, but for the program, would not have been admitted, and to assist these students in obtaining a legal education and law degree.

(20 U.S.C. 1134l)

§ 651.2 Eligible parties.

(a) Public and private agencies and organizations other than institutions of higher education may receive grants or contracts under these regulations.

(b) The Secretary may implement this program through the award of a single grant or contract.

(c) Unless the Secretary implements the program through one or more procurement contracts or through a single noncompetitive grant, applications will be invited annually through an application notice published in the **Federal Register.**

(20 U.S.C. 1134l(a))

§ 651.3 Regulations that apply to this program.

(a) *Regulations for procurement contracts.* The following regulations apply to any procurement contract under the Legal Profession Training Program:

(1) Federal and U.S. Department of Education procurement regulations in 41 CFR Chapters 1 and 34; and

(2) The regulations in this Part 651.

(b) *Regulations for grants.* The following regulations apply to any grants under the Legal Profession Training Program:

(1) The Education Division General Administrative Regulations (EDGAR) in Part 75 (Direct Grant Program) and Part 77 (General).

(2) The regulations in this Part 651.

(20 U.S.C. 1221e–3)

§ 651.4 Definitions.

As used in these regulations—

(a) "Act" means the Higher Education Act of 1965, as amended.

(20 U.S.C. 1221e–3)

(b) "Disadvantaged Backgrounds" are backgrounds that hinder individuals from gaining admission to law school and completing a course of legal study, including:

(1) Family income dependent in whole or in part on public assistance or inadequate to provide for needs beyond basic necessities such as food, housing and clothing;

(2) Rural isolation;

(3) Limited English proficiency as defined in section 703(a)(1) of the Bilingual Education Act (20 U.S.C. 880b–1(a)(1)); or

(4) Attendance at a minority group isolated school, as defined for purposes of the Emergency School Aid Act in § 185.02(g) of this chapter; or

(5) Other cultural or educational deprivations resulting from an environment that failed to develop skills and understandings that would enable an individual to gain admission to law school and complete a legal course of study.

(20 U.S.C. 1221e–3)

Subpart B—What Kinds of Activities Does the Secretary Support Under this Program?

§ 651.10 What kinds of support does the program provide?

The program provides financial support for activities that assist individuals from disadvantaged backgrounds in obtaining a legal education.

(20 U.S.C. 1134l(a))

§ 651.11 What activities are eligible for support?

The following activities are eligible for support under a grant or contract awarded under these regulations:

(a) Selecting individuals from disadvantaged backgrounds for training for the legal profession, including disseminating information about the program to eligible students;

(b) Making arrangements with accredited law schools to arrange entry of participating students into these schools;

(c) Providing counseling and related services—both prior to and during law school training—designed to assist participating students in preparing for and completing law school training;

(d) Providing preliminary legal education training for participating students to prepare them for law school.

(1) Preliminary training may include, but need not be limited to, orientation of students to the legal process, the epistemology of law, and law school learning methods; evaluation of the law school potential of students; and development of students' legal reading, research, and writing skills.

(2) Preliminary training may be provided for participating students not more than six months prior to their commencement of law school courses; and

(e) Stipends to participating students for any period of preliminary training and for the period of law school training, as provided in § 651.30.

(20 U.S.C. 1134l(b))

Subpart C—[Reserved]

Subpart D—How Is an Award Made?

§ 651.20 How does the Secretary select an award recipient?

(a) The Secretary decides to make one or more awards and selects the award recipient(s) based on a judgment of what arrangements most effectively contribute to the purposes of Title IX–D of the Act.

(b) The Secretary may decide to make a non-competitive award to implement the program if—in the Secretary's judgment—there is one eligible organization that is exclusively or predominantly qualified to carry out effectively the purposes of Title IX–D of the Act in the light of its legislative history. If a noncompetitive contract award is made, the decision will be made in accordance with 41 CFR Chapter 34.

(20 U.S.C. 1221e–3; 1134l)

Subpart E—What Conditions Must Be Met By an Award Recipient?

§ 651.30 What are the limitations on allowable costs?

(a) Allowable costs under an award are direct and indirect costs incurred by the award recipient in carrying out the approved project.

(b) Allowable costs include, but are not limited to:

(1) Administrative costs of the award recipient in carrying out the eligible activities described in § 651.11.

(2)(i) Stipends for participating students, including allowances for travel and for dependents of participating students—during any period of preliminary training—or for the period of law school training during which the student maintains satisfactory academic progress, as determined by the Secretary.

(ii) The Secretary annually may set limits on the amount of stipends.

(20 U.S.C. 1134l(b))

[FR Doc. 80–40428 Filed 12–29–80; 8:45 am]

BILLING CODE 4000–01–M

34 CFR Part 690

Pell Grant Program

AGENCY: Department of Education.

ACTION: Notice of Proposed Rulemaking: Cross-reference.

SUMMARY: The Secretary proposes regulations for the Pell Grant Program in Title 34 of the Code of Federal Regulations.

The text of the regulations on which the Secretary invites comments are published in the Rules and Regulations section of this issue of the **Federal Register**. They have been adopted as final regulations and will govern this program until the Secretary issues new regulations based on public comment.

DATES: All comments, suggestions, or objections must be received on or before March 2, 1981.

ADDRESSES: Comments should be addressed to: William L. Moran, Chief of the Policy Section, Basic Grant Branch, and Division of Policy and Program Development, U.S. Department of Education, 400 Maryland Avenue SW. (Room 4318, ROB–3), Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Mr. William L. Moran, Telephone: (202) 472–4300.

INVITATION TO COMMENT: For additional details on how to comment, see the Preamble of the final regulations for these programs published in this issue of the **Federal Register.**

(Catalog of Federal Domestic Assistance Numbers 84.063, Pell Grant Program)

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

[FR Doc. 80–40429 Filed 12–29–80; 8:45 am]

BILLING CODE 4000–01–M

34 CFR Part 206

Special Educational Programs for Students Whose Families Are Engaged in Migrant and Other Seasonal Farmwork—High School Equivalency Program and College Assistance Migrant Program

AGENCY: Department of Education.

ACTION: Proposed regulations.

SUMMARY: The Secretary proposes regulations to govern grants under the High School Equivalency Program (HEP) and the College Assistance Migrant Program (CAMP). These programs provide grants to institutions of higher education for projects of educational and supporting services designed to assist students—whose families are engaged in migrant and other seasonal farmwork—in obtaining the equivalent of a secondary school diploma and in successfully adjusting to postsecondary school. These programs implement Title IV, Section 418A, of the Higher Education Act (HEA), as amended by the Education Amendements of 1980.

DATES: Comments must be received on or before March 2, 1981.

ADDRESSES: Comments should be addressed to Mr. Vidal A. Rivera, Jr., Deputy Assistant Secretary for Migrant Education, Office of Migrant Education, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue SW. (ROB–3, Room 3608), Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Mr. Vidal A. Rivera, Jr. Telephone No. (202) 245–2222.

SUPPLEMENTARY INFORMATION:

Background

The High School Equivalency Program (HEP) and the College Assistance Migrant Program (CAMP) were previously authorized under Title III, section 303(c)(2), of the Comprehensive Employment and Training Act (CETA) (Pub. L. 93–203), and were administered by the Department of Labor. However, the Department of Education Reorganization Act (Pub. L. 96–88) transferred the authority for the administration of HEP and CAMP to the Department of Education (ED).

On October 3, 1980, the Education Amendments of 1980 (Pub. L. 96–374) became law. These amendments provide a new Title IV of the Higher Education Act (Pub. L. 89–329), entitled "Student Assistance." Title IV, HEA, now includes a new Part A, Subpart 5, entitled "Student Assistance." Title IV, HEA, now includes a new Part A, Subpart 5, entitled "Special Programs For Students Whose Families Are Engaged In Migrant and Seasonal Farmwork," which authorizes the HEP and CAMP programs.

In summary, these proposed regulations—

(a) Describe the types of projects that may be funded under HEP and CAMP;

(b) Describe the types of services that may be provided by a project;

(c) Describe the evaluation process for grant proposals and the selection criteria that the Secretary uses in that evaluation process;

(d) Describe conditions and requirements that must be met by a grantee; and

(e) Define the eligibility requirements for students to participate in a project.

How To Review These Proposed Regulations

These proposed regulations (34 CFR Part 206) contain only those requirements that are proposed to apply solely to HEP and CAMP. These proposed regulations do not contain certain types of general requirements that are covered in the Education Division General Administrative Regulations, which are found in 34 CFR Parts 75–77. EDGAR contains requirements that apply to all ED programs, including by incorporation the Grants Administration regulations, 34 CFR Part 74, that apply to all ED programs.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations. Written comments and recommendations may be sent to the address given at the beginning of this preamble. All comments that are received on or before March 2, 1981, will be considered in developing the final regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Regional Office Building 3, Room 3608, 7th and D Streets, S.W., Washington, D.C., between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Information Requirements

The Department particularly requests comments on whether the program requirements in this document would require transmission of information that is already being gathered by or is available from any other agency or Department of the United States.

Citation of Legal Authority

A citation of statutory or other legal authority is placed in parentheses on the line following each substantive provision of these proposed regulations. References to "sec." in these citations refer to sections of the Higher Education Act of 1965, as amended by the Education Amendments of 1980.

(Catalog of Federal Domestic Assistance No. 84.144; Migrant Education Program—High School Equivalency Program and College Assistance Migrant Program)

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

The Secretary proposes to amend Title 34 of the Code of Federal Regulations by adding Part 206 to read as follows:

PART 206—SPECIAL EDUCATIONAL PROGRAMS FOR STUDENTS WHOSE FAMILIES ARE ENGAGED IN MIGRANT AND OTHER SEASONAL FARMWORK—HIGH SCHOOL EQUIVALENCY PROGRAM AND COLLEGE ASSISTANCE MIGRANT PROGRAM

Subpart A—General

Sec.

Subpart B—What Kinds of Activities Does the Secretary Assist Under these Programs?

Subpart C—How Does One Apply for a Grant?

Subpart D—How Is a Grant Made to an Applicant?

Subpart E—What Conditions Must be Met by a Grantee?

Authority: Subpart 5, Part A, of Title IV of the Higher Education Act of 1965 (Pub. L. 89–329), as amended by the Education Amendments of 1980 (Pub. L. 96–374)(20 U.S.C. 1070d–2).

Subpart A—General

§ 206.1 What are the special educational programs for students whose families are engaged in migrant and other seasonal farmwork?

(a) The High School Equivalency Program (HEP) is designed to assist students—whose families are engaged in migrant and other seasonal farmwork—to obtain the equivalent of a secondary school diploma and to subsequently gain employment or be placed in an insitution of higher education (IHE).

(b) The College Assistance Migrant Program (CAMP) is designed to assist students—whose families are engaged in migrant and other seasonal farmwork—who are enrolled on a full-time basis in the first academic year at an IHE.

(Sec. 418A(a); 20 U.S.C. 107d–2)

§ 206.2 Who is eligible to particpate as a grantee?

An institution of higher education may apply for a grant to operate a HEP or a CAMP project.

(Sec. 418A(a); 20 U.S.C. 1070d–2

§ 206.3 What regulations apply to these programs?

The following regulations apply to HEP and CAMP:

(a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 75 (Direct Grant Programs) and 34 CFR Part 77 (General).

(b) The regulations in this Part 206.

(Sec. 418A(a); 20 U.S.C. 1070d–2)

§ 206.4 What defintions apply to these programs?

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR Part 77 (EDGAR, General):

Applicant
Application
Department
Elementary school
Facilities
Project
Secondary school
Secretary
State

(b) *Definitions in the Grants Administration Regulations.*

The following terms used in this part are defined in 34 CFR Part 74 (Administration of Grants):

Budget
Equipment
Grant
Grantee
Supplies

(c) *Program definitions.* The following additional definitions apply specifically to the HEP and CAMP programs:

(1) "Act" means the Higher Education Act of 1965, as amended by the Education Amendments of 1980.

(2) "Agricultural activity" means—

(i) Any activity directly related to the production of crops, dairy products, poultry, or livestock;

(ii) Any activity directly related to the cultivation or harvesting of trees; or

(iii) Any activity directly related to fish farms.

(3) "Farmwork" means any agricultural activity, performed for

either wages or personal subsistence, on a farm, ranch, or similar establishment.

(4) "Full-time," with respect to an individual, means a student who is carrying a full-time academic workload, as defined in 34 CFR Part 690 (Basic Educational Opportunity Grant Program Regulations).

(5) "Institution of higher education" means an educational institution that—

(i) Is in a State;

(ii) Is authorized by that State to provide a program of education beyond secondary school;

(iii) Is a public or nonprofit institution;

(iv) Admits as a regular student only a person who—

(A) Has a secondary school diploma;

(B) Has the recognized equivalent of a secondary school diploma; or

(C) Is beyond the age of compulsory school attendance in that State and has the ability to benefit from the training offered by the institution;

(v) Provides—

(A) An educational program for which it awards a bachelor's degree; or

(B) At least a two-year program that is acceptable for full credit toward a bachlor's degree;

(vi)(A) Is accredited by a nationally recognized accrediting agency or association;

(B) Has satisfactorily assured the Secretary that it will meet the accreditation standards of a nationally recognized accrediting agency or within a reasonable time considering the resources available to the institution, the period of time, if any, it has operated, and its effort to meet accreditation standards; or

(C) Has its credits accepted on transfer by at least three accredited institutions on the same basis as those institutions accept transfer credits from fully accredited institutions.

(6) "Migrant farmworker" means a seasonal farmworker—as defined in paragraph (c)(7) of this section—whose employment required travel such that the farmworker was unable to return to his or her domicile (permanent place of residence) within the same day.

(7) "Seasonal farmworker" means a person who, within the past 24 months, was employed for at least 100 days in farmwork, and whose primary employment was in farmwork on a temporary or seasonal basis (that is, not a constant year-round activity).

(Sec. 418A(a); 20 U.S.C. 1070d–2)

Subpart B—What Kinds of Activities Does the Secretary Assist Under these Programs?

§ 206.10 What types of services may be provided?

(a) *General.* A grantee may use funds to support approved projects designed to provide educational and supporting services to students whose families are engaged in migrant and other seasonal farmwork.

(b) *Types of services.* (1) *HEP projects.* A HEP project may provide the following types of services to assist participants in obtaining the equivalent of a secondary school diploma and as needed to ensure the success of the participants in meeting the project's objectives and in succeeding at the secondary school level and beyond:

(i) Recruitment services for enrolling project participants.

(ii) Institutional services in academic subject areas such as reading, writing, oral language skills, and mathematics, and in related areas such as study skills.

(iii) Special academic, career, and personal guidance, counseling, and testing services.

(iv) Housing support or on-campus residential programs during the operation of the project.

(v) Services designed to acquaint participants with the range of career options available to them—including appropriate career-oriented work study activities.

(vi) Services designed to expose participants to academic institutions and programs, cultural events, and other activities not usually available to the participants and supportive of their intellectual, cultural, social, and personal development.

(vii) Appropriate in-service training activities for project staff members.

(viii) Other essential supporting services that have been approved by the Secretary as needed to ensure the success of the participants in meeting the project's objectives and in succeeding at the secondary school level and beyond.

(2) *CAMP projects.* A CAMP project may provide the following types of services to assist the participants in meeting the project's objectives and in succeeding in postsecondary school:

(i) The services described in items (i) and (iii) through (vii), inclusive, of paragraph (b)(1) of this section.

(ii) Tutoring and supplementary instructional services in the following areas:

(A) Basic skills.

(B) Subject areas in which the participants are enrolled.

(C) Related areas such as study skills.

(iii) Other essential supporting services that have been approved by the Secretary as needed to ensure the success of the participants in meeting the project's objectives and in completing postsecondary school.

(Sec. 418A(a); 20 U.S.C. 1070d–2)

Subpart C—How Does One Apply for a Grant?

§ 206.20 What must be included in an application?

In applying for a grant, an applicant shall—

(a) Follow the procedures and meet the requirements stated in Subpart C of 45 CFR Part 75 (EDGAR-Direct Grant Programs); and

(b) Provide the following assurances:

(1) The grantee will develop and implement a plan for identifying, informing, and recruiting eligible participants who need the assistance provided by the project.

(2) The grantee will develop and implement a plan for identifying and using the resources of the IHE and the community to supplement and enhance the services provided by the project.

(Sec. 418A(a); 20 U.S.C. 1070d–2)

Subpart D—How Is a Grant Made to an Applicant?

§ 206.30 How does the Secretary evaluate an application?

(a) The Secretary evaluates an application under HEP or CAMP on the basis of the selection criteria listed in § 206.31 of these regulations.

(b) The Secretary awards up to 100 possible points for meeting these criteria.

(c) The maximum number of points possible for meeting each individual criterion is indicated in parentheses after the heading for that criterion.

(Sec. 418A(a); 20 U.S.C. 1221e–3(a)(1))

§ 206.31 What selection criteria does the Secretary use to evaluate an application?

(a) *Plan of operation.* (40 points)

(1) The Secretary reviews each application for information that shows the quality of the plan of operation for the project.

(2) The Secretary looks for information that shows the following:

(i) High quality in the design of the project.

(ii) An effective plan of management that assures proper and efficient administration of the project.

(iii) A clear description of how the objectives of the project relate to the purpose of the program.

(iv) A clear description of the way that the applicant plans to use its

resources and personnel to achieve each objective of the project.

(v) A clear description of how the applicant will provide equal access and treatment for eligible participants who are members of groups that have been traditionally underrepresented, such as—

(A) Members of racial or ethnic minority groups;

(B) Women;

(C) Handicapped persons; and

(D) The elderly.

(b) *Quality of key personnel.* (15 points)

(1) The Secretary reviews each application for information that shows adequate qualifications for the key personnel the applicant plans to use in the project.

(2) The Secretary looks for information that shows the following:

(i) The qualifications of the project director (if one is to be used).

(ii) The qualifications of each of the other key personnel to be used in the project.

(iii) The time that each person referred to in paragraphs (b)(2)(i) and (ii) of this section plans to commit to the project.

(iv) The extent to which the applicant, as part of its nondiscriminatory employment practices, encourages applications for employment from persons who are members of groups that have been traditionally underrepresented, such as—

(A) Members of racial or ethnic minority groups;

(B) Women;

(C) Handicapped persons; and

(D) The elderly.

(3) To determine personnel qualifications, the Secretary considers experience and training—in fields related to the objectives of the project—as well as other information that the applicant provides.

(c) *Budget and cost-effectiveness.* (10 points)

(1) The Secretary reviews each application for information that shows that the project has an adequate budget and is cost effective.

(2) The Secretary looks for information that shows the following:

(i) The budget for the project is adequate to support the project activities.

(ii) Costs are reasonable in relation to the objectives of the project.

(d) *Evaluation plan.* (20 points)

(1) The Secretary reviews each application for information that shows the quality of the evaluation plan for the project.

(2) The Secretary looks for information that shows methods of evaluation that are appropriate for the project and, to the extent possible, are objective and produce data that are quantifiable.

(e) *Adequacy of resources.* (5 points)

(1) The Secretary reviews each application for information that shows that the applicant plans to devote adequate resources to the project.

(2) The Secretary looks for information that shows the following:

(i) The facilities that the applicant plans to use are adequate.

(ii) The equipment and supplies that the applicant plans to use are adequate.

(f) *Recruitment.* (10 points)

(1) The Secretary reviews each application for information that shows the quality of the recruitment plan for the project.

(2) The Secretary looks for information that shows that the applicant has adequate plans for identifying, informing, and recruiting eligible participants who are most in need of the assistance provided by the project.

(20 U.S.C. 1221e-3(a)(1))

Subpart E—What Conditions Must Be Met by a Grantee?

§ 206.40 What is the special population to be served?

(a) *General.* To be eligible to participate in a HEP or CAMP project, an individual must be a migrant or other seasonally-employed farmworker (or a dependent of a migrant or other seasonally-employed farmworker), as defined in § 206.4(c) of these regulations.

(b) *Special HEP qualifications.* To be eligible to participate in a HEP project, a migrant or other seasonally-employed farmworker (or dependent) must—

(1) Not have earned a secondary school diploma or its equivalent;

(2) Not be currently enrolled in an elementary or secondary school;

(3) Be above the age of compulsory school attendance in the State where the project is located; and

(4) Be determined by the grantee to need the financial and academic services provided by the project in order to attain the equivalent of a secondary school diploma.

(c) *Special CAMP qualifications.* To be eligible to participate in CAMP, a migrant or other seasonally-employed farmworker (or dependent) must—

(1) Be enrolled as a full-time student at the IHE that is serving as the grantee;

(2) Not be beyond the first academic year of a program of study at the participating IHE, as determined under the standards of the IHE; and

(3) Be determined by the grantee to need the financial and academic services provided by the project in order to complete an academic program of study at the IHE.

(Sec. 418A(a); 20 U.S.C. 1070d-2)

§ 206.41 What is the requirement for maintaining participant records?

(a) *General.* A grantee shall develop and implement a system that provides accurate and accessible records on participants.

(b) *Contents.* To document the progress of each participant, each record must include at least the following:

(1) Information used to determine the participant's eligibility, as stated in § 206.4(c) of these regulations.

(2) The criteria used to identify the participant as needing the financial and academic services provided by the project.

(3) A statement of the participant's academic needs at the time of entering into the project.

(4) A description of the individual program designed to assist the participant in meeting the project's objectives.

(5) A brief summary of the actual services the participant received including both educational and education-support services.

(Sec. 418A(a); 20 U.S.C. 1070d-2)

§ 206.44 What restrictions are there on expenditures?

Funds provided under HEP or CAMP may not be used for construction of facilities or remodeling.

(Sec. 418A(a); 20 U.S.C. 1070d-2)

[FR Doc. 80-40430 Filed 12-29-80; 8:45 am]

BILLING CODE 4000-01-M

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34 CFR Part 703

Experimental Program for Opportunities in Advanced Study and Research in Education

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the regulations that apply to grants administered under the National Institute of Education's Experimental Program for Opportunities in Advanced Study and Research in Education. This amendment does not change the program objectives. The changes include revised language and format necessary to make the regulations conform with administrative directives to improve the quality of all regulations. These regulations, previously designated as Part 1430 of Title 45 CFR Chapter XIV, are now included under Title 34 CFR Chapter VII, and as revised are redesignated as Part 703.

DATES: Public comments must be received on or before January 29, 1981.

ADDRESSES: Comments should be addressed to Mr. Frank Z. Alejandro, U.S. Department of Education, National Institute of Education, Room 609, 1200 19th Street, N.W., Washington, D.C. 20208.

FOR FURTHER INFORMATION CONTACT: Mr. Frank Z. Alejandro, Telephone number (202) 254–8827.

SUPPLEMENTARY INFORMATION:

A. Background of the Program

In 1978, the National Institute of Education (NIE) established an experimental program to improve opportunities for minorities and women emphasizing such opportunities for advanced study and research on problems in educational research and development. Grants for institutional projects as well as for special projects were awarded in order to enable the Federal government to utilize the existing capabilities of institutions and organizations that have a record of success in recruiting and training minorities and women in educational research, and in advancing the careers of those traditionally underrepresented persons.

B. Changes in the Regulations

(1) The Education Department General Administrative Regulations (EDGAR) were published on April 3, 1980 (45 FR 22494) and, at the same time, amendments to these program regulations were published in the **Federal Register** (45 FR 22544) to make them conform with EDGAR in all respects other than the selection criteria. Those selection criteria did not change.

(2) Inasmuch as EDGAR applies to this program, the amended program regulations do not repeat certain types of requirements that are covered in EDGAR. These include

- Subpart C,
  How to apply for a grant;
- Subpart, D,
  How grants are made;
- Subpart D,
  How grants are made;
- Subpart E,
  What conditions must be met by a grantee;
- Subpart F,
  What are the administrative responsibilities of a grantee;
- Subpart C,
  What procedures does the Secretary use to assure compliance.

(3) the following changes are made in order to make these program regulations comply with current policies and practices of the Department of Education:

(i) § 703.1 makes for-profit organizaions eligible for grants;

(ii) § 703.4 limits the effective period for these regulations;

(iii) § 703.14 specifies activities which are ineligible for support under this program;

(iv) § 703.31(d) provides for a balanced distribution of awards based upon geographic considerations;

(v) § 703.32 (f) and (g) are restatements of the criteria which previously appear in these regulations.

(vi) § 703.32(e) adds a criterion which is required by EDGAR;

(vii) § 703.32 (a) through (g) assign new weight values to each selection criterion;

(viii) § 703.43 places certain financial restrictions on a profit-type grantee.

Effective Period of These Regulations

These regulations apply only to awards made prior to December 31, 1981.

Classification and Regulatory Analysis

The Department of Education has determined that these regulations will not impose an unnecessary burden on the economy or on individuals and, therefore, are not significant for the purpose of Executive Order 12044 (Improving Government Regulations). Further, a regulatory analysis is not required for this particular rulemaking process.

Application Information

An application notice, containing the closing date for receipt of applications under this program, is being published in the **Federal Register** concurrently with the publication of this Notice of Proposed Rulemaking. To obtain the program announcement, which supplements the information of the application notice, please contact Mr. Frank Z. Alejandro, at telephone number (202) 254–8827.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding these proposed amendments. Written comments and recommendations may be sent to the address given in this preamble. All comments received by the date that public comments are due will be considered in the development of the final regulations. All comments submitted will be available for public inspection during and after the comment period in Room 609, 1200 19th Street, N.W., Washington, D.C., between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

Citation of Legal Authority

A citation of statutory or other legal authority appears in parentheses in each section of these regulations.

(Catalog of Federal Domestic Assistance Number 84.117, Education Research and Development, formerly 13.950)

December 23, 1980.

Shirley M. Hufstedler,

Secretary of Education.

Title 34 of the Code of Federal Regulations adds a new Part 703 to read as follows:

PART 703—EXPERIMENTAL PROGRAM FOR OPPORTUNITIES IN ADVANCED STUDY AND RESEARCH IN EDUCATION

Subpart A—General

Sec.

Subpart B—What Types of Projects are Assisted Under this Program?

Subpart C—How Does One Apply for a Grant?

Subpart D—How Does the Secretary Make a Grant?

Subpart E—What Conditions Must be Met by a Grantee?

Authority.—Section 405 of the General Education Provisions Act, Sec. 301(a)(2) of Pub. L. 92–318, 86 Stat. 328, 332, as amended (20 U.S.C. 1221e).

Subpart A—General

§ 703.1 Purpose of the experimental program for opportunities in advanced study and research in education.

This Program supports experimental activities that demonstrate effective

ways of increasing the participation of minorities and women in the field of education and educational research. These activities are expected to be used to—

(a) Enhance equality of opportunity within the educational research workforce;

(b) Increase the relevance and credibility of educational research through greater inclusion of contributions and perspectives of minorities and women; and

(c) Improve the overall quality of educational research by drawing upon those talented minorities and women who currently are engaged in research other than educational research or are non-research professionals who are capable of making a significant contribution to educational research.

(20 U.S.C. 1221e(b)(2))

§ 703.2 Eligible parties.

A college, university, State or local educational agency, other public or private non-profit or for-profit agency or organization, or any combination of these, is eligible to receive a grant.
(20 U.S.C. 1221e(e)(1))

§ 703.3 Regulations that apply to this program.

The following regulations apply to this program:

(a) In addition to the regulations in this part, the Education Department General Administrative Regulations (EDGAR) in 34 CFR Part 75 (Direct Grant Programs) and 34 CFR Part 77 (General) apply, except sections 75.130 through 75.134 which concern preapplications.

(b) Administration of Grants in 34 CFR Part 74, as republished in the Federal Register on May 9, 1980. (45 FR 30856).

§ 703.4 Effective period of these regulations.

These regulations apply only to awards made prior to December 31, 1981.

(20 U.S.C. 3474)

§ 703.5 Definitions that apply to this program.

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR Part 77:

Applicant
Application
Award
Local Educational Agency
Non-profit
Public
Project
Secretary
State Educational Agency.

(b) *Specific program definitions:* Other definitions used in this part are:

"Educational research" means research (basic and applied), planning, surveys, evaluation, investigations, experiments, developments, or demonstrations in the field of education.

"Minorities" means individuals who compose the following groups: Black, Hispanic, American, Indian, Asian, Pacific Islander, or Alaskan Native.

"Experienced professional" means a person with a year or more of graduate level education that is relevant to educational research and at least one more year of related professional work experience.

(20 U.S.C. 3474)

Subpart B—What Types of Projects are Assisted Under This Program?

§ 703.11 Types of projects and general requirements.

The Secretary awards grants for two types of projects: Institutional Projects and Special projects. Each project must satisfy one or more of the following general requirements:

(a) Develop and demonstrate effective ways to overcome barriers to the employment and advancement of minorities and women in educational research;

(b) Provide advanced study opportunities needed especially by minorities and women who are preparing for employment in educational research or who are seeking ways to improve utilization of their educational research capabilities. Such advanced study is to occur only in conjunction with research under the grant;

(c) Furnish information about such advanced study opportunities provided by others;

(d) Make arrangements for obtaining advice from experts on the application of concepts and methods from relevant fields and disciplines to research or other project activities;

(e) Engage persons to serve as mentors and role models. One function of such persons is to advise minorities and women about means for gaining access to essential communication channels in educational research;

(f) Assist well-qualified minorities and women to participate at an advanced level in educational research and related work;

(g) Ensure the participation of minorities and women in planning for and advising on the conduct of the project; or

(h) Coordinate the planning and conduct of the project with organizations, associations, or institutions which represent minorities or women.

§ 703.12 Additional requirements for Institutional Projects.

Each Institutional Project must meet the following additional requirements:

(a) Support opportunities for individuals engaged in post-doctoral studies or for experienced professionals to conceive and conduct educational research that reflects concerns and perspectives of minorities and women. (Full-time predoctoral graduate work is not a priority, and support is not provided for this activity without the prior approval of the Secretary.)

(b) Develop and implement a set of policies and procedures for increasing the involvement and professional growth and the opportunities for advancement, of minorities and women within one or more units of the grantee organization.

(c) These projects are funded for an initial period of 12 months and if an application is for a multi-year project, the project may be continued for additional periods provided the project does not exceed 36 months.

§ 703.13 Additional requirements for special projects.

Each Special Project must meet one or more of the following additional requirements:

(a) Provide short-term advanced study opportunities, including, but not limited to, workshops, seminars, short courses, or brief residential programs directed toward the specific needs of minorities and women who are preparing for, entering, or advancing within educational research careers;

(b) Furnish information abut such short-term advanced study opportunities which are provided by others;

(c) Develop and demonstrate replicable, short-term activities intended to accomplish one or more of the following objectives:

(1) Increase the involvement of minorities and women in communication networks by providing information about, or access to, groups or individuals who informally share knowledge of training and employment opportunities, funding sources, and substantive educational research results;

(2) Assist mid-career entry and re-entry of minorities and women into educational research by using methods that:

(i) Stimulate the interest of non-educational researchers to enter the educational research field or

(ii) Attract to the educational research field those non-research persons who

have appropriate academic backgrounds and experience;

(3) Identify and promote non-traditional research in areas, on approaches, or on topics associated with the needs and status of minorities and women in education.

(4) Provide for the development of specific skills needed in educational research. These include statistical skills and skills needed to conduct syntheses and transformations of knowledge.

(5) Enhance the potential for publication and dissemination of the results of significant educational research performed by minorities and women by providing information and training concerning research techniques, report writing, and publishing processes.

(d) These projects are funded for an initial period of 12 months and if an application is for a multi-year project, the project may be continued for additional periods provided the project does not exceed 36 months and provided also that the project offers a sequence of short-term activities that are recurring or intermittent.

§ 703.14 Projects and activities that are ineligible for support.

Grants will not be awarded in support of the following:

(a) Pre-college or undergraduate programs of any type.

(b) Course work or other education or training that is not adapted specifically to the requirements of this program.

(c) Research that is not part of an Institutional Project as described in these regulations.

(d) Activities that do not emphasize the increasing or strengthening of participation by minorities and women in educational research.

(20 U.S.C. 1221e(e)(1), 3474)

Subpart C—How Does One Apply for a Grant?

§ 703.21 Application procedures.

One applies for a grant under the procedures of EDGAR sections 75.100 through 75.129.

(20 U.S.C. 3474)

Subpart D—How Does the Secretary Make a Grant?

§ 703.31 How Does the Secretary Evaluate an Application?

(a) The Secretary evaluates an application on the basis of the selection criteria in section 703.32.

(b) The Secretary awards up to 100 total points based upon the degree to which each of these criteria is satisfied.

(c) The maximum possible score for each criterion is indicated in parenthesis following the identification of each selection criterion.

(d) The Secretary decides whether or not to fund a meritorious application, based on its rank order as determined by the independent review process and on whether the funding of the proposed project will contribute to the widest possible distribution of projects throughout the United States.

(20 U.S.C. 3474)

§ 703.32 What selection criteria does the Secretary use?

(a) *Plan of operation. (20 points)*

(1) The Secretary reviews each application for information that shows the quality of the plan of operation for the project.

(2) The Secretary looks for information that shows—

(i) High quality in the design of the project;

(ii) An effective plan of management that ensures proper and efficient administration of the project;

(iii) A clear description of how the objectives of the project relate to the purpose of the program;

(iv) The way the applicant plans to use its resources and personnel to achieve each objective; and

(v) A clear description of how the applicant will provide equal access and treatment for eligible project participants who are members of groups that have been traditionally underrepresented, such as—

(A) Members of racial or ethnic minority groups;

(B) Women;

(C) Handicapped persons; and

(D) The elderly.

(b) *Quality of key personnel.* (15 points)

(1) The Secretary reviews each application for information that shows the qualifications of the key personnel the applicant plans to use on the project.

(2) The Secretary looks for information that shows—

(i) The qualifications of the project director;

(ii) The qualifications of each of the other key personnel to be used in the project;

(iii) The time that each key person will commit to the project; and

(iv) The extent to which the applicant, as part of its nondiscriminatory employment practices, encourages applications for employment from persons who are members of groups that have been traditionally underrepresented, such as—

(A) Members of racial or ethnic minority groups;

(B) Women;

(C) Handicapped persons; and

(D) The elderly.

(3) In determining the qualifications of key personnel, the Secretary considers evidence of past experience and training in fields related to the objectives of the program as well as other information that the applicant provides.

(c) *Budget and cost effectiveness.* (5 points)

(1) The Secretary reviews each application for information that shows that the project has an adequate budget and is cost effective.

(2) The Secretary looks for information that shows—

(i) The budget for the project is adequate to support the project activities; and

(ii) Costs are reasonable in relation to the objectives of the project.

(d) *Evaluation Plan.* (10 points)

(1) The Secretary reviews each application for information that shows the quality of the evaluation plan for the project.

(2) The Secretary looks for information that shows methods of evaluation that are appropriate for the project and, to the extent possible, are objective and produce data that are quantifiable.

(e) *Adequacy of resources* (5 points)

(1) The Secretary reviews each application for information that shows that the applicant plans to devote adequate resources to the project.

(2) The Secretary looks for information that shows that the facilities, equipment, and supplies planned to be used are adequate.

(f) *Significance of the proposed project in meeting the purpose of the program.* (25 points)

The Secretary looks for information that shows the significance of the proposed project in terms of the potential for developing methods for removing barriers to the participation of minorities and women in educational research and in advancing careers for minorities and women in educational research.

(g) *Commitment of the applicant to the purpose of the program.* (20 points)

(1) The Secretary reviews each application for information that shows the extent to which the applicant is committed to meeting the purpose of the program.

(2) The Secretary looks for information that shows the commitment of the applicant to—

(i) The adoption of successful methods which are developed under the project; or

(ii) The continuation of exemplary practices initiated under the project.

(20 U.S.C. 3474)

Subpart E—What Conditions Must be Met by a Grantee?

§ 703.41 Restrictions on the use of grant funds.

No grant funds may be used for construction, repair, modeling, or alteration of facilities or sites.

(20 U.S.C. 3474)

§ 703.42 Allowable costs.

(a) Allowable direct costs for each grant under this program may not exceed the amount set forth in the grant award document.

(b) Assistance for Special projects may be provided at $30 for each full day of participation, but may not exceed $150 a week.

(230 U.S.C. 3474)

§ 703.43 Restriction on for-profit type grantees.

A for-profit type grantee is required to forgo profits and to cost-share to the same extent that is required of a non-profit grantee.

(20 U.S.C. 3474)

[FR Doc. 80-40431 Filed 12-29-80; 8:45 am]
BILLING CODE 4000-01-M

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34 CFR Parts 617, 618, 619, 620, and 621

Financial Assistance for Construction, Reconstruction, and Renovation of Higher Education Facilities

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the regulations for the programs of Financial Assistance for Construction, Reconstruction, and Renovation of Higher Education Facilities to reflect statutory changes contained in the Education Amendments of 1980. The proposed regulations revise certain selection criteria for grants and loans in order to focus applications for Federal financial assistance on special purposes specified in the amended statute.

DATES: All comments, suggestions, or objections must be received on or before March 2, 1981.

ADDRESSESS: Comments should be addressed to Thomas F. McAnallen, Office of Institutional Support, Office of Postsecondary Education, U.S. Department of Education, (Room 3716, ROB-3), 400 Maryland Avenue, S.W., Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Thomas F. McAnallen. Telephone No. (202) 245-3235.

SUPPLEMENTARY INFORMATION: The Education Amendments of 1980 amended Title VII of the Higher Education Act. That title authorizes programs of grants and loans to public and private institutions of higher education for the construction, reconstruction, and renovation of higher education academic facilities. The amended statute repeals the general purpose of providing Federal financial assistance to meet the expansion of student enrollment capacity and provides, instead, specified purposes for which funds under this law may be expended.

Funds appropriated under the Act may now be used to enable institutions—

(a) To economize on the use of energy resources;

(b) To improve their research facilities, including libraries, and to acquire special research equipment;

(c) To construct, reconstruct, or renovate facilities to meet unusual increases in enrollments;

(d) To remove architectual barriers to the handicapped in order to comply with the Architectual Barriers Act of 1968 and Section 504 of the Rehabilitation Act of 1973;

(e) To bring facilities into conformity with environmental protection or health and safety laws enacted subsequent to the date of construction; and

(f) To detect, remove, or contain asbestos hazards in academic or other facilities used by students.

Summary of Proposed Changes

(a) The proposed regulations are simplified in language and divided into five separate regulations: one containing general provisions common to all or most of the four other parts, and the other four governing, respectively, procedures for obtaining—

(1) Grants for undergraduate facilities;

(2) Grants for graduate facilities;

(3) Loans for undergraduate or graduate facilities; and

(4) Annual interest grants for undergraduate or graduate facilities.

(b) The proposed regulations contain the following provisions to reflect changes made by the Education Amendments of 1980:

(1) Definitions are provided for new terms in the Act, such as "research facilities, including libraries," "usual increases in enrollment," and "other facilities used by students" in relation to removal of asbestos hazards.

(2) Through the assignment of maximum possible points for individual criteria used in the selection of grant and loan recipients, the proposed regulations emphasize certain aspects of the special purposes:

(i) For energy conservation projects, the Secretary proposes to give greater consideration to projects proposing to use one or more of: coal, solar energy, and renewable resources.

(ii) For projects to remove architectural barriers, the Secretary proposes to give greater consideration to projects that hold promise of accomplishing exemplary programs of compliance with Section 504 that would be helpful to other institutions around the country and would not likely be carried out in the absence of Federal funds.

(iii) For projects to improve research facilities, the Secretary proposes to give greater consideration to projects that hold promise of having the greatest impact on the up-grading of institutions' research facilities.

(iv) For projects to accommodate unusual increases in student enrollment, the Secretary proposes to give greater consideration to projects that serve otherwise underserved student populations.

(v) For projects relating to asbestos hazards, the Secretary proposes to give greater consideration to projects addressing conditions of critical need.

(c) The proposed regulations provide that in any year in which the Congress appropriates funds for fewer than all of the special purposes, the Secretary will announce the congressional priorities or priorities through a notice in the Federal Register. If the Congress appropriates funds without specification, no special purpose will be given priority by the Secretary.

(d) The proposed regulations omit a previous provision in the definitions establishing a "period of Federal interest" in facilities *renovated or reconstructed* for a special purpose. The statutory provision on which this was based was repealed. However, in the case of facilities *constructed* with Federal assistance, the proposed regulations retain the "period of Federal interest" for 20 years after construction, since this provision was reenacted by the Education Amendments of 1980.

(e) The proposed regulations incorporate a change made by the Secretary in response to comments on interim final provisions of the regulations for Title VII published on April 29, 1980 (45 FR 28666-28683).

Comment. Several commenters felt that the "threshold cost" requirement for eligibility for assistance to remove architectural barriers unduly reduced the number of eligible applicants.

Response. A change has been made. The Secretary has omitted the

"threshold cost" requirement from these proposed regulations.

These proposed regulations also contain, in §§ 618.60 through 618.62, provisions for which there is no statutory authority. Before it was amended by the Education Amendments of 1980, Title VII of the Higher Education Act provided for allocation to the States of funds for construction of undergraduate facilities and a State plan for ranking applications, but it also provided for the awarding of grants by the Secretary.

In order to continue orderly administration of the program, a technical amendment to restore the authority of the Secretary to make the awards is being presented to the Congress. If the Congress enacts the technical amendment, these provisions will be part of the final regulations. The public is invited to comment on the appropriate course of action for the Department if the Congress does not enact the technical amendment.

Assesssment of Educational Impact

The Department particularly requests comments on whether the proposed regulations in this document would require transmission of information that is already being gathered by or is available from any other agency or authority of the United States.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding the proposed regulations. Written comments and recommendations may be sent to the address given at the beginning of this preamble. All comments submitted on or before (the 60th day after publication of this document) will be considered in the development of the final regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in Room 3716, ROB–3, 7th and D Streets S.W., Washington, D.C., between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

Citation of Legal Authority

A citation of statutory or other legal authority is placed in parentheses on the line following each substantive provision of these regulations.

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

The Secretary proposes to revise Part 617 of Title 34 of the Code of Federal Regulations to read as follows:

PART 617—FINANCIAL ASSISTANCE FOR CONSTRUCTION, RECONSTRUCTION, AND RENOVATION OF ACADEMIC FACILITIES: GENERAL

Subpart A—General

Sec.

Subpart B—What Kinds of Projects Does the Department of Education Assist Under These Programs?

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

Subpart E—What Conditions Must Be Met by an Applicant?

Authority: Secs. 701–742 of Pub. L. 96–374, Title VII of the Higher Education Act, as amended (20 U.S.C. 1132a–1132e–1) unless otherwise noted.

Subpart A—General

§ 617.1 Financial assistance for construction, reconstruction, and renovation of academic facilities.

The Secretary awards financial assistance to institutions of higher education for the construction, reconstruction, and renovation of academic facilities through four programs:

(a) Grants for the Construction, Reconstruction, and Renovation of Undergraduate Academic Facilities (34 CFR Part 618).

(b) Grants for the Construction, Reconstruction, and Renovation of Graduate Academic Facilities (34 CFR Part 619).

(c) Loans for the Construction, Reconstruction, and Renovation of Academic Facilities (34 CFR Part 620).

(d) Annual Interest Grants for the Construction, Reconstruction, and Renovation of Academic Facilities (34 CFR Part 621).

(20 U.S.C. 1132a–1132e–1)

§ 617.2 Eligible parties: Grants for the construction, reconstruction, and renovation of undergraduate academic facilities.

The following two categories of institutions (paragraphs (a) and (b) of this section) are eligible to apply for grants for the construction, reconstruction, and renovation of undergraduate facilities:

(a)(1) Under section 713(b) of the Act (allotment of funds for grants to public community colleges and public technical institutes)—

(i) Public community colleges;

(ii) Public technical institutes; and

(iii) Branch campuses of other types of institutions of higher education.

(20 U.S.C. 1132e–1 (6)

(2) An institution qualifies for grants under Section 713(b) of the Act if—

(i) The Secretary determines that the institution meets the requirements of both of the following definitions in the Act:

(A) Section 742(6) of the Act (definition of "public community college and public technical institute").

(B) Section 1201(a) of the Act (definition of "institution of higher education"); and

(ii) The State commission has found that—

(A) The institution is organized principally to provide two-year academic programs of the types specified in Section 742(6) of the Act; and

(B) More than 50 percent of the institution's full-time equivalent student enrollment is in those types of programs.

(20 U.S.C. 1132b–2; 1132e–1(6))

(b)(1) Under section 713(c) of the Act (allotment of funds for grants to all institutions of higher education other than public community colleges and public technical institutes), all other institutions of higher education.

(2) An institution qualifies for grants under Section 713(c) of the Act if the Secretary determines that the institution does not meet the requirements of Section 742(6) of the Act (definition of "public community college and public technical institute") but does meet the requirement of Section 1201(a) of the Act (definition of "institution of higher education").

(20 U.S.C. 1132b–2, 1141(a))

§ 617.3 Eligible parties: Grants for the construction, reconstruction, and renovation of graduate academic facilities.

(a) Institutions of higher education are eligible to apply to grants for the construction, reconstruction, and renovation of graduate academic facilities.

(20 U.S.C. 1132c)

(b) For a construction, reconstruction, or renovation project involving combined graduate and undergraduate facilities, an otherwise eligible applicant shall apply for a grant under 34 CFR Part 618 (Grants for the Construction, Reconstruction, and Renovation of Undergraduate Academic Facilities).

(20 U.S.C. 1132b(g))

§ 617.4 Eligible parties: Loans for the construction, reconstruction, and renovation of academic facilities.

The following are eligible to apply for loans for the construction, reconstruction, and renovation of academic facilities:

(a) Institutions of higher education.

(b) Higher education building agencies.

(20 U.S.C. 1132d(a))

§ 617.5 Eligible parties: Annual interest grants for construction, reconstruction, and renovation of academic facilities.

The following are eligible to apply for annual interest grants for the construction, reconstruction, and renovation of academic facilities:

(a) Institutions of higher education.

(b) Higher education building agencies.

(20 U.S.C. 1132d–3(a))

§ 617.6 Regulations that apply to programs of financial assistance for construction, reconstruction, and renovation of academic facilities.

The following regulations apply to programs of Financial Assistance for Construction, Reconstruction, and Renovation of Academic Facilities:

(a) For grants for the construction, reconstruction and renovation of undergraduate or graduate academic facilities (34 CFR Parts 618 and 619):

(1) The Education Division General Administrative Regulations (EDGAR), 34 CFR Part 75, with the following exceptions:

(i) Section 75.107: Applications for new grants under a discretionary grant program.

(ii) Sections 75.150 through 75.154, regarding State approval procedures.

(iii) Sections 75.155 through 75.160, regarding State comment procedures.

(iv) Sections 75.200 through 75.206, regarding selection of new projects.

(v) Sections 75.215 through 75.222, regarding selection procedures.

(vi) Section 75.232: The cost analysis; basis for grant amount.

(vii) Section 75.233: Setting the amount of the grant.

(viii) Sections 75.580 and 75.581, regarding coordination.

(b) Assistance under 34 CFR Part 620 (loans) and 34 CFR Part 621 (annual interest grants) is subject to the provisions of EDGAR relating to construction, 34 CFR 75.600 through 75.615.

(c) EDGAR, 34 CFR Part 75 (General).

(d) The regulations in this Part 617.

(e) The regulations in 34 CFR Parts 618, 619, 620, or 621 as applicable.

(20 U.S.C. 1232)

§ 617.7 Definitions that apply to programs of financial assistance for construction, reconstruction, and renovation of academic facilities.

(a) Definitions in EDGAR. The following terms used in this part are defined in 34 CFR Part 77:

Applicant
Application
Award
Budget
Department
EDGAR
Facilities
Fiscal Year
Grant
Grantee
Nonprofit
Private
Public
Recipient
Supplies
Secretary
Work of art.

(b) The following definitions apply to this part: "Academic facilities," as defined in section 742(1)(A) of the Act, are further defined and subdivided into the following categories:

(1) "Instructional and library facilities" means—

(i) All rooms or areas used regularly for instruction of students, for faculty offices, or for library purposes; and

(ii) Service areas that adjoin and are used in connection with the rooms or areas referred to in paragarph (a)(1) of this definition.

(2) "Instruction-related facilities" means—

(i) All rooms or areas—other than instructional and library facilities—used for purposes related to the instruction of students, for research, or for the general administration of the educational or research programs of an institution of higher education; and

(ii) Service areas that adjoin and are used in conjunction with the rooms or areas referred to in paragraph (2)(i) of this definition.

(3) "Health-care facilities," as authorized under Parts A and C of Title VII of the Act, means—

(i) Infirmaries and all other rooms or areas used for medical examination or treatment of students and institutional personnel; and

(ii) Service areas that directly serve the rooms or areas referred to in paragraph (3)(i)of this definition.

(20 U.S.C. 1132e–l(1)(A))

(4) "Public health facilities" means facilities as defined in section 742(1)(B)(v) of the Act (Definitions) if—

(i) These facilities are owned, operated, and maintained by the institution of higher education requesting the approval of a project authorized under section 701(l) of the Act (funds to enable an institution to economize on energy);

(ii) Funds available for the project are used solely for conversion or modernization to economize on the use of energy resources; and

(iii) The project is not limited to facilities described in section 742(1)(B)(v) of the Act (facilities excluded from the definition of academic facilities).

(20 U.S.C. 1132e–l(1)(B)(v))

(5) "Related supporting facilities" means all other areas and facilities necessary for the use, operation, and maintenance of instructional and library facilities, instruction-related facilities, or health-care facilities. This term includes building service and circulation areas and central maintenance and utility facilities that serve more than one building, to the degree that these central facilities are used to serve academic facilities eligible under Title VII of the Act.

(20 U.S.C. 1132e–l(1)(A))

"Acquisition" means taking ownership of property through purchase.

(20 U.S.C. 1132e-l(3)(A))

"Act" means the Higher Education Act of 1965 (Pub. L. 89-329), as amended. Unless otherwise indicated, title references are to titles of the Act.

"Assignable areas"—

(1) Means square footage of floor space in facilities designed and available for assignment to specific functional purposes—such as instruction, research, and administration—and including purposes that are ineligible for assistance under Title VII—such as students' sleeping rooms, apartments, or chapels; but

(2) Does not mean—

(i) Areas used for general circulation within a building;

(ii) Areas for public washrooms;

(iii) Areas for building maintenance or custodial services; or

(iv) Areas in central maintenance and utility facilities that exist only to support the operation and use of other structures on the campus and that are not available for assignment to specific functional purposes as illustrated in paragraph (1) of this definition.

(20 U.S.C. 1123e-l(1)(A))

"Brach campus" means, an institution of higher education, in a unit that—

(a) Is separately organized;

(b) Is located apart from the parent institution; and

(c) Meets in its own right the definition of an institution of higher education as defined in the Act.

(20 U.S.C. 1123e-l(6))

"Capacity/enrollment ratio."

(1) This term means the ratio of (i) the square feet of assignable area of instructional and library facilities to (ii) the total student clock-hour enrollment at the campus of an institution.

(2) For purposes of this definition, "student clock-hour enrollment" means the aggregate clock hours (sometimes called contact hours) per week in classes or supervised laboratory or shop work for which all resident students—i.e., students enrolled for credit courses on the campus—are enrolled as of a particular date.

(3) A campus having a formally established independent study program or programs may include systematically determined equivalents of class or laboratory hours.

(20 U.S.C. 1132a (4))

"Equipment"—other than special research equipment—means a manufactured item that has an extended useful life, is not consumed in use, and has an identity and function that are not lost through incorporation into a different or more complex unit of substance. Equipment is further subdivided into two categories—built-in equipment and intitial equipment—defined as follows:

(1) "Built-in equipment" means equipment that is a permanent part of a structure.

(2) "Initial equipment" means equipment—other than built-in equipment—necessary and appropriate for the initial functioning of a particular academic facility for that facility's specific purpose.

(20 U.S.C. 1132e-l(2)(A) and (B))

"Full-time-equivalent number of students" means the following:

(1)(i) For purposes of determining State allotments—

(A) The number of full-time students enrolled in programs that consist wholly or principally of studies normally creditable toward a bachelor's or higher degree;

(B) One third of the number of part-time students enrolled in the programs referred to in paragraph (1)(i)(A) of this definition;

(C) Forty percent of the number of students enrolled in programs that are not normally creditable toward a bachelor's or higher degree; and

(D) Twenty-eight percent of the remaining number of the students referred to in paragraph (1)(i)(C) of this definition.

(ii) For the purposes of this computation, student enrollment figures for each fiscal year will be those in the most recent U.S. Department of Education survey containing data on opening fall enrollment in higher education.

(2)(i) For purposes of reporting undergraduate enrollment trends and projections in connection with an application for financial assistance for an individual institution under 34 CFR Part 618, the "full-time equivalent number of students" may be defined by each State commission through a specific provision in its State plan.

(ii) If a State plan does not define the term, "full-time-equivalent number of students"—for application purposes—means the total number of full-time students plus one-third of the number of part-time students.

(3) For the purpose of the definition of "full-time-equivelant number of students," full-time students are those carrying at least 75 percent of a normal student-hour load.

(20 U.S.C. 1132b-2(c))

"Higher education building agency" means any public or nonprofit entity—other than the applicant institution—legally established for the purpose of providing or financing the construction, reconstruction, or renovation of academic facilities for the applicant institution.

(20 U.S.C. 1132e-l(5))

"Institution" or "institutions of higher education" meand that part of an educational institution that meets the requirements in section 1201(a) of the Act. The term "educational institution" is limited to an institution at which teaching is conducted.

(20 U.S.C. 1141(a))

"Other facilities used by students" means, in connection with projects relating to asbestos hazards, any facilities that are normally used by students on campus, even if those facilities are otherwise ineligible for Federal assistance under Title VII of the Act.

(20 U.S.C. 1132a(5))

"Project" means all or a portion of one or more structures—

(1) That are eligible for grant or loan assistance under Title VII;

(2) For which grant or loan assistance is requested in a single application; and

(3) That are part of a unified construction, reconstruction or renovation activity on the same campus.

(20 U.S.C. 1132e-l(2))

"Reconstruction or renovation project under section 701 (1), (2), and (5) of the Act" means a reconstruction or renovation project designed primarily to enable an institution to—

(1) Economize on the use of energy resources;

(2) Bring its facilities into conformity with the requirements of Pub. L. 90-480, commonly known as the Architectural Barriers Act of 1968, as amended by Pub. L. 91-205;

(3) Bring its facilities into conformity with the requirements of Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93-112, as amended);

(4) Bring its academic facilities into conformity with environmental protection or health and safety programs mandated by Federal, State, or local law, if those requirements were not in effect at the time the facilities were constructed; or

(5) Detect, remove, or contain asbestos hazards in academic or other facilities used by students.

(20 U.S.C. 1132a (1), (2), and (5))

"Research facilities, including libraries."

(1) This term means facilities used in connection with research at institutions of higher education that have been

defined and classified as research universities by the Carnegie Council on Policy Studies in Higher Education.

(2) No distinction is made with regard to the type of research.

(20 U.S.C. 1132a(3))

"Special research equipment."

(1) This term means equipment used in connection with research at institutions of higher education that have been defined and classified as research universities by the Carnegie Council on Policy Studies in Higher Education.

(20 U.S.C. 1132a(3))

(2) No distinction is made with regard to the type of research equipment.

(3) However, books or other library materials are excluded from this definition.

"Section 504" means Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112, as amended) and its implementing regulations (34 CFR Part 104).

"State commission" means, in each State, the agency designated or established by that State—in its agreement with the Secretary under section 1203 of the Act—to administer a program of construction, reconstruction, and renovation of undergraduate academic facilities.

(20 U.S.C. 1132b; 1143)

"State plan" means the document—submitted by a State and approved by the Secretary of Education—that describes the standards, methods, and administrative procedures the State commission uses to—

(1) Review each project proposed by an applicant in its State for a Federal grant for the construction, reconstruction, and renovation of undergraduate academic facilities;

(2) Determine and recommend the relative priority of that project; and

(3) Determine and recommend for that project the Federal share of the costs eligible for Federal financial assistance.

(20 U.S.C. 1132b

"Unusual increase in enrollment" means, at institutions of higher education listed in paragraphs (1) through (3) of this definition, an average increase in student enrollment of more than 10 percent per year, over a period of three years going back to the fall term beginning three years prior to the filing date for applications. The institutions to which this definition applies are those that—

(1) Enroll traditionally underserved populations;

(2) Have been successful in their access and outreach efforts; and

(3) Now find themselves with increasing enrollments and limited facilities.

(20 U.S.C. 1132a(4); House Report 96–520, page 53)

Subpart B—What Kinds of Projects Does the Department of Education Assist Under These Programs?

§ 617.10 Grants and loans for academic facilities and special research equipment.

These programs provide grants and loans for the construction, reconstruction, and renovation of academnic facilities and the acquisition of special research equipment if the primary purpose of an applicant's proposed project is to achieve one or more of the following—

(a) Economize on the use of energy resources. The Secretary gives priority consideration to a project that includes the use of one or more of the following: coal, solar energy, and renewable resources;

(b) Bring the applicant's academic facilities into conformity with the requirements of—

(1) Pub. L. 90–480, commonly known as the Architectural Barriers Act of 1968, as amended by Pub. L. 91–205; or

(2) Section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112), as amended;

(c) Bring the applicant's academic facilities into conformity with the requirements of environmental protection or health and safety programs mandated by Federal, State, or local law, if those requirements were not in effect at the time the facilities were constructed;

(d) Detect, remove, or contain asbestos hazards in academic or other facilities used by students;

(e) Construct, reconstruct, or renovate the applicant's research facilities, including libraries, and acquire special research equipment; or

(f) Construct, reconstruct, or renovate the applicant's facilities to provide for unusual increases in enrollment.

(20 U.S.C. 1132b-1132d-4)

§ 617.11 Types of projects the Secretary considers for assistance.

(a) The Secretary may announce the specific project purpose or purposes—from among those listed in § 617.10—that the Secretary will consider for assistance in any given fiscal year.

(b) The Secretary makes the announcement referred to in paragraph (a) of this section through a notice published in the Federal Register.

(c) The Secretary makes this announcement based on the purpose or purposes for which the Congress has appropriated funds for that year.

(20 U.S.C. 1132a-1132e-1 House Report 96–520, page 54)

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

§ 617.30 Determination of costs eligible for Federal assistance: general.

The Secretary determines separately for each proposed project the costs eligible for Federal assistance.

The Secretary bases the determination on—

(a) The factors in § 617.31 or § 617.32, as applicable;

(b) The factors in § 617.33, if applicable; and

(c) The following:

(1) The date on which the applicant incurred or contracted for a given cost.

(2) Whether the cost is an allowable development cost, as defined in section 742(3) of the Act (Definitions).

(3) Whether the applicant has incurred that cost in accordance with these regulations.

(4) That portion of the facility eligible under the type of assistance for which the applicant has submitted the application.

(5) The amount of any other Federal financial assistance the applicant has obtained or is assured of obtaining for the project.

§ 617.31 Conditions for grant approval and determination of costs eligible for Federal assistance: projects related to energy conservation, architectural barriers, environmental protection, health and safety, or asbestos hazards.

(a) The conditions in paragraphs (b) through (c) of this section apply to an application for assistance for—

(1) A construction, reconstruction, or renovation project related to energy conservation; or

(2) A reconstruction or renovation project related to—

(i) Bringing facilities into conformity with the Architectural Barriers Act of 1968 or Section 504 of the Rehabilitation Act of 1973;

(ii) Bringing facilities into conformity with environmental protection or health and safety programs mandated by law; or

(iii) The detection and control of asbestos hazards.

(b) The Secretary approves an application only if it contains sufficient information to demonstrate that the applicant's proposed project meets the following requirements:

(1) For assistance for energy conservation, the applicant—

(i) Must have accomplished minimum energy conservation measures required by the Secretary; and

(ii) Must have demonstrated that the proposed project will result in significant savings in energy consumption or related costs;

(iii) To receive priority consideration by the Secretary, must include in the proposed project the use of one or more of the following: coal, solar energy, and renewable resources.

(2) For assistance for the removal of architectural barriers for the handicapped, the proposed project must—

(i) Be deemed necessary to provide program accessibility under Section 504; and

(ii) Conform to the requirements of Pub. L. 90–480 commonly known as the Architectural Barriers Act of 1968;

(iii) Meet the most recently published standards of the American national Standards Institute (ANSI Standards); and

(iv) To receive priority consideration by the Secretary, hold promise of accomplishing an exemplary program of compliance with Section 504 that would be helpful to similar institutions around the country and would not likely be carried out in the absence of Federal funds.

(House Report 96–520, page 54)

(3) For assistance in meeting environmental or health and safety requirements, the proposed project must be required by local, State, or Federal law provided—in the case of a reconstruction or renovation project—those requirements were not in effect at the time the facilities were constructed.

(4) For projects relating to asbestos hazards, the applicant must justify to the satisfaction of the Secretary that the proposed project is urgently needed to detect, remove or contain asbestos hazards in academic or other facilities used by students.

(5)(i) An application involving a combination of two or more of the purposes in paragraphs (b)(1), (2), (3), or (4) of this section must satisfy each of the specific requirements.

(ii) Any portion of an application not meeting the applicable requirements is ineligible for assistance, except as permitted under paragraph (d)(2)(ii) of this section.

(c) The Secretary considers a project only if it has a total eligible cost, as specified in paragraph (c) of this section, of at least $10,000.

(d)(1) The Secretary bases the determination of costs eligible for Federal assistance on a review of each application.

(2)(i) The Secretary considers as eligible only those costs specifically related to one—or a combination—of the reconstruction or renovation purposes specified in the definition of "Reconstruction or renovation project under section 701 (1), (2), and (5) of the Act."

(ii) However, the Secretary may approve costs not specifically related to the purposes in that definition to the extent that they do not exceed 10 percent of costs that are specifically related, if the Secretary finds that the costs not specifically related are part of the project for which Federal assistance is requested.

(e) The Secretary awards a grant or loan on condition that the recipient award the contract or begin on-site work within 18 months from the date of loan approval or the date of grant approval or—in the case of a recipient having both a grant and a loan—the earlier of the date of loan approval or the date of grant approval.

(20 U.S.C. 1132a (1), (2), (5); 20 U.S.C. 1132e-1(3))

§ 617.32 Determination of costs eligible for Federal assistance: projects related to research facilities, research equipment, or unusual increases in enrollment.

(a) The conditions in paragraphs (b) and (c) of this section apply to an application for assistance for a construction, reconstruction, or renovation project related to—

(i) Research facilities;

(ii) The acquisition of special research equipment; or

(iii) An unusual increase in enrollment.

(b) The Secretary approves the development cost of a proposed project only if the application contains sufficient information to demonstrate that the applicant's proposed project meets the following requirements:

(1) For assistance to construct, reconstruct, or renovate research facilities, including libraries, or to acquire special research equipment, the applicant must have demonstrated that the proposed project is necessary for the up-grading of the research facilities at the institution.

(2) For assistance to construct, reconstruct, or renovate academic facilities to increase student enrollment capacity, the applicant must have demonstrated that the institution has experienced an unusual increase in enrollment as defined in § 617.7(b).

(c) The Secretary bases the determination of costs eligible for Federal assistance on a review of each application.

§ 617.33 Avoidance of duplication of facilities and programs.

(a) In addition to other eligibility requirements in the Act and these regulations, a project proposed by a public institution of higher education must—in order to avoid duplication of facilities and programs—meet the requirements of urgency as described in paragraph (b) of this section.

(b)(1) The Secretary bases the determination of urgency of need under paragraph (a) of this section on whether—

(i) The applicant has a history of not serving persons of a particular race, color, or national origin; or

(ii) There are within the geographic area the applicant serves one or more other public institutions of higher education that have a history of not serving persons of a particular race, color, or national origin.

(2) If either condition described in paragraph (b)(1) of this section is present, the Secretary determines—or the State commission, in the case of an application for a grant for undergraduate academic facilities shall determine—that urgency of need does not exist unless the applicant provides evidence satisfactory to the Secretary—or to the commission, if appropriate—that the proposed project and the proposed use of the facilities to be constructed, reconstructed, or renovated under the project will not—

(i) Establish or increase the identifiability of any of the institutions on the basis of race, color, or national origin; or

(ii) Impede the elimination of the identifiability of any of the institutions on the basis of race, color, or national origin.

(20 U.S.C. 1132a; 1132b—1132d–3; Shannon vs. HUD, 436 F. 2d 809)

Subpart E—What Conditions Must Be Met by an Applicant?

§ 617.40 Cost requirements.

(a) If, under the Act, an applicant files for assistance for a proposed project for the first time on or after the effective date of these regulations, the Secretary excludes the following from eligible development costs:

(1) Any cost for land incurred more than two years before the applicant files the application.

(2) Any cost for land in connection with an application for reconstruction or renovation.

(3) Any cost for the acquisition of a structure incurred more than one year before the applicant files the application.

(4) Any cost for the acquisition of a structure in connection with an application for reconstruction or renovation.

(5) Any cost for initial equipment incurred before the date the applicant files the application.

(6) Any cost for construction, reconstruction, renovation, or built-in equipment if the contract was entered into—

(i) Before the date the applicant filed the application; and

(ii) Before the Secretary concurred in the awarding of the contract.

(b) A grantee must obtain from the Secretary a determination of eligible costs—

(1) Before advertising for or soliciting bids; and

(2) Before awarding any contract for construction, reconstruction, or renovation under the Act.

(c) The Secretary approves costs only after the Secretary or the appropriate official of another Federal agency has approved Federal assistance for the construction, reconstruction, or renovation of the facility.

(20 U.S.C. 1132e-1(3))

The Secretary proposes to add a new Part 618 to Title 34 of the Code of Federal Regulations to read as follows:

Part 618—GRANTS FOR THE CONSTRUCTION, RECONSTRUCTION, AND RENOVATION OF UNDERGRADUATE ACADEMIC FACILITIES

Subpart A—General

Sec.

Subpart B—How Does a State Apply To Participate?

Subpart C—How Does the Secretary Approve a State Plan?

Subpart D—How Does an Applicant Apply to a State for a Grant?

Subpart E—How Does a State Rank Applications and Recommend Them for Approval by the Secretary?

Subpart F—How Does the Secretary Make a Grant?

Authority.—Secs. 701–742 of Pub. L. 96–374, title VII, the Higher Education Act, as amended, (20 U.S.C. 1132a–1132e–1) unless otherwise noted.

Subpart A—General

§ 618.1 Grants for the construction, reconstruction, and renovation of undergraduate academic facilities.

This State-administered program provides grants for the construction, reconstruction, and renovation of undergraduate academic facilities if the primary purpose of an applicant's proposed project is to achieve one or more of the objectives listed in 34 CFR 617.10.

(20 U.S.C. 1132b)

§ 618.2 Eligible parties.

(a) The two categories of parties eligible to apply for grants for consfruction, reconstruction, and renovation of undergraduate facilities are listed in 34 CFR 617.2.

(20 U.S.C. 1132(b) and (c))

(b) An applicant shall apply under this part for a project involving combined graduate and undergraduate facilities.

(20 U.S.C. 1132b-2(g))

§ 618.3 Regulations that apply to grants for the construction, reconstruction, and renovation of undergraduate academic facilities.

The following regulations apply to this program:

(a) The regulations in 34 CFR 617.6.

(b) The regulations in this Part 618.

(c) The regulations in 34 CFR Part 604, which implements section 1203 of the Act (Federal-State agreement).

(20 U.S.C. 1132)

§ 618.4 Definitions that apply to grants for the construction, reconstruction, and renovation of undergraduate academic facilities.

The definitions in 34 CFR 617.7 apply to this program.

Subpart B—How Does a State Apply to Participate?

§ 618.10 State plan.

(a) A State that desires to participate in the program of Grants for the Construction, Reconstruction, and Renovation of Undergraduate Academic Facilities shall—

(1) Have an agreement with the Secretary under section 1203 of the Act; and

(2) Submit annually, through its State commission, a State plan.

(b) The Secretary—

(1) Determines the form in which the State submits its plan;

(2) Specifies the type of information that the State shall supply; and

(3) Specifies criteria the State plan must include for determining relative priorities of proposed projects (as explained in § 618.40).

(c) The plan may include a definition of "full-time-equivalent number of students" other than the definition in 34 CFR 617.7(b).

(d) The Secretary must receive the plan at least 60 days prior to the first closing date contained in the plan.

(20 U.S.C. 1132b; 1143)

§ 618.11 Continuation of State plan.

If a State intends to continue its existing plan for the following fiscal year, the Secretary must receive notification of this in writing from the State at least 60 days before the first closing date of that next fiscal year.

§ 618.12 Amendment to State plan.

(a) A State may at any time submit a proposed amendment to its State plan.

(b) The Secretary determines the form in which the State submits the proposed amendment.

(c) If the Secretary approves the amendment, the State shall uniformly apply that amendment to all applications received by the first closing date following the approval.

(d) Unless otherwise specified in the State plan, an amendment becomes effective immediately when the Secretary approves it.

(e) Paragraph (d) of this section does not apply to an amendment that—

(1) Affects the standards and methods for determining priorities;

(2) Alters the Federal share; or

(3) Changes a closing date.

(f) The types of amendments referred to in paragraph (e) of this section become effective—

(1) No sooner than 60 days after the Secretary receives them; and

(2) In any event, no sooner than 30 days after the Secretary approves them.

(g) If an amendment to the State plan is required by legislation or new or revised regulations, that amendment may be effective immediately after the Secretary approves it.

(20 U.S.C. 1132b)

§ 618.13 Standards for determining the Federal share of eligible projects.

(a) A State plan must—

(1) Specify as a uniform percentage the Federal share of the costs eligible for Federal financial assistance; or

(2) Prescribe the standards or methods by which the State commission determines the Federal share of the costs.

(20 U.S.C. 1132b(a)(2)(B))

(b) The Federal share of a project's costs may not exceed 50 percent of the eligible development costs.

(20 U.S.C. 1132b–1(a)(3); 1132–1(4))

(c) Standards and methods for determining the Federal share of eligible costs must—

(1) Be objective and simple to apply;

(2) Be based on the data that an applicant is required to include in its application; and

(3) Be consistent with the standards in the State plan for determining relative priorities.

(20 U.S.C. 1132b(a)(2)(B))

Subpart C—How Does the Secretary Approve a State Plan?

§ 618.20 Approval of a State plan.

The Secretary approves a State plan if the Secretary is satisfied it meets the requirements of section 711 of the Act (State plan).

(20 U.S.C. 1132b)

Subpart D—How Does an Applicant Apply to a State for a Grant?

§ 618.30 Submission of application to State commission.

(a) An applicant shall submit directly to its State commission—

(1) Its application; and

(2) Any supplemental information the commission may require.

(b) The commission shall officially record the date of receipt of the application.

(20 U.S.C. 1132b(a)(4))

§ 618.31 Application closing dates.

(a) In its State plan a State shall establish closing dates for submission of applications for funds allotted under section 713(b) and 713(c) of the Act (allotment for grants to public community colleges and public technical institutes; allotment for grants to all other institutions of higher education).

(b) The State plan shall provide at least two closing dates during a Federal fiscal year for each of the two categories of institutions referred to in 34 CFR 617.2.

(c)(1) All closing dates established in the State plan must be between October 31 and May 15.

(2) The first closing date must be prior to January 1.

(d) If the Secretary permits, after determining the presence of unusual circumstances—

(1)(i) The State commission may waive a closing date if the commission gives reasonable prior notice of waiver to the institutions that may be affected by that date.

(ii) In that case an applicant may file an application before the next closing date established by the State commission for that fiscal year;

(2) The State plan may provide for a closing date after May 15; or

(3) Both paragraphs (d)(1) and (2) of this section.

(20 U.S.C. 1132b–2(b) and (c))

§ 618.32 Invitation for bids.

(a) An applicant may not invite bids for construction, reconstruction, or renovation under its proposed project before submitting its initial application to the State commission.

(b)(1) However, paragraph (a) of this section does not apply if an agency of the United States has already approved assistance for the project under Title VII or some other Federal construction program.

(2) In that case the commission shall consider the application at only those closing dates that occur no later than 12 months after the applicant has begun the construction, reconstruction, or renovation.

(20 U.S.C. 1132b–2 (b) and (c)

§ 618.33 Documents a State commission must submit to the Secretary.

On completing its consideration of applications for each closing date, but no later than 45 days after each closing date, a State commission shall forward the following to the Secretary:

(a) A current application summary report, in a form prescribed by the Secretary, for each category of applicants. The commission shall list in its report—

(1) Each application received for that closing date, including those carried over from the previous closing date;

(2) Each application returned to an applicant and the reason for the return of that application; and

(3) The priority and Federal share—determined according to the State plan—for each project recommended for Federal assistance.

(b) For each project to which the commission has assigned a priority high enough to enable that project to qualify for a Federal grant within the amount of funds available in the allotment for the State, the application form and exhibits in the number of copies the Secretary requests.

(20 U.S.C. 1132b(a)(2); 1132b–2(e))

§ 618.34 Notification of an applicant.

A State commission shall—

(a) Promptly notify an applicant of the results of all determinations regarding its application as of each closing date; and

(b) On request and according to procedures that the commission has established, give an applicant access to the records of official proceedings on the basis of which the commission determined relative priorities and Federal shares of all applications.

§ 618.35 Disposition of all applications not recommended for a grant.

(a) A State commission shall notify all unsuccessful applicants when funds are no longer available in the State allotments for that fiscal year.

(b) The commission may retain until the end of the fiscal year an application that it does not recommend for a grant.

(c) The commission may reconsider for the following fiscal year an application that it has not recommended for a grant if the applicant requests the commission, in writing, to reconsider its application in that subsequent year.

(d) If the commission carries over an application from one closing date to the next, the applicant—if necessary—shall amend those portions of the application requiring data on enrollments and available instructional and library or health care facilities or both—as appropriate—to reflect most recent fall term data.

(20 U.S.C. 132b(a))

§ 618.36 Amendments to an application.

(a) Any time prior to a closing date for which an applicant asks its State commission to consider its application, the applicant may make changes in the application by informing the commission, in writing, of those changes.

(b) After the closing date the commission may not permit changes in the application except for corrections or the submission of additional data the commission requests.

(20 U.S.C. 1132b–1)

§ 618.37 Project changes.

After a State commission has forwarded a recommended project to the Secretary, the Secretary does not approve any substantial changes in the nature or scope of the project unless the Secretary determines that those changes would not have affected the commission's original recommendation of the project for a grant.

(20 U.S.C. 1132b–1)

§ 618.38 Supplemental application.

(a) If an applicant has received approval of a grant for undergraduate academic facilities but has not received the maximum Federal share allowable under the Act or the applicable State plan, the applicant may file a supplemental application.

(b) A supplemental application—

(1) Must be in the form of a written request to the State commission; and

(2) Must contain all amended application data necessary to enable the commission to assign a priority to the application and to calculate a revised eligible development cost of the project, if applicable.

(c) However, the commission may not consider a supplemental application for—

(1) A closing date that is more than 12 months after the applicant has started construction, reconstruction, or renovation; or

(2) A closing date that is after the date the applicant has substantially completed the project.

(20 U.S.C. 1132b–1)

Subpart E—How Does a State Rank Applications and Recommend Them for Approval by the Secretary?

§ 618.40 Standards and methods for ranking proposed projects.

The following requirements govern the standards and methods for ranking proposed projects under a State plan:

(a) In its plan a State shall specify criteria and methods for assessing and ranking proposed projects for the construction, reconstruction, and renovation of undergraduate academic facilities. The State shall specify these criteria and methods separately for—

(1) Public community colleges and public technical institutes; and

(2) Other institutions of higher education.

(b) For all proposed projects under this program, the State plan must include—

(1) The selection criteria in § 618.41; and

(2) As applicable, the selection criteria in §§ 618.42, 618.43, 618.44, 618.45, 618.46, 618.47, or 618.48.

(c) (1) The State plan may include additional criteria—worth up to 40 percent of the total possible point score—for assessing and ranking proposed projects as long as none of those criteria is inconsistent with the criteria specified in §§ 618.41 through 618.48.

(2) The State commission may apply the additional criteria referred to in paragraph (c)(1) of this section if those criteria are approved by the Secretary.

(d) (1) The State commission shall assign points to each criterion according to an objective method contained in the State plan.

(2) In determining relative priorities among applicants, the commission shall apply each criterion uniformly.

(e) The State shall develop its criteria and methods for determining relative priorities on the basis of—

(1) Information to be included by the applicant in the application form that the Secretary prescribes;

(2) Supplemental information requested from all applicants by the State commission; and

(3) Data on file with the State commission, including public reports or publications.

(f) In its plan the State shall specify criteria and methods for determining priority between or among applications receiving identical scores.

(g) The State plan may not consider adverse to the ranking of an application an institution's readiness to admit out-of-State students.

(h) The State plan may not consider any of the following as a priority either in favor of or adverse to the ranking of an application:

(1) The type of control or sponsorship of the applicant institution.

(2) The fact that the project had commencd before the date of the application.

(3) The fact that part of the cost of the project had been incurred prior to, or under a contract entered into before, the date of the application.

(i) The commission shall insure that all potential applicants are informed about the forms, definitions, and supplementary data sources that the commission uses—

(1) In applying the required and optional criteria in the State plan; and

(2) In determining relative priorities.

(20 U.S.C. 1132b(a)(2)(A))

§ 618.41 Selection criteria: general.

Among its criteria for determining relative priorities for institutions and branch campuses under this program, the State shall include the following:

(a) *Use of existing facilities.* (1) One or more criteria shall deal with the effective use of existing academic facilities.

(2) The commission shall assign at least 10 percent of the total possible point score to this criterion.

(b) *Enrollment of low-income students.* (1) A criterion shall deal with the extent of the applicant's commitment to the enrollment of a substantial number of students from low-income families.

(2) The commission shall assign at least five percent of the total possible point score to this criterion.

(c) *Enrollment of disabled veterans.* (1) A criterion shall deal with the extent of the applicant's commitment to the enrollment of a substantial number of disabled veterans.

(2) The commission shall assign at least five percent of the total possible point score to this criterion.

(20 U.S.C. 1132b)

§ 618.42 Selection criteria: projects based on unusual increases in enrollment.

For construction, reconstruction, or renovation projects based on unusual increases in enrollment (section 701(4) of the Act), the State plan shall, in addition to the criteria in § 618.41, include at least the following criteria:

(a) *Increase in enrollment.* (1) One or more criteria shall deal with the extent of the actual numerical or percentage increase, or both, in full-time-equivalent student enrollment at the campus at which the construction, reconstruction, or renovation is to take place.

(2) The increase shall be measured by covering three years separately, starting

with the year that began three years preceding the closing date for which the application is being considered.

(3) The commission shall assign at least 20 percent of the total possible point score to this criterion.

(b) *Increase in capacity.* (1) One or more criteria shall deal with the amount or percentage, or both, by which the proposed project will increase the assignable area at that campus.

(2) The commission shall assign at least 20 percent of the total possible point score to this criterion.

(20 U.S.C. 1132b–1; 1132a(4))

§ 618.43 Selection criteria: projects dealing with research facilities, including libraries, and the acquisition of special research equipment.

For construction, reconstruction, or renovation projects dealing with research facilities, including libraries, and the acquisition of special research facilities (section 701(3) of the Act), the State plan shall, in addition to the criteria in § 618.41, include at least the following criteria:

(a) *Amount of research space to be upgraded.* (1) One or more criteria shall deal with the amount of research space to be upgraded by the proposed project.

(2) The commission shall assign at least 20 percent of the total possible point score to this criterion.

(b) *Percentage of research space to be upgraded.* (1) One or more criteria shall deal with the percentage of the applicant's research space—on that campus—that is to be upgraded by the proposed project.

(2) The commission shall assign at least 20 percent of the total possible point score to this criterion.

(20 U.S.C. 1132b–1; 1132a(3))

§ 618.44 Selection criteria: projects based on energy conservation.

For construction, reconstruction, or renovation projects based on energy conservation (section 701(1) of the Act), the State plan shall, in addition to the criteria in § 618.41, include at least the following criteria:

(a) *Use of coal, solar, and renewable resources.* (1) One or more criteria shall deal with the extent to which an institution proposes to use one or more of the following: coal, solar energy, and renewable resources.

(2) The commission shall assign at least 20 percent of the total possible point score to this criterion.

(b) *Estimated savings in annual operating costs.* (1) One or more criteria shall deal with the extent to which the proposed project is likely to enable the institution to economize on the use of energy resources, based on an estimate of savings in annual operating costs.

(2) The estimated savings, if any, in annual operating costs are the difference between—

(i) The average routine operating expenses for the previous three years; and

(ii) Future annual operating expenses based on the current prices of fuel supplies and related services.

(3) The commission shall assign at least 20 percent of the total possible score to this criterion.

(20 U.S.C. 1132b–1; 1132a(1))

§ 618.45 Selection criteria: projects to remove architectural barriers.

For construction or renovation projects to remove architectural barriers (section 701(2) (A) and (B) of the Act), the State plan shall, in addition to the criteria in § 618.41, include at least the following criteria:

(a) Exemplary program of compliance with Section 504.

(1) One or more criteria shall deal with the extent to which a proposed project holds promise of accomplishing an exemplary program of compliance with Section 504 that would be helpful to similar institutions around the country and that would not likely be carried out in the absence of Federal funds.

(2) The commission shall assign at least 10 percent of the total possible point score to this criterion. (House Report 96–520, page 54)

(b) *Amount of assignable square feet of academic facilities to be made accessible by the proposed project.* (1) One or more criteria shall deal with the amount of assignable square feet of academic facilities to be made accessible to the handicapped by the proposed project.

(2) The commission shall assign at least 10 percent of the total possible point score to this criterion.

(c) *Percentage of assignable square feet of academic facilities to be made accessible by the proposed project.* (1) One or more criteria shall deal with the percentage of assignable square feet of academic space—on the applicant's campus—to be made accessible to the handicapped by the proposed project.

(2) The commission shall assign at least 10 percent of the total possible point score to this criterion.

(d) *Costs required by Section 504 per full-time-equivalent student enrollment.* (1) One or more criteria shall deal with the costs required by Section 504 per full-time-equivalent student enrollment.

(2) The commission shall assign at least 10 percent of the total possible point score to this criterion.

§ 618.46 Selection criteria: projects to meet environmental protection or health and safety programs mandated by law.

For reconstruction or renovation projects to meet environmental protection or health and safety programs mandated by Federal, State or local law (section 701(2)(C) of the Act), the State plan shall, in addition to the criteria in § 618.41, include at least the following criteria:

(a) *Campuswide cost per full-time-equivalent student.* (1) One or more criteria shall deal with the campuswide cost—per full-time-equivalent student—of complying with the law.

(2) The commission shall assign at least 20 percent of the total possible point score to this criterion.

(b) *Campuswide cost per square foot of assignable space.* (1) One or more criteria shall deal with the campuswide cost—per square foot of assignable space—of complying with the law.

(2) The commission shall assign at least 20 percent of the total possible point score to this criterion.

(20 U.S.C. 1132b–1; 1132a(2)(c))

§ 618.47 Selection criteria: projects to detect, remove, or contain asbestos hazards.

For reconstruction or renovation projects to detect, remove, or contain asbestos hazards (section 701(5) of the Act), the State plan shall, in addition to the criteria in § 618.41, include at least the following criteria:

(a) *Amount of gross square feet of facilities space with known or suspected asbestos hazards.* (1) One or more criteria shall deal with the amount of gross square feet of facilities space with known or suspected asbestos hazards.

(2) The commission shall assign at least 20 percent of the total possible point score to this criterion.

(b) *Estimated cost of detecting, removing, or containing asbestos hazards.* (1) One or more criteria shall deal with the estimated cost—per campuswide assignable square foot—of one or more of the following: detecting, removing, or containing asbestos hazards.

(2) The commission shall assign at least 20 percent of the total possible point score to this criterion.

(20 U.S.C. 1132b–1; 1132a(5))

§ 618.48 Selection criteria: project directed to two or more purposes.

If a proposed project is directed to a combination of two or more of the purposes under section 701 of the Act, the State plan shall, in addition to the criteria in § 618.41, include at least the following criteria in place of the criteria in §§ 618.42 through 618.47:

(a) *Readiness to commence project.* (1) One of more criteria shall deal with the timeliness by which an applicant can start its project.

(2) The commission shall assign at least 20 percent of the total possible point score to this criterion.

(b) *The cost of the project as a percentage of the applicant's average annual educational and general expenditures.* (1) One or more criteria shall deal with the cost of the project as a percentage of the applicant's average annual educational and general expenditures, as reported in the annual NCES Survey "Financial Statistics of Institutions of Higher Education" for the three most recent institutional fiscal years.

(2) The commission shall assign at least 20 percent of the total possible point score to this criterion.

§ 618.49 Selection criteria: additional criteria.

For any types of projects under this program, a State commission may uniformly apply additional criteria—as described in § 618.40(d)—worth up to 40 percent of the total possible point score.

(20 U.S.C. 1132b–1)

§ 618.50 Verification of application data and institutional and project eligibility.

(a) Before determining the relative priority or Federal share for any application under this program, the State commission shall determine that—

(1) The data in the application are valid; and

(2) The institution and the project meet basic eligibility requirements of the Act and the regulations governing the administration of the Act.

(b)(1) If, in the opinion of the commission, the eligibilty of an institution is questionable, the commission shall promptly forward a copy of the application to the Secretary for a clarification of the eligibilty.

(2) In that case the commission shall—

(i) Continue to process and rank the application as if that application were eligible; and

(ii) Delay final action on that application until the Secretary notifies the commission regarding the applicant's eligibility.

(20 U.S.C. 1132b–2)

§ 618.51 Determination of relative priorities and Federal shares.

A State commission shall—

(a) Consider each eligible application received by each specified closing date together with all other applications in the same category of eligible applicants (34 CFR 617.2); and

(b) Assign to that application, in accordance with the provisions of the State plan, its—

(1) Relative priority; and

(2) Recommended Federal share.

(20 U.S.C. 1132b(a)(2))

§ 618.52 Procedure if funds are insufficient.

(a) If, under a State's allotment, funds are insufficient to cover all eligible applications that the state commission considers in a particular category as of a particular closing date, the commission shall follow the procedures in paragraph (b) of this section.

(b) The commission shall determine—according to the State plan—the full Federal share for each project, in order of relative priority, until the remaining funds are insufficient to provide the full Federal share for the next project in order of priority.

(20 U.S.C. 1132b(a)(2)(B))

§ 618.53 Apportionment of State allotment among closing dates.

(a) A State plan may provide for apportionment of the State's allotment among closing dates during the same fiscal year.

(b) If the State plan provides for the apportionment described in paragraph (a) of this section, the plan may also provide for the commission to make available immediately—from funds apportioned to later closing dates, if any, in the same fiscal year—funds sufficient to provide a full Federal share, as initially calculated, for the first project for which only part of the Federal share would otherwise have been available.

(20 U.S.C. 1132b–1(a)(1))

§ 618.54 Procedures if State allotment is apportioned or not apportioned among closing dates.

(a) If a State plan contains the provision described in both paragraphs (a) and (b) of 618.53, the commission shall—

(1) Make available immediately funds sufficient to provide a full Federal share, as initially calculated, for the first project for which only part of the Federal share would otherwise have been available; and

(2) Carry over to any subsequent closing dates in the same fiscal year all other eligible but unfunded applications in that category without requiring the applicants to submit new applications for those projects for that fiscal year.

(b) If the State plan contains the provision described in paragraph (a) of § 618.53 but does not contain the provision described in paragraph (b) of § 618.53, the commission—

(1) Shall carry over to any subsequent closing dates in the same fiscal year all eligible applications for which a full Federal share is not available; and

(2) Is prohibited from requiring those applicants to submit new applications for those projects for the same fiscal year.

(c) However, if the State plan does not apportion the State's allotment among closing dates or if the closing date is the last closing date in a fiscal year, the commission shall offer the remaining Federal funds as a partial Federal share for the first project—in order of relative priority—for which less than the full Federal share, as calculated, is available.

(20 U.S.C. 1132b(a))

§ 618.55 Offer of a partial Federal share.

(a) A State commission or the applicant may not regard an offer and acceptance of a partial Federal share as diminishing the scope of the project for which the partial share is accepted.

(b) The commission shall give the applicant that agrees to accept a partial federal share the option to submit a supplemental application, as provided in § 618.38.

(c) If an applicant declines to accept the commission's offer of a partial Federal share, the commission shall carry over to the next closing date, if any, in the same fiscal year—

(1) The remaining funds; and

(2) The application for which an applicant declined the partial Federal share.

(20 U.S.C. 1132b(a))

Subpart F—How Does the Secretary Make a Grant?

§ 618.60 Conditions for grant approval.

The Secretary approves the development costs under this program only if the Secretary is satisfied, on the basis of information submitted with the application, that—

(a) The facilities included in the proposed project are intended predominately for—

(1) Programs of undergraduate instruction or programs of graduate instruction if the project involves combined undergraduate and graduate facilities;

(2) Health care to students or personnel of the institution; or

(3) Both; and

(b) The application meets all of the requirements of the Act regarding the submission and contents of applications.

§ 618.61 Grant award.

For an application that meets all eligibility requirements for an award of

funds under this program and has been recommended by the State commission, the Secretary—

(a) Approves the development costs contained in the application;

(b) Reserves for the project proposed in the application Federal funds from the appropriate State allotment; and

(c) Prepares and sends to the applicant a grant award that contains the pertinent terms and conditions of the grant.

§ 618.62 Adjustment in the amount of the Federal share.

(a) If the Secretary finds that the costs eligible for Federal assistance in a project are less than those provided for in the grant award, the Secretary redetermines the amount of the Federal share.

(b) The Secretary bases the amount of the revised grant on—

(1) The lesser eligible costs, using the State plan provisions that were in effect at the time the State commission recommended the project for a grant; and

(2) The assumption that sufficient funds were available in the State allotment at that time to provide the maximum Federal share.

(c)(1) If the Secretary finds that the redetermined share is less than the maximum amount authorized by the grant, the Secretary reduces the grant accordingly.

(2) If the Secretary finds that there has been an overpayment of Federal funds, the grantee shall immediately remit that overpayment to the Secretary.

(3) If the Secretary finds that the redetermined Federal share is equal to or greater than the maximum amount authorized by the grant, the amount of the grant shall be the Federal share.

The Secretary proposes to add a new Part 619 to Title 34 of the Code of Federal Regulations to read as follows:

PART 619—GRANTS FOR THE CONSTRUCTION, RECONSTRUCTION, AND RENOVATION OF GRADUATE ACADEMIC FACILITIES

Subpart A—General

Sec.

Subpart B—What Kinds of Projects Does the Department of Education Assist under This Program?

Sec.

Subpart C—How Does One Apply for a Grant?

Subpart D—How Does the Secretary Make a Grant?

Authority: Secs. 701–742 of Pub. L. 96–374, Title VII, of the Higher Education Act, as amended (20 U.S.C. 1132a–1132e–1) unless otherwise noted.

Subpart A—General

§ 619.1 Grants for the construction, reconstruction, and renovation of graduate academic facilities.

This program provides grants for the construction, reconstruction, and renovation of graduate academic facilities.

(20 U.S.C. 1132c)

§ 619.2 Eligible parties.

Institutions of higher education are eligible to apply for grants for the construction, reconstruction, and renovation of graduate academic facilities.

(20 U.S.C. 1132e)

§ 619.3 Regulations that apply to grants for the construction, reconstruction, and renovation of graduate academic facilities.

The following regulations apply to this program:

(a) The regualtions in 34 CFR 617.6.

(b) The regulations in this Part 619.

(20 U.S.C. 1132)

§ 619.4 Definitions that apply to grants for the construction, reconstruction, and renovation of graduate academic facilities.

The definitions in 34 CFR 617.7 apply to this program.

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

§ 619.10 Projects for which grants may be used.

This program provides grants for the construction, reconstruction, or renovation of graduate academic facilities if the primary purpose of an applicant's proposed project is to achieve one or more of the objectives listed in 34 CFR 617.10.

(20 U.S.C. 1132c; 1132a)

Subpart C—How Does One Apply for a Grant?

§ 619.20 Submission of application.

(a) An applicant shall submit its application for construction, reconstruction or renovation of graduate facilities to the Secretary in response to an application notice published in the **Federal Register.**

(20 U.S.C. 1132c)

(b) For a construction, reconstruction, or renovation project involving combined graduate and undergraduate facilities, an otherwise eligible applicant shall submit its application under 34 CFR Part 618 (Grants for the Construction, Reconstruction, and Renovation of Undergraduate Academic Facilities).

(20 U.S.C. 1132b–2(g))

§ 619.21 Invitiation for bids.

(a) An applicant may not invite bids for construction, reconstruction, or renovation under its proposed project before submitting its application to the Secretary.

(b)(1) However, paragraph (a) of this section does not apply if—

(i) The Secretary has already approved assistance for the project under Title VII; or

(ii) Some other agency of the United States has already approved assistance for the project under some other Federal construction program.

(2) In that case, the Secretary considers the application only if the applicant submits it in response to an application notice or State plan closing date occurring no later than 12 months after the applicant has begun the construction, reconstruction, or renovation.

(20 U.S.C. 1132c)

Subpart D—How Does the Secretary Make a Grant?

§ 619.30 Facilities panel reviews applications.

(a) The Secretary considers an application for a grant for construction, reconstruction, or renovation of graduate academic facilities only after obtaining the advice and recommendation of a panel of specialists who are not regular full-time employees of the Federal Government and who are competent to evaluate the application.

(b) The panel—referred to in this Part 619 as a facilities panel—

(1) Reviews the application in terms of the applicable criteria listed in § 619.31; and

(2) Makes a recommendation to the Secretary for the approval or disapproval—in whole or in part—of the application.

(20 U.S.C. 1132c(b))

§ 619.31 Selection criteria for evaluation proposed projects.

In determining relative priorities for recommending to the Secretary applications for grants for the construction, reconstruction, or renovation of graduate academic facilities, a facilities panel takes into consideration—

(a) The criteria in § 619.32, worth up to 60 possible points; and

(b) As applicable, the criteria in §§ 619.33, 619.34, 619.35, 619.36, 619.37, 619.38 or 619.39, worth up to 40 possible points.

§ 619.32 Selection criteria: general.

Among its criteria for determining relative priorities for graduate institutions under this program, a facilities panel takes into consideration the following:

(a) *Use of existing facilities.* (1) The extent to which an applicant makes effective use of its existing facilities.

(2) The Secretary awards up to a maximum of 15 points for this criterion.

(b) *The need to upgrade the applicant's existing academic facilities.* (1) The extent of the applicant's need to upgrade its existing academic facilities with respect to the demand made on those facilities and the demands that can reasonably be expected to be made on them in the foreseeable future.

(2) The Secretary awards up to a maximum of 15 points for this criterion.

(c) *The quality of the applicant's graduate programs.* (1) The quality of the applicant's graduate programs, in particular those programs that are housed or are to be housed in the facilities for which assistance is being requested.

(2) The Secretary awards up to a maximum of 15 points for this criterion.

(d) *The extent to which the proposed project is likely to preserve and enhance the applicant's programs.* (1) The extent to which the proposed project is likely to preserve and enhance the applicant's graduate programs, in particular those programs that are housed or to be housed in the facilities that are to be constructed, reconstructed, or renovated.

(2) The Secretary awards up to a maximum of 15 points for this criterion.

§ 619.33 Selection criteria: projects based on unusual increases in enrollment.

For construction, reconstruction, or renovation projects based on unusual increases in enrollment (section 701(4) of the Act), the facilities panel applies the following criteria in addition to the criteria in § 619.32:

(a) *Increase in enrollment.* (1) The extent of the actual numerical or percentage increase, or both, in full-time-equivalent student enrollment at the campus at which the construction, reconstruction, or renovation is to take place.

(2) The increase is measured by covering three years separately, starting with the year that began three years preceding the closing date for which the application is being considered.

(3) The Secretary awards up to a maximum of 20 points for this criterion.

(b) *Increase in capacity.* (1) The amount or percentage, or both, by which the proposed project will increase the assignable area at that campus.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

§ 619.34 Selection criteria: projects dealing with research facilities, including libraries, and the acquisition of special research equipment.

For construction, reconstruction, or renovation projects dealing with research facilities, including libraries, and the acquisition of special research facilities (section 701(3) of the Act), the facilities panel in addition to the criteria in § 619.32:

(a) *Amount of research space to be upgraded.* (1) The amount of research space to be upgraded by the proposed project.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(b) *Percentage of research space to be upgraded.* (1) The percentage of the applicant's research space—on that campus—that is to be upgraded by the proposed project.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(20 U.S.C. 1132c(b), 1132a(3))

§ 619.35 Selection criteria: projects based on energy conservation.

For construction, reconstruction, or renovation projects based on energy conservation (section 701(1) of the Act), the facilities panel applies the following criteria in addition to the criteria in § 619.32:

(a) *Use of coal, solar energy, and renewable resources.* (1) The extent to which an institution proposes to use one or more of the following: coal, solar energy, and renewable resources.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(b) *Estimated savings in annual operating costs.* (1) The extent to which the proposed project is likely to enable the institution to economize on the use of energy resources, based on an estimate of savings in annual operating costs.

(2) The estimated savings, if any, in annual operating costs are the difference between—

(i) The average routine operating expenses for the previous three years; and

(ii) Future annual operating exepenses based on the current prices of fuel supplies and related services.

(3) The Secretary awards up to a maximum of 20 points for this criterion.

§ 619.36 Selection criteria: projects to remove architectural barriers.

For reconstruction or renovation projects to remove architectural barriers (section 701(2) (A) and (B) of the Act), the facilities panel applies the following criteria in addition to the criteria in § 619.32:

(a) Exemplary program of compliance with Section 504.

(1) The extent to which a proposed project holds promise of accomplishing an exemplary program of compliance with Section 504 that would be helpful to similar institutions around the country and that would not likely be carried out in the absence of Federal funds.

(2) The Secretary awards up to a maximum of 10 points for this criterion.

(House Report 96–520, page 54)

(b) *Amount of assignable square feet of academic facilities to be made accessible by the proposed project.* (1) The amount of assignable square feet of academic facilities to be made accessible to the handicapped by the proposed project.

(2) The Secretary awards up to a maximum of 10 points for this criterion.

(c) *Percentage of assignable square feet of academic facilities to be made accessible by the proposed project.* (1)

The percentage of assignable square feet of academic space—on the applicant's campus—to be made accessible to the handicapped by the proposed project.

(2) The Secretary awards up to a maximum of 10 points for this criterion.

(d) Costs required by Section 504 per full-time-equivalent student enrollment.

(1) The costs required by Section 504 per full-time-equivalent student enrollment.

(2) The Secretary awards up to a maximum of 10 points for this criterion.

(20 U.S.C. 1132c(b); 1132a(2)(A) and (B))

§ 619.37 Selection criteria: projects to meet environmental protection or health and safety programs mandated by law.

For reconstruction or renovation projects to meet environmental protection or health and safety programs mandated by Federal, State, or local law (section 701(2)(C) of the Act), the facilities panel applies the following criteria in addition to the criteria in § 619.32:

(a) *Campus-wide cost per full-time-equivalent student.* (1) The campus-wide cost—per full-time-equivalent student—of complying with the law.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(b) *Campus-wide cost per square foot of assignable space.* (1) The campus-wide cost—per square foot of assignable space—of complying with the law.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(20 U.S.C. 1132c(b); 1132a(2) (A) and (B))

§ 619.38 Selection criteria: projects to detect, remove, or contain asbestos hazards.

For reconstruction or renovation projects to detect, remove, or contain asbestos hazards (section 701(5) of the Act), the facilities panel applies the following criteria in addition to the criteria in § 619.32:

(a) *Amount of gross square feet of facilities space with known or suspected asbestos hazards.* (1) The amount of gross square feet of facilities space with known or suspected asbestos hazards.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(b) *Estimated cost of detecting, removing, or containing asbestos hazards.* (1) The estimated cost of one or more of the following: detecting, removing, or containing asbestos hazards.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(20 U.S.C. 1132c(b); 1132(a)(5))

§ 619.39 Selection criteria: projects directed to two or more purposes.

If a project is directed to a combination of two or more of the purposes under section 701 of the Act, the facilities panel in addition to applying the criteria in § 619.32, applies the following criteria in place of the criteria in 619.33–619.38:

(a) *Readiness to commence project.* (1) The timeliness by which an applicant can state its project.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(b) *The cost of the project as a percentage of the applicant's average annual educational and general expenditures.* (1) The cost of the project as a percentage of the applicant's average annual educational and general expenditures, as reported in the annual NCES Survey "Financial Statistics of Institutions of Higher Education," for the three most recent institutional fiscal years.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(20 U.S.C. 1132c(b); 1132a)

§ 619.40 Applications with identical scores.

If the facilities panel assigns identical total scores to two or more applications, the Secretary assigns priority on the basis of the projected date for the start of construction, reconstruction, or renovation, with the project having the earliest date receiving the highest priority.

(20 U.S.C. 1132c)

The Secretary proposes to add a new Part 620 to Title 34 of the Code of Federal Regulations to read as follows:

PART 620—LOANS FOR THE CONSTRUCTION, RECONSTRUCTION, AND RENOVATION OF ACADEMIC FACILITIES

Subpart A—General

Sec.

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

Subpart C—How Does One Apply for a Loan?

Subpart D—How Does the Secretary Make a Loan?

Subpart E—What Conditions Must Be Met by a Borrower?

Authority: Secs. 701–742 of Pub. L. 96–374, Title VII of the Higher Education Act, as amended, (20 U.S.C. 1132a–1132e–1) unless otherwise noted.

Subpart A—General

§ 620.1 Loans for the construction, reconstruction, and renovation of academic facilities.

This program provides loans for the construction, reconstruction, and renovation of academic facilities.

(20 U.S.C. 1132d–1132d–2)

§ 620.2 Eligible parties.

The following are eligible to apply for loans for the construction, reconstruction, and renovation of academic facilities:

(a) Institutions of higher education.

(b) Higher education building agencies.

(20 U.S.C. 1132d(a))

§ 620.3 Regulations that apply to loans for the construction, reconstruction, and renovation of academic facilities.

The following regulations apply to this program:

(a) The regulations in 34 CFR 617.6 (b) through (e), as appropriate.

(b) The regulations in this Part 620.

(20 U.S.C. 1232)

§ 620.4 Definitions that apply to loans for the construction, reconstruction, and renovation of academic facilities.

The definitions in 34 CFR 617.7 apply to this program.

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

§ 620.10 Projects for which loans may be used.

This program provides loans for the construction, reconstruction, and renovation of graduate and undergraduate academic facilities if the primary purpose of an applicant's proposed project is to achieve one or more of the objectives listed in 34 CFR 617.10.

(20 U.S.C. 1132d; 1132a)

Subpart C—How Does One Apply for a Loan?

§ 620.20 Submission of application.

An applicant for a loan shall submit its application at the time, in the manner, and containing the information that the Secretary specifies.

(20 U.S.C. 1132d)

§ 620.21 Special application procedures.

(a) An applicant shall send a copy of its application to its State commission before submitting the application to the Secretary.

(b) The commission shall review and evaluate the application and provide comments to the Secretary regarding—

(1) Use of space;

(2) Enrollment data; and

(3) The overall need for the facility—or for the reconstruction or renovation of the facility—for which the applicant has requested assistance.

(c) Following its review, the commission shall furnish its evaluation to the applicant.

(d) If the applicant does not agree with the evaluation, the applicant may include with its application to the Secretary a statement supporting its position.

(e) The commission shall submit the application to the Secretary together with all State clearinghouse comments required by OMB Circular A–95.

(20 U.S.C. 1132d(a))

§ 620.22 Special terms and conditions.

The applicant shall submit to the Secretary, together with its application, the following evidence and assurances:

(a) Satisfactory evidence that the applicant has or will have a full title or interest in the site, including right of access, that is sufficient to insure the applicant's undisturbed use and possession of the facilities for not less than the useful life of the facilities or 50 years, whichever is longer.

(b) Satisfactory assurance that if the Secretary grants the loan and the applicant accepts the loan, the applicant will comply with the appropriate terms and conditions for repayment of the loan.

(c) Satisfactory assurance that the applicant will secure the loan in a manner the Secretary finds will reasonably assure repayment. The security may be one or a combination of the items listed in § 620.34.

(d) Satisfactory evidence that the applicant has the necessary legal authority to—

(1) Finance; construct, reconstruct, or renovate, and maintain the proposed facilities;

(2) Apply for and receive the proposed loan; and

(3) Pledge or mortgage any assets or revenues to be given as security for the proposed loan.

(e) Satisfactory assurance that the applicant will not, without the consent of the Secretary, mortgage to others during the life of the loan the facility constructed, reconstructed, or renovated with the aid of the loan.

(f)(1) Satisfactory assurance that the applicant will finance not less than 20 percent of the development cost of the facility from non-Federal sources.

(2) However, the Secretary waives this assurance for an institution that is eligible for assistance under Title III of the Act.

(20 U.S.C. 1132d(a))

§ 620.23 Opinion of bond counsel.

(a) At appropriate stages in a loan application and development procedure, an applicant shall submit—or arrange to have submitted—to the Secretary opinions of bond counsel—or of legal counsel, as provided in paragraph (d) of this section—with respect to—

(1) The legality of the bond or note issue that the applicant proposes to offer to secure the loan;

(2) The legal authority of the applicant to offer the issues and secure it by the proposed collateral; and

(3) The legality of the issue on delivery.

(b) As used in this section, "bond counsel" means a law firm or individual lawyer—

(1) Who is thoroughly experienced in the financing of construction, reconstruction, and renovation projects by the issuance of bonds;

(2) Whose approving opinions have previously been accepted by purchasers of bonds offered at public sales; and

(3) Who, if the borrower is a public institution or agency, is a recognized bond counsel in the municipal field.

(c) In each case the applicant shall present the following:

(1) A memorandum by the counsel, submitted with the loan application—

(i) Stating that the applicant has or will have authority to—

(A) Finance, construct, and maintain the project;

(B) Issue the proposed obligations; and

(C) Pledge or mortgage the assets or revenues that the applicant is offering to secure the loan; and

(ii) Citing the basis for the authority referred to in paragraph (C)(1)(i) of this section.

(2) A preliminary approving opinion of the counsel—submitted at the time the applicant proposes to advertise for bids for construction, reconstruction, or renovation—to the effect that when the bonds or notes described in the loan agreement are sold and delivered, they will—

(i) Comply with the applicable provisions of the loan agreement; and

(ii) Be valid and binding obligations of the issuer payable in accordance with their terms.

(3) A final approving opinion of the counsel—delivered at the same time as the delivery of the bonds or notes—stating that the bonds or notes—

(i) Are those described in the loan agreement and the authorizing proceedings;

(ii) Have been duly authorized, sold, and delivered to the Secretary; and

(iii) Constitute the valid and binding obligations of the issuer payable in accordance with their terms.

(d)(1) The Secretary may accept the opinion of legal counsel, other than a bond counsel as defined in paragraph (b) of this section, after considering such factors as—

(i) The amount, term, and security for the loan; and

(ii) The legal or financial complexity of the transaction.

(2) As used in paragraph (d)(1) of this section, "Legal counsel" means a law firm or individual lawyer—

(i) Having experience in the financing of construction, reconstruction, and renovation projects; and

(ii) Whose opinions with regard to that type of financing have been previously accepted by responsible lenders of lending institutions.

(20 U.S.C. 1132d-1(b)(1))

§ 620.24 Invitation for bids.

(a) An applicant may not invite bids for construction, reconstruction, or renovation under its proposed project before submitting its application to the Secretary.

(b)(1) However, paragraph (a) of this section does not apply if—

(i) The Secretary has already approved assistance for the project under Title VII; or

(ii) Some other agency of the United States has already approved assistance for the project under some other Federal assistance program.

(2) In that case the Secretary considers the application only if the applicant submits it in response to an application notice occurring no later than 12 months after the applicant has begun the construction, reconstruction, or renovation.

(20 U.S.C. 1132d-1(b)(1))

Subpart D—How Does the Secretary Make a Loan?

§ 620.30 Selection criteria for evaluating proposed projects.

In evaluating a proposed project for which an applicant has applied for a loan under this program, the Secretary takes into consideration—

(a) The criterion in 620.31, worth up to 20 possible points; and

(b) As applicable, the criteria in §§ 620.32, 620.33, 620.34, 620.35, 620.36, 620.37, or 620.38, worth up to 80 possible points.

§ 620.31 Selection criterion: general.

(a) Among the criteria for evaluating a proposed project under this program, the Secretary considers the extent to which the applicant makes effective use of its existing facilities.

(b) The Secretary awards up to a mximum of 20 points for this criterion.

(20 U.S.C. 1132d; 1132a)

§ 620.32 Selection criteria: projects based on unusual increases in enrollment.

For construction, reconstruction, or renovation projects dealing with unusual increases in enrollment (section 701(4) of the Act), the Secretary applies the following criteria in addition to the criterion in § 620.31:

(a) *Increase in enrollment.*

(1) The extent of the actual numerical or percentage increase, or both, in full-time-equivalent student enrollment at the campus at which the construction, reconstruction, or renovation is to take place.

(2) The Increase is measured by covering three years separately, starting with the year that began three years preceding the closing date for which the applicaiton is being considered.

(3) The Secretary awards up to a maximum of 40 points for this criterion.

(b) Increase in capacity.

(1) The amount of percentage, or both, by which the proposed project will increase the assignable area at that campus.

(2) The Secretary awards up to a maximum of 40 points for this criterion.

(20 U.S.C. 1132d; 1132a(4))

§ 620.33 Selection criteria: projects dealing with research facilities, including libraries, and the acquisition of special research equipment.

For construction, reconstruction, or renovation projects dealing with research facilities, including libraries, and the acquisition of special research equipment (section 701 (3) of the Act), the Secretary applies the following criteria in addition to the criterion in § 620.31:

(a) *Amount of research space to be upgraded.* (1) The amount of research space to be upgraded by the proposed project.

(2) The Secretary awards up to a maximum of 40 points for this criterion.

(b) *Percentage of research space to be upgraded.* (1) The percentage of the applicant's research space—on that campus—that is to be upgraded by the proposed project.

(2) The Secretary awards up to a maximum of 40 points for this criterion.

(20 U.S.C. 1132d; 1132a(3))

§ 620.34 Selection criteria: projects based on energy conservation.

For construction, reconstruction, or renovation projects dealing with energy conservation (section 701(1) of the Act), the Secretary applies the following criteria in addition to the criterion in § 620.31:

(a) *Use of coal, solar energy, and renewable resources.* (1) The extent to which an institution proposes to use one or more of the following: coal, solar energy, and renewable resources.

(2) The Secretary awards up to a maximum of 40 points for this criterion.

(b) *Estimated savings in annual operating costs.* The extent to which the proposed project is likely to enable the institution to economize on the use of energy resources, based on an estimate of savings in annual operating costs.

(2) The estimated savings, if any, in annual operating costs are the difference between—

(i) The average routine operating expenses for the previous three years; and

(ii) Future annual operating expenses based on the current prices of fuel supplies and related services.

(3) The Secretary awards up to a maximum of 40 points for this criterion.

(20 U.S.C. 1132d; 1132a(1))

§ 620.35 Selection criteria: projects to remove architectural barriers.

For reconstruction or renovation projects to remove architectural barriers (section 701(2)(A) and (B) of the Act), the Secretary applies the following criteria in addition to the criterion in § 620.31:

(a) *Exemplary program of compliance with Section 504.* The extent to which a proposed project holds promise of accomplishing an exemplary program of compliance with Section 504 that would be helpful to similar institutions around the country and that would not likely be carried out in the absence of Federal funds.

(House Report 96-520, page 54)

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(b) *Amount of assignable square feet of academic facilities to be made accessible by the proposed project.*

(1) The amount of assignable square feet of academic facilities to be made accessible to the handicapped by the proposed project.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(c) *Percentage of assignable square feet of academic facilities to be made accessible by the proposed project.*

(1) The percentage of assignable square feet of academic space—on the applicant's campus—to be made accessible to the handicapped by the proposed project.

(2) The Secretary awards up to a maximum of 20 points for this criterion.

(d) *Costs required by Section 504 per full-time-equivalent student enrollment.* (1) The costs required by Section 504 per full-time-equivalent student enrollment.

(2) The Secretary awards up to a maximum of 20 points this criterion.

(20 U.S.C. 1132d; 1132a(2)(A) and (B))

§ 620.36 Selection criteria: projects to meet environmental protection or health and safety programs mandated by law.

For reconstruction or renovation projects to meet environmental protection or health and safety programs mandated by Federal, State, or local law (section 701(2)(C) of the Act), the Secretary applies the following criteria in addition to the criterion in § 620.31:

(a) *Campuswide cost per full-time-equivalent student.* (1) The campuswide cost—per full-time-equivalent student—of complying with the law.

(2) The Secretary awards up to a maximum of 40 points for this criterion.

(b) *Campuswide cost per square foot of assignable space.* (1) The campuswide cost—per square foot of assignable space—of complying with the law.

(2) The Secretary awards up to a maximum of 40 points for this criterion.

§ 620.37 Selection criteria: projects to detect, remove, or contain asbestos hazards.

For reconstruction or renovation projects to detect, remove, or contain asbestos hazards (section 701(5) of the Act), the Secretary applies the following criteria in addition to the criterion in § 620.31:

(a) *Amount of gross square feet of facilities space with known or suspected asbestos hazards.* (1) The amount of gross square feet of facilities space with known or suspected asbestos hazards.

(2) The Secretary awards up to a maximum of 40 points for this criterion.

(b) *Estimated cost of detecting, removing, or containing asbestos hazards.* (1) The estimated cost—per campuswide assignable square foot—of one or more of the following: detecting, removing, or containing asbestos hazards.

(2) The Secretary awards up to a maximum of 40 points for this criterion.

§ 620.38 Selection criteria: projects directed to two or more purposes.

If a project is directed to a combination of two or more of the purposes under section 701 of the Act, the Secretary, in addition to applying the criterion in § 620.30, applies the following criterion in place of the criteria in §§ 620.31–630.37:

(a) *Readiness to commence project.* (1) The timeliness by which an applicant can start its project.

(2) The Secretary awards up to a maximum of 40 points for this criterion.

(b) *The cost of the project as a percentage of the applicant's average annual educational and general expenditures.* The cost of the project as a percentage of the applicant's average annual educational and general expenditures, as reported in the annual NCES Survey "Financial Statistics of Institutions of Higher Education," for the three most recent institutional fiscal years.

(2) The Secretary awards up to a maximum of 40 points for this criterion.

(20 U.S.C. 1132d; 1132a)

§ 620.39 Ranking applications with identical scores.

If two or more applications receive equal total scores, the Secretary gives priority consideration to the following types of applicants in this order:

(a) An institution eligible for assistance under Title III of the Act.

(b) An institution with the earliest date for the start of construction, reconstruction, or renovation.

(20 U.S.C. 1132d–1(b)(1))

§ 620.40 Determination of non-availability of equally-as-favorable terms and conditions.

(a) The Secretary considers making a loan only if the Secretary finds that the applicant is unable to secure from other sources a loan with terms and conditions equally as favorable as the terms and conditions applicable to loans under this part.

(b) In order to assist the Secretary in making this determination, the applicant shall comply with any procedures the Secretary may establish, including public advertising for bids.

(20 U.S.C. 1132d(a)(2))

§ 620.41 Loan offer.

(a) The Secretary prepares and sends a loan offer to an applicant if—

(1) The application meets all requirements of the Act and the regulations governing administration of the Act; and

(2) The Secretary approves the project and reserves funds for it.

(b) The loan offer—

(1) Contains the terms and conditions for the loan; and

(2) Is conditioned on the fulfillment of these terms and conditions.

(20 U.S.C. 1132d(a))

§ 620.41 Loan agreement.

The accepted loan offer constitutes the loan agreement between the Secretary and the applicant for the partial financing of the construction, reconstruction, or renovation of the approved project.

(20 U.S.C. 1132d(a))

§ 620.42 Security for loan.

At the time of accepting a loan offer, a borrower shall secure the loan in a manner the Secretary finds will reasonably assure repayment. The security may be one or a combination of the following:

(a) A first mortgage on the facilities and site of those facilities.

(b) Negotiable stocks or bonds of a quality and value acceptable to the Secretary.

(c) A pledge of unrestricted and unencumbered income from an endowment or other trust fund acceptable to the Secretary.

(d) A pledge of a specified portion of the applicant's annual general or special revenues acceptable to the Secretary.

(e) General obligations issued by a State or local public body on behalf of the applicant.

(f) Other types of security that the Secretary finds acceptable in specific instances.

(20 U.S.C. 1132d–1(b)(6))

§ 620.44 Evidence of approved debt instrument.

(a) After signifying to the Secretary its acceptance of a loan offer, a borrower shall furnish to the Secretary the approved debt instrument in the form the Secretary prescribes in the loan agreement and in the terms and conditions of the loan agreement.

(b) The approved debt instrument referred to in paragraph (a) of this section shall include—

(1) A recorded copy of the executed trust indenture between the borrower and the trustee institution or other paying agent; and

(2) The bond, note, or other security approved by the Secretary.

(20 U.S.C. 1132d–(b)(1))

§ 620.45 Loan closing.

Loan closing occurs at a time determined by the Secretary.

(20 U.S.C. 1132d–1(b)(1))

§ 620.46 Interim financing.

(a) If necessary, an applicant shall arrange for interim financing, subject to the approval of the Secretary, to cover the cost of construction, reconstruction, or renovation pending the loan closing.

(b) If the Secretary finds that the applicant is unable to secure necessary interim financing on reasonable terms, the Secretary may provide for advances against the approved loan.

(20 U.S.C. 1132d–1(b)(1))

Subpart E—What Conditions Must Be Met by a Borrower?

§ 620.50 Length and maturity of loan.

(a) The maximum repayment period for a loan under this program shall be 30 years, unless the Secretary finds that a longer repayment period required.

(b) In no case may a loan repayment period exceed the estimated useful life of the facilities to be constructed, reconstructed, or renovated with the aid of the loan.

(c) Unless the Secretary authorizes otherwise, the borrower shall repay the loan in substantially level annual installments of principal and interest.

(d) The Secretary may approve a loan that does not mature serially if that type of loan is necessary to be compatible with an applicant's total financial planning.

(20 U.S.C. 1132d(b))

§ 620.51 Construction funds.

(a)(1) A borrower shall deposit in a separate bank account—

(i) The proceeds of the sale of the bonds or notes;

(ii) Any interim advances against the approved loans; and

(iii) All other money that the borrower will use in paying for the construction, reconstruction, or renovation of the approved project.

(2) The separate account shall be known as the construction fund.

(3) The borrower shall keep this account in a bank of its choice.

(4) The borrower shall make all expenditures for the construction, reconstruction, or renovation from this fund.

(5) Accounting for this fund shall be in accordance with accepted accounting principles.

(b)(1) If necessary and appropriate, the Secretary may approve other arrangements for—

(i) The deposit of construction funds; and

(ii) The accounting for those funds.

(2) Those other arrangements must provide adequate accountability for all receipts to and expenditures from the funds.

(20 U.S.C. 1132d-1(b)(1))

§ 620.52 Investment of idle construction funds.

(a) If the money on deposit in the construction fund exceeds the estimated disbursements for the project for the next 90 days, the Secretary encourages the borrower—if permitted by State or local law—to invest those excess funds.

(b) If the borrower chooses to invest the funds referred to in paragraph (a) of this section, the borrower—unless otherwise prohibited by State of local law—shall invest those funds in—

(1) Direct obligations of the U.S. Government; or

(2) Obligations whose principal and interest are guaranteed by the U.S. Government.

(c) An investment made in accordance with paragraph (b) of this section shall be in obligations that will mature not later than 18 months from the date of the investment.

(20 U.S.C. 1132d-1(b)(1))

§ 620.53 Disposal of balance remaining in the construction fund.

Upon full settlement with all contractors, suppliers, and the other parties to whom it has incurred obligations under the project, the borrower shall dispose of any money remaining in the construction fund in accordance with the provisions of the loan agreement.

(20 U.S.C. 1132d-1(b)(1))

§ 620.54 Moratorium on principal or interest payments on a loan.

A borrower may request—and the Secretary may approve—a moratorium on the repayment of principal and interest installments on a loan if the borrower—

(a) Can demonstrate a temporary inability to make those payments without undue financial hardship; and

(b) Furnishes, in a plan acceptable to the Secretary, a specific schedule for repayment of the amounts in arrears. However, the Secretary may permit the borrower to defer submission of the plan if the borrower—

(1) Clearly demonstrates that it cannot reasonably project a specific repayment schedule due to circumstances beyond its control; and

(2) Satisfactorily assures the Secretary that it will develop a repayment schedule for consideration at a future date that the Secretary designates.

(20 U.S.C. 1132d-1(b)(5))

The Secretary proposes to add a new Part 621 to Title 34 of the Code of Federal Regulations to read as follows:

PART 621—ANNUAL INTEREST GRANTS FOR THE CONSTRUCTION, RECONSTRUCTION, AND RENOVATION OF ACADEMIC FACILITIES

Subpart A—General

Sec.

Subpart B—What Kinds of Projects Does the Department of Education Assist under This Program?

Subpart C—How Does One Apply for an Annual Interest Grant?

Subpart D—How Does the Secretary Make an Annual Interest Grant?

Subpart E—What Conditions Must Be Met by a Grantee?

Authority: Secs. 701–742 of Pub. L. 96–374, Title VII of the Higher Education Act, as amended (20 U.S.C. 1132a–1132e–1) unless otherwise noted.

Subpart A—General

§ 621.1 Annual interest grants for the construction, reconstruction, and renovation of academic facilities.

This program provides annual interest grants to reduce the cost of borrowing funds—other than those available under 34 CFR Part 620—for the construction, reconstruction, and renovation of academic facilities.

(20 U.S.C. 1132d-3)

§ 621.2 Eligible parties.

(a) The following are eligible to apply for annual interest grants for the construction, reconstruction, and renovation of academic facilities:

(1) Institutions of higher education.

(2) Higher education building agencies.

(20 U.S.C. 1132d-3(a))

§ 621.3 Regulations that apply to annual interest grants for the construction, reconstruction, and renovation of academic facilities.

The following regulations apply to this program:

(a) The regulations in 34 CFR 617.5(b) through (e), as appropriate.

(b) The regulations in 34 CFR 620.31 through 620.39.

(c) The regulations in this Part 621.

(20 U.S.C. 1232)

§ 621.4 Definitions that apply to annual interest grants for the construction, reconstruction, and renovation of academic facilities.

The definitions in 34 CFR 617.7 apply to this program.

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

§ 621.10 Projects for which annual interest grants may be used.

This program provides annual interest grants to reduce the cost of borrowing funds—other than those available under 34 CFR Part 620—for the construction, reconstruction, or renovation of academic facilities if the primary purpose of an applicant's proposed project is to achieve one or more of the objectives listed in 34 CFR 617.10.

(20 U.S.C. 1132d-3)

Subpart C—How Does One Apply for an Annual Interest Grant?

§ 621.20 Application dates.

The Secretary publishes an application notice in the **Federal Register** establishing the date for submission of applications for annual interest grants.

(20 U.S.C. 1132d-3)

§ 621.21 Submission of application.

An applicant for an annual interest grant shall submit its application at the time, in the manner, and containing the information that the Secretary specifies.

§ 621.22 Special application procedure.

(a) An applicant shall send a copy of its application to its State commission before submitting the application to the Secretary.

(b) The commission shall review and evaluate the application and provide comments to the Secretary regarding—

(1) Use of space;

(2) Enrollment data; and

(3) The overall need for the facility—or for the reconstruction or renovation of the facility for which the applicant has requested assistance.

(c) Following its review the commission shall furnish its evaluation to the applicant.

(d) If the applicant does not agree with the evaluation, the applicant may include with its application to the Secretary a statement supporting its position.

(e) The commission shall submit the application to the Secretary, together with all State clearinghouse comments required by OMB Circular A-95.

(f) The applicant may not invite bids under the project before submitting its application to the Secretary.

(20 U.S.C. 1132d-3)

§ 621.23 Approvable financing plan.

(a) Except as provided in paragraph (b) of this section, in order to be approved by the Secretary, a financing plan submitted under this program must—

(1) Provide that the terms of the loan for which the applicant requests an annual interest grant does not exceed the lesser of—

(i) Thirty years; or

(ii) The useful life of the facilities that the applicant proposes to construct, reconstruct, or renovate with the help of the loan;

(2) Provide that the borrower is to repay the loan in substantially level annual installments of interest and principal over the term of the loan, except that the borrower may pay interest only for an initial period not exceeding five years; and

(3) Contain other provisions that will assure the Secretary that the support provided by the Secretary over the term of the loan is no more than is necessary to carry out the purposes of this program.

(b)(1) If the Secretary finds that unusual circumstances warrant an exception, the Secretary may accept a financing plan related to a loan for which—

(i) The term is longer than 30 years;

(ii) The annual installments of interest and principal are not substantially level; or

(iii) Both.

(2) However, the term of a loan otherwise eligible for assistance under this subpart may not exceed 40 years.

(20 U.S.C. 1132d-3(a))

§ 621.24 Evidence of lowest possible cost of loan.

(a) An applicant shall demonstrate to the satisfaction of the Secretary that the loan it proposes to obtain is at the lowest possible net interest cost.

(b)(1) If an applicant proposes to issue tax-exempt bonds to finance the construction, reconstruction, or renovation of academic facilities, the Secretary considers the applicant to meet the requirement in paragraph (a) of this section if the applicant proposes to sell those securities after publicly advertising for bids for the securities in an advertising medium acceptable to the Secretary.

(2) Before advertising these bonds for sale, the applicant shall submit for the Secretary's approval—

(i) A draft of the notice of sale; and

(ii) A statement of essential facts concerning the sale.

(c)(1) An applicant proposing to issue securities that are not tax-exempt shall submit to the Secretary offers from at least three lending institutions normally engaged in making long-term construction, reconstruction, and renovation loans.

(2) The applicant shall have given each of those institutions the information necessary to enable it to specify in its offer the—

(i) Amount of the loan;

(ii) Interest rate;

(iii) Maturity period;

(iv) Security provisions; and

(v) Repayment provisions.

(d) The applicant—whether proposing to issue tax-exempt bonds or proposing to issue securities that are not tax-exempt—may not enter into a firm and binding agreement with a lender before the Secretary has approved the loan offer.

(20 U.S.C. 1132d-3(c))

§ 621.25 Invitation for bids.

(a) An applicant may not invite bids for construction, reconstruction, or renovation under its proposed project before submitting its application to the Secretary.

(b)(1) However, paragraph (a) of this section does not apply if—

(i) The Secretary has already approved assistance for the project under Title VII; or

(ii) Some other agency of the United States has already approved assistance for the project under some other Federal assistance program.

(2) In that case the Secretary considers the application only if the applicant submits it in response to an application notice occurring no later than 12 months after the applicant has begun the construction, reconstruction, or renovation.

(20 U.S.C. 1132d-3)

Subpart D.—How Does the Secretary Make an Annual Interest Grant?

§ 621.30 Selection criteria for evaluating a proposed project.

(a) In evaluating a proposed project for which an applicant has applied for an annual interest grant under this program, the Secretary applies—

(1) The criterion in 34 CFR 620.31, worth up to 20 possible points;

(2) As applicable, the criteria in 34 CFR 620.32, 620.33, 620.34, 620.35, 620.36, 620.37, or 620.38, worth up to 80 possible points; and

(3) For ranking applications with identical scores, the priority considerations in 34 CFR 620.39.

(b) In applying the criteria referred to in paragraph (a) of this section, the Secretary awards the same maximum possible points as those contained in 34 CFR 620.31 through 620.38.

(20 U.S.C. 1132d-3)

§ 621.31 Conditions for approval of annual interest grants.

The Secretary approves an application for annual interest grants only if the Secretary is satisfied that—

(a) The applicant will have available, as required, funds to pay the total development cost of the facilities;

(b) The applicant has or will have a full title or interest in the site, including right of access, that is sufficient to insure the applicant's undisturbed use and possession of the facilities for not less than the useful life of the facilities or 50 years, whichever is longer;

(c) The applicant has the necessary legal authority to—

(1) Finance; construct, reconstruct, or renovate; and maintain the proposed facilities;

(2) Apply for and receive the proposed loan and annual interest grants; and

(3) Pledge or mortgage any assets or revenues to be given as security for the proposed loan; and

(d) The applicant's financing plan meets the conditions of § 621.22 and is otherwise practicable and feasible.

(20 U.S.C. 1132d–3)

§ 621.32 Conditions for making an annual interest grant.

(a)(1) The Secretary considers making an annual interest grant only if the applicant is unable to secure from other sources a loan—up to the amount the Secretary may subsidize under the law—with an interest rate equally as favorable as the rate applicable to direct Federal loans under section 734 of the Act.

(2) In order to assist the Secretary in making this determination, the applicant shall comply with any procedures the Secretary may establish, including public advertising for bids.

(b) The Secretary does not make an annual interest grant for a loan if a borrower is legally obligated under that loan before it has filed an application under this program.

(20 U.S.C. 1132d–3(d)(2))

§ 621.33 Annual interest grant agreement.

(a)(1) After approving an application for an annual interest grant, the Secretary prepares and sends to the applicant a proposed agreement containing the terms and conditions of the grant.

(2) The Secretary enters into this agreement for the benefit of the applicant institution only.

(b) The proposed agreement provides that the Secretary does not make any grant payments under the agreement unless the Secretary concurs in the rate of interest and other terms and conditions of the loan.

(c)(1) The applicant may not enter into the agreement—

(i) For the benefit of third parties; or

(ii) To induce—

(A) The making of loans by third parties; or

(B) The sale of bonds to third parties;

(2) The Secretary does not entertain grievances or claims of third parties with respect to the agreement between the Secretary and the applicant institution.

(20 U.S.C. 1132d–3)

§ 621.34 Amount of annual interest grant.

(a) Each interest grant that the Secretary makes is approximately equal to, but not more than, the difference between—

(1) The average annual debt service that the borrower is required to pay on the amount borrowed from private sources for the project covered by the application; and

(2) An average annual debt service on the same amount at an interest rate of four percent.

(b) The Secretary may amend the amount of the annual interest grant stipulated in the agreement to reflect changes in the amount or terms of the loan.

(c)(1) If the borrower increases its loan, it may request of the Secretary an increase in the amount of its annual interest grant.

(2) The borrower must make this request—

(i) Not later than 12 months after it has begun construction, reconstruction, or renovation; and

(ii) By submitting to the Secretary an amended application.

(3) The Secretary considers the request subject to the availability of funds.

(d) If, at the time the borrower becomes legally obligated under a loan, there has been a change in the rate of interest or the terms of the loan, the borrower may request of the Secretary an increase in the amount of its annual interest grant.

(20 U.S.C. 1132d–2(a))

§ 621.35 Limits of Federal assistance.

(a) The principal amount of a loan—or portion of a loan—on which the Secretary approves an annual interest grant, together with the amount of any other Federal financial assistance the applicant has obtained or is assured of obtaining under any other Federal program, may not exceed 90 percent of the eligible development costs.

(20 U.S.C. 1132d–3(d)(1))

(b) The aggregate principal amount of loans—or portions of loans—on which the Secretary approves annual interest grants does not exceed $5 million per campus for a Federal fiscal year.

(20 U.S.C. 1132d–3)

§ 621.36 Payment of annual interest grant.

(a) The Secretary makes payments under an annual interest grant agreement once a year.

(b) The date of payment coincides as closely as possible with—

(1) The anniversary date of the loan; or

(2) The date when debt service requirement related to the loan is greatest.

(c) The payment date remains fixed for the duration of the loan.

(d) The Secretary pays an annual interest grant—

(1) Directly to the grantee; or

(2) To a trustee, paying agent, or lender to whom the grantee assigns the payment with the permission of the Secretary.

(20 U.S.C. 1132d–3)

§ 621.37 Preceding provisions not exhaustive of authority of the Secretary.

The provisions of this Subpart D do not exhaust the authority of the Secretary to impose, at any time the Secretary considers appropriate, additional limitations with regard to—

(a) The amount of an annual interest grant; or

(b) The amount on which that grant is based.

(20 U.S.C. 1132d–3)

Subpart E—What Conditions Must Be Met by a Grantee?

§ 621.40 Reduction of grant if refinancing produces lower costs.

If the Secretary finds that a grantee could have accelerated repayment of an outstanding loan or obtained a new loan that would have resulted in a net savings in the cost of the loan, the Secretary may recompute the amount of the annual interest grant as though the grantee had undertaken that refinancing.

(20 U.S.C. 1132d–3)

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Part XI

Department of Health and Human Services

Food and Drug Administration

Infant Formula Quality Control Procedures; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 106

[Docket No. 80N-0025]

Infant Formula Quality Control Procedures

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: In accordance with the Infant Formula Act of 1980 (Pub. L. 96-359; 94 Stat. 1190), the Food and Drug Administration (FDA) is proposing to establish a new Part 106 (21 CFR Part 106) that requires quality control procedures for the manufacture of infant formula products. The proposed regulations specify a systematic procedure of sampling, testing, analyses, and recordkeeping for in-process and finished formulas and require manufacturers to establish the following: an acceptance protocal for ingredients assuring that they conform to strict specifications for composition and purity; and in-process operational control program of ingredient addition, blending, homogenization, and standardization; and a finished product evaluation system that specifies sampling frequency and an analytical format that defines product release ranges at which the product may be shipped. This proposal ensures that infant formula products contain the necessary nutrients at the specified levels as required by the Infant Formula Act of 1980.

DATES: Comments by March 2, 1981. Proposed compliance date for all affected products initially introduced or initially delivered for introduction in interstate commerce or prepared from raw materials shipped in interstate commerce is 180 days after date of publication of the final regulation.

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fisher Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Edward Scarbrough, Bureau of Foods (HFF-204), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-3117.

SUPPLEMENTARY INFORMATION: In 1978 a major manufacturer of soy protein-based infant formulas reformulated two of its products. The reformulation resulted in products containing an inadequate amount of the essential nutrient, chloride. By 1979 a substantial number of cases concerning a medical disorder, known as hypochloremic metabolic alkalosis, were reported. This serious medical condition is most frequently characterized by the infant's failure to thrive. These cases of infant illness were found to be associated with prolonged exclusive use of the chloride-deficient soy formulas. This incident made it clear that greater regulatory control over the formulation and processing of infant formulas was necessary.

In response to the chloride-deficient soy formula occurrence, the Commissioner of Food and Drugs contacted members of the infant formula industry requesting information concerning quality assurance and quality control procedures and nutrient analytical methodology. After the submission of these data, the agency, held an open public meeting and an informal public hearing on the general issues of infant formula processing, testing, composition, and safety (see the **Federal Register** of January 29, 1980; 45 FR 6702). The meeting was conducted in Washington, DC on February 19, 1980, to obtain public comment on the issues of open date labeling, quality control and quality assurance practices, and clinical testing needs for infant formulas. The hearing, also in Washington, DC, was conducted on March 12, 1980, and gathered public comment on the adequacy of the current nutrient composition of infact formulas and whether revision of FDA's infant formula nutritional labeling regulation, 21 CFR 105.65, was necessary. The comments relevant to the proposed quality control procedure regulations which were received in response to these public proceedings are on file with the Dockets Management Branch under the docket number set forth above.

The Congress was also quick in recognizing the need for more stringent government control over these vital food products. As early as November 8, 1979, several legislative proposals, each entitled the Infant Formula Act of 1980, were introduced by various members of the U.S. House of Representatives, most notably by Messrs. Gore, Mottl, and Carter, and were referred to the House Subcommittee on Health and the Environment (Subcommittee). These proposals were intended to require a broad range regulatory scheme for infant formula products which included periodic testing, a statutory nutrient table, and recordkeeping requirements for assuring their safety and nutritional quality. Hearings on these proposals were conducted by the Subcommittee in February and March 1980. The final House bill, H.R. 6940, was considered by the Committee on Interstate and Foreign Commerce on April 16, 1980, and ordered reported by unanimous vote (see H.R. Rept. No. 96-936, 96th Cong., 2d Sess., p. 4 (May 12, 1980)).

Similar legislation to tighten regulatory control over infant formulas was introduced in the U.S. Senate by Messrs. Metzenbaum, Baucus, and Leahy on March 27, 1980. The Senate bill, S. 2490, was referred to the Committee on Labor and Human Resources (Committee). Hearings on the legislation were conducted by the Subcommittee on Health and Scientific Research on June 12 and August 5, 1980, and it adopted and accepted the House companion bill, H.R. 6940, with one amendment. On August 21, 1980, S. 2490 was ordered reported by the full Committee (see S. Rept. No. 96-916, 96th Cong., 2d Sess., p. 2 (August 26, 1980)).

Thereafter, this bill was passed by both Houses of Congress. On September 26, 1980, the President signed into law the Infant Formula Act of 1980 (Pub. L. 96-359, 94 Stat. 1190). This amendment to the Federal Food, Drug, and Cosmetic Act (the act) establishes a new section 412 (21 U.S.C. 350a) and creates a separate category of food designated as "infant formula." It requires that infant formulas meet specified standards of quality and safety. Section 412(g) of the act provides that an infant formula shall contain nutrients at specified levels in accordance with a table set forth therein. If a formula product, except for a special formula as defined in section 412(f) of the act, fails to contain the nutrients in the specified amounts, it is deemed adulterated under new section 412(a)(1)(A). In addition, if a formula, except for one defined in section 412(f), does not meet certain quality factor requirements (section 412(a)(1)(B)) or if a formula is not manufactured or processed in compliance with certain quality control procedures (section 412(a)(1)(C)), it is also deemed adulterated.

Section 412(a)(2)(D) of the new law gives the Secretary of Health and Human Services the authority to promulgate regulations* establishing:

> Such quality control procedures * * * necessary to assure that an infant formula provides nutrients in accordance with this section and establish requirements respecting the retention of records of procedures required under this clause (including maintaining necessary nutrient testing records) * * *. Quality control procedures prescribed by the Secretary shall include the

*This authority is delegated to the Commissioner of Food and Drugs, 21 CFR 5.1(a)(1).

periodic testing of infant formulas to determine whether they are in compliance with this section.

The legislative history describes the anticipated infant formula "quality control procedure" regulations in terms which encompass the entire manufacturing process:

> * * * Quality control procedures are those procedures which would assure proper manufacturing of formula products.
>
> Quality control procedures are not limited to those "good manufacturing practices" applicable to food. Quality control procedures are intended to insure that the safety and nutritional potency of a formula is built into the manufacturing process. This authority is necessary as the absence of quality control mechanisms was a major factor in the production and subsequent sale last year of two formula products critically deficient in chloride. Existing statutory authority in this area is inadequate as it is limited to assurances that infant formula is filth free and is manufactured in a sanitary facility. S. Rept. No. 96–916, 96th Cong., 2d Sess., pp. 5–6 (August 26, 1980); H.R. Rept. No. 96–936, 96th Cong. 2d Sess., pp. 6–7 (May 12, 1980).

It is therefore clear that such procedures for infant formulas are to be in addition to those procedures currently codified under the good manufacturing practice (GMP) regulations applicable to food sanitation (21 CFR Part 110) and the GMP requirements for low-acid canned foods (21 CFR Part 113).

Until the agency promulgates infant formula quality control procedure regulations, the new law requires manufacturers to test their formula products to assure their nutritional quality and safety and report to FDA every 90 days that their formulas provide nutrients required by the table in section 412(g) (see section 412(b)(1) of the act).

The Congress expected FDA to move expeditiously in proposing, promulgating, and establishing quality control procedures for the manufacturing of infant formulas. S. Rept. No. 96–916, 96th Cong., 2d Sess., p. 6 (August 26, 1980). Thus, the agency is now proposing to establish new Part 106 (21 CFR Part 106) specifying the infant formula quality control procedures. These procedures are applicable to the entire infant formula manufacturing process, from the receipt of ingredients until the finished infant formula is released for shipping.

A total quality control program for the manufacture of infant formulas is necessary to ensure that each batch of the formula is uniform in its composition and conforms to the requirements of section 412 of the act. These proposed regulations constitute a planned and systematic procedure of sampling, testing, and analysis which requires (1) an acceptance protocol for ingredients assuring that they conform to strict specifications for composition and purity; (2) an in-process operational control program of ingredient addition, blending, homogenization, and standardization; and, (3) a finished product evaluation system that specifies sampling frequency and an analytical format that defines the product release ranges at which the product may be shipped. These procedures necessarily include requirements for establishing and maintaining adequate quality control records to document that each formula meets the testing and nutrient requirements of section 412 of the act. In addition, the agency is including as a subpart to this proposal the notification format to be followed by manufacturers in reporting to FDA under those situations set forth at sections 412(b) and 412(c) of the act. Notice of these reporting procedures was published in the **Federal Register** of November 21, 1980 (45 FR 77136) and do not require public comment. The instruction to promptly notify FDA of a suspected adulteration or misbranding of an infant formula has been modified to provide for telephone notification (see § 106.130(d)) of either the Director of the appropriate FDA district office or the Emergency and Epidemiological Operations Branch in headquarters.

Status and Applicability of Quality Control Procedure Regulations

Proposed § 106.1 (21 CFR 106.1) states that the criteria set forth in proposed §§ 106.20, 106.25, 106.30, and 106.100 shall apply in determining whether the controls used in the manufacture, processing, and packing of infant formula products meet the requirements of section 412 of the act as to safety, quality, and nutritional composition. (See sections 412(a)(1)(C) and 412(a)(2)(D) of the act.) A manufacturer's failure to comply with the applicable requirements of these regulations after their effective date shall render the infant formula product adulterated under section 412(a)(1)(C) of the act, and such formula as well as the person who is responsible for the failure to comply may be subject to regulatory action. Thus, these regulations, after promulgation, will have the full force and effect of law. See *Weinberger* v. *Hynson, Wescott & Dunning, Inc.*, 412 U.S. 609 (1973); *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977); *National Nutritional Foods Ass'n* v. *Weinberger*, 512 F.2d 688 (2d Cir. 1975).

Definitions

Proposed section 106.3 (21 CFR 106.3) incorporates the definitions and interpretations contained in section 201 of the act (21 U.S.C. 321), when such terms are used in these proposed regulations. Other more technical terms are defined in this proposed regulation and are based on FDA's experience in regulating foods and common usage in the infant formula industry.

Quality Control Requirements

Receipt of ingredients. Proposed § 106.20 (21 CFR 106.20) describes those procedures applicable to the receipt of infant formula ingredients which are essential for assuring that each ingredient meets its stated specifications and, therefore, assuring that the finished product conforms to section 412(g) of the act. To assure that ingredients, which contain nutrients likely to be affected by shipping, storage, or other conditions (such as an error in the mixing of nutrients by the supplier), conform to their specifications, each lot of ingredient which may be affected must be analyzed for such nutrients, or if appropriate, an indicator nutrient. An indicator nutrient is one, usually a label ingredient of a premix, the concentration of which is measured at several stages during the production of the infant formula product because it is most likely to be affected by the process. If ingredients, including nutrients and nutrient premixes, are not certified or guaranteed by the supplier or labeled as meeting prescribed standards, an extensive sampling and testing plan must be employed utilizing a statistically random sampling followed by confirmatory quantitative analysis for each nutrient required by section 412(g) of the act. The proposed section requires that an identifying number or code be used in recording the disposition of each nutrient ingredient, as examples, when they are rejected to the supplier or when they are added to a premix or batch.

In-Process Control

Proposed § 106.25 (21 CFR 106.25) describes the requirements for infant formula in-process control. Each distinct processing operation shall be entered on a batch record and its satisfactory completion recorded by the operator. A designated supervisor shall check and sign each batch record. A second person shall confirm the addition of each ingredient. Sampling the in-process batch after various additions of nutrients, analyzing the composition for uniformity and indicator nutrients, and standardizing the completed batch

assures the formula's conformity to the nutritional requirements of section 412(g) of the act.

Base Blend

Production of an in-process batch usually begins with the formulation of a base blend, generally from either milk or soy ingredients, or other sources of protein, as well as other sources of fat or carbohydrate. The base blend may also contain various electrolytes, emulsifiers, stabilizers, and other functional ingredients. FDA is proposing in § 106.25(b) that each base blend be sampled after thorough mixing and analyzed for protein, fat, ash, moisture, and carbohydrate to confirm the levels of the major components in the base blend.

Premixes

Certain infant formula ingredients such as vitamins, minerals, and amino acids are sometimes added to the in-process batch as premixes. Commonly used premixes for infant formula production generally include an oil-soluable premix and one or more water-soluble premixes. FDA is proposing in § 106.25(c) that a premix which is made from individual nutrient components by the infant formula manufacturer shall be analyzed for each nutrient prior to its addition to the base blend, unless analyses for each nutrient contributed by the premix are performed on the contents of the holding tank(s) as prescribed in proposed § 106.25(e). When a premix is analyzed for each nutrient as set forth in proposed § 106.25(c), FDA is proposing that the in-process batch be analyzed for the appropriate indicator nutrient as provided by § 106.25(d). After the addition of premixes to the base blend, the proper quantity of each premix in an in-process batch may be verified (proposed in paragraph (d)) by analyzing each in-process batch for one or more of the indicator nutrients of each of the premixes used. Unless analyses for each nutrient contributed by a premix are perfomed in-process, such analyses must be performed on the contents of the holding tank(s). If the indicatior nutrient is within the prescribed limit of specification, the other component nutrients are expected to be in the in-process batch within specification. However, selected batches of finished product in containers are to be analyzed for all nutrients specified in section 412(g) of the act (proposed in § 106.30(a), (b), and (c)).

When a nutrient ingredient is not suitable for use in the preparation of a uniform, stable premix, that nutrient is sometimes added separately to the in-process batch. FDA is proposing in § 106.25(d) to require that the presence of the proper quantity of that nutrient be verifed by analysis of each in-process batch for that nutrient, unless the analysis is later performed on samples from the holding tank(s) as prescribed in proposed § 106.25(e). After the addition of premixes and nutrients added individually, proposed § 106.25(f) requires the in-process batch to be adjusted as necessary to confrom to the batch formula.

Product in Holding Tanks

One or more in-process batches may be accumulated in a holding tank(s) to form a filling batch which then is standardized prior to further processing. FDA is proposing in § 106.25(e) to require the testing of samples from each holding tank of the product for solids, homogeneity, osmolality, and sedimentation as indicators of nutrient dispersal and consequent product uniformity. Testing for other physical attributes of infant formulas is not included in this proposed regulation because most physical attributes normally are used as a measure of the organoleptic properties of the product and do not aid in determining that nutrient levels in the product are being maintained. FDA is also proposing in § 106.25(e)(1) to (5) to require that samples taken from the holding tank be analyzed for major nutrients (protein, fat, and carbohydrate); for indicator nutrients in premixes; for each nutrient in a premix made from individual nutrient components by the infant fromula manufacturer unless analyzed prior to use; and for nutrients added independently of premixes during formulation of the product, unless analyzed in the in-process batch.

The level of testing and analyses proposed for the product in the holding tank, together with the previously discussed requirements for the sampling and analysis of ingredients and in-process product, provides the manufacturer with an increased ability to detect and correct product compositional defects prior to heat sterilization or dehydration and packaging into individual containers. For those nutrients that are heat-labile, appropriate indicator nutrients shall be checked after heat processing or dehydration to assure their adequacy in the finished product (proposed in § 106.30(b)(1)(ii)). In this manner, an increased level of assurance of finished product integrity is attained at the earliest possible time in the porcess, thus averting expensive finished product rework or recall if distributed. At the same time, a decreased level and frequency of sampling and analysis of finished product after processing and packaging is required.

Release of Product for Heat Sterilization or Dehydration

FDA proposes in § 106.25(f) that if the product in each holding tank conforms to its specifications, it may be released for subsequent heat sterilization or dehydration and packaging. Otherwise, it shall be adjusted and reanalyzed to verify the efficacy of standardization.

Finished Product Analyses Prior to Shipment

FDA proposes in § 106.30 (21 CFR 106.30) that random samples of product taken after heat sterilization or dehydration and packaging be tested for physical attributes and analyzed for indicator nutrients that measure possible product damage before the product is released from the manufacturer's control. FDA is proposing product analysis for indicator nutrients that measure possible damage because certain nutrients that are sensitive to heat, light, oxygen, pH, or a combination thereof may be affected by the manufacturing processes. Trace minerals, such as copper and iron, and enzymes may catalyze these effects. Heating and/or the presence of reducing sugars may degrade protein quality by decreasing the biological availability of certain essential amino acids of the protein. The indicator nutrient(s) selected to measure process damage in any formulation must be the nutrient(s) most susceptible to process damage.

When two or more nutrients are equally suitable to fulfill an indicator role, the complexity and cost of the analytical methods for these nutrients are additional factors affecting the selection decision. In addition, the same nutrient may be adequate to fulfill more than one indicator role, simplifying part of the control process. Thus, vitamin A may serve as an indicator of the oil-soluble premix addition to the in-process batch and as a measure of process damage in the finished product.

When the history of nutrient stability gathered during product development indicates that a satisfactory indicator nutrient level gives assurance of proper levels of nutrients similar to the indicator, the product may be shipped if the result of that analysis is satisfactory.

Finished Product Analyses of Selected Batches

FDA proposes in § 106.30(b) a three-tiered staggered analyses program for finished formula products. While samples of the finished product must be monitored for all nutrients required by

section 412(g) of the act and those claimed on the label, the timeframe for analyses is not uniform for all nutrients. FDA believes that less frequent analyses for certain nutrients are reasonable; many require a longer time to analyze than other nutrients that can satisfactorily serve as indicators. There are no documented cases of deficiencies in normal infants of biotin, choline, and inositol. Vitamins D and K are well retained in the human body; vitamin D also is highly stable in infant formulas, while vitamin K intake in infants other than newborns is usually augmented by intestinal bacterial production of this vitamin. The vegetable oils now used as fat sources are rich in linoleic acid. Protein efficiency ratio (PER) and tryptophan (the content of which may be used in meeting the niacin requirement in section 412(g) of the act) are not expected to vary unless there is a change in the protein ingredients or processing procedures, at which time an analysis of these components is required.

Although thickening and stabilizing agents may be added to infant formulas to maintain the consistency and to prolong the stability of the product over its shelf life, there may be some changes in consistency and nutritional qualities during storage. Therefore, FDA is proposing in § 106.30(b)(3) that samples from selected filling batches be checked at 3 month intervals throughout the shelf life of the product to ascertain its stability and nutritional adequacy. Scheduling a bioanalysis of vitamin D and the biological evaluation of PER to occur over a 6-month cycle rather than every 3 months is considered appropriate because of the length of time required to complete the bioanalysis.

Criteria for accepting and rejecting a product

FDA is proposing in § 106.30(c) that the ranges of nutrient composition in the finished product shall be such that their lower limits do not fall below, and their upper limits do not exceed, the minimum and maximum levels, respectively, specified in section 412(g) of the act and that the composition shall be consistent with label declarations. To assure that the upper and lower levels of the listed nutrients in the act are met, proposed § 106.30(d) requires the establishment of an appropriate finished product acceptance/rejection system based on statistical quality control criteria. The proposal further requires that when the results of testing three consecutive filling batches show a trend in deviations from specified ranges in one or more nutrients, the product shall be evaluated to ascertain and implement steps that need to be taken to maintain the product in conformity with section 412(g) of the act.

Changes in Ingredients or Processes

FDA proposes in § 106.30(e) that an infant formula manufactured after changes in the formulation or processing has occurred must be controlled more stringently than products manufactured without such changes. To assure the adequacy of the nutrient composition of formulas manufactured after a change in formulation or processing has occurred, FDA is proposing that a manufacturer be required to evaluate the effects of changes in ingredients or processing conditions in the first and last of the first 10 filling-batches together with product from any 2 of the other 8 filling batches. As set forth in proposed § 106.30(e)(1), if the changes in formula are minor (e.g., changing ingredients from one supplier to another whose products differ only in minor aspects from those previously used), composite samples are to be analyzed for all nutrients changed and for those nutrients affected by the change. As set forth in proposed § 106.30(e)(2), if the changes in formulation are major (e.g., changing type of ingredients, such as soy flour to soy isolate, or replacing a heat exchanger with a steam injector-vapor tank system), a complete analysis of all required nutrients and of PER is to be performed on the 1st and 10th filling batches as well as on any two of the other eight filling batches, except that analyses for linoleic acids, vitamin D, vitamin K, choline, inositol, biotin, PER, and tryptophan (if necessary as part of the declaration of niacin equivalents) need be made only on the 1st and 10th batches if they meet specifications. These detailed analyses are necessary to further assure nutritional adequacy, i.e., that the priemix system is functioning as intended, and that no unexpected losses of nutrients are occurring during processing.

Coding

The coding of food products is necessary and important in ascertaining positive lot identification. Positive lot identification facilitates the identification, the segregation, and the traceability of contaminated products or products that may be otherwise unfit for their intended use. Congress has recognized the utility of this type of product coding, as have many members of the food industry, who have developed guidelines for their segments of the industry. The courts too recognized the self-evident rationality of the coding of food products. See *National Confectioner Ass'n* v. *Califano*, 569 F.2d 690, 695 (D.C. Cir. 1978).

In addition, Congress has reemphasized in the Infant Formula Act of 1980 the importance of the concepts of coding and traceability for infant formulas by requiring each infant formula manufacturer to make and retain necessary records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor a recall of the formula. (See section 412(e)(1) of the act). Accordingly, FDA is proposing in § 106.90 (21 CFR 106.90) to require the manufacturer to place permanent and conspicuous legible coding marks on each infant formula package delivered or displayed to pruchasers, so that such code marks can be easily seen on the unopened package. The marks must identify at a minimum, the establishment where the formula is packed, the product that is contained therein, the year and day and product that is packed, and the period during which, the product is packed. Further, FDA is proposing that the packing period code be changed with sufficient frequency to enable the identification of a period of time when certain personnel were on duty and in-plant conditions were relatively constant.

Records and Reports

The Infant Formula Act of 1980 expanded the agency's inspectional authority in section 704 of the act (21 U.S.C. 374), by permitting duly authorized FDA employees to have access to and to copy and verify any records bearing on whether any infant formula meets the requirements of section 412 of the act. Thus, FDA is proposing in § 106.100 (21 CFR 106.100) that infant formula manufacturers maintain: (a) Records of the results of examinations or copies of supplier guarantees or certifications verifying that the raw materials, packing materials, and infant formulas comply with section 412 of the act and with FDA regulations, guidelines, or action levels, and (b) those quality control procedure records, including in-process and finished product testing records, necessary to show that the nutrient content of infant formulas meets the requirements of section 412 of the act. FDA proposes that these records be kept for a period of time that meets or exceeds the shelf life of the product.

Notification

FDA is including as subpart D to the proposed quality control procedure regulations (proposed §§ 106.120, 106.122, and 106.130; 21 CFR 106.120,

106.122, and 106.130) the notification procedures and format to be followed by manufacturers in reporting to FDA as required by sections 412(b) and 412(c) of the act. Notice of these reporting procedures was published in the Federal Register of November 21, 1980 (45 FR 77136) to advise manufacturers of the reporting requirements in new section 412 of the act and to inform them of how to notify the agency and which offices at FDA to submit the required reports.

In that notice, the agency included the reporting requirement of section 412(b)(1) of the act, which directs manufacturers to notify FDA within 90 days following the date of enactment of the Infant Formula Act and on each 90th day thereafter, that each "existing" infant formula produced by a manufacturer provides nutrients required by section 412(g) of the act. Because this reporting requirement expires on the effective date of these proposed quality control procedure regulations, the agency is not including the format for the section 412(b)(1) reporting requirement herein. In addition, the reporting format in § 106.122 for reformulations as required by section 412(b)(3) of the act, has been modified to include a short description of the change(s) in formulation; and the telephone notification in § 106.130(d) has been modified to give the manufacturer the option of contacting either the appropriate FDA District Director or the FDA Emergency and Epidemiological Operations Branch. However, all other reporting formats required by section 412(b) and (c) of the act will continue to be applicable and are therefore being included in these proposed regulations. Because these notification requirements are not substantive and reflect only a statutory interpretation of section 412(b) and (c), public comment is not required.

Clinical Testing

FDA recognizes that premarket clinical evaluation in humans may be appropriate whenever certain changes affecting the nutritional profile of an infant formula are made, particularly in the case of new or reformulated products. FDA also recognizes that the degree and complexity of clinical testing would vary according to the extent of the changes in the formula. The testimony that was received during the February 19, 1980, public meeting was supportive of the need for clinical trials in appropriate situations and indicated that the infant formula industry now makes ad hoc decisions to clinically evaluate formulas based upon recommendations of physicians and nutritionists. However, the discussion provided at the public meeting was not sufficiently specific to constitute a basis for the development of an FDA policy on clinical testing of infant formulas. A copy of the testimony received at the public meeting concerning infant formula clinical testing is on file with the Dockets Management Branch under the docket number set forth above.

FDA also requested recommendations from the Committee on Nutrition of the American Academy of Pediatrics (CON/AAP) on clinical testing of infant formulas. In a statement on June 23, 1980, CON/AAP reported to FDA that clinical testing of new and reformulated products is considered advisable from time to time, and is now carried out in established clinical research centers with the collaboration of technical experts, nutrition scientists, and pediatricians. CON/AAP recommended that, in view of the existing practices governing nutrient content and manufacturing procedures, no regulations be devised for infant formula clinical testing. This recommendation was based on three reasons: (1) Problems with the manufacture of infant formulas have been exceptionally rare in the past; (2) future modifications of infant formulas that are justified nutritionally or economically cannot be wholly predicted, and no simple code can govern all anticipated eventualities; and, (3) future clinical trials will have to be adapted to the evolving ethical codes governing research on infants. A copy of the CON/AAP statement with accompanying background information on infant formula regulations is also on file with the Dockets Management Branch.

Considering the complexities surrounding clinical testing of infant formulas in infants and the fact that such testing is currently an integral part of the manufacturer's development of new formulas, FDA is not now proposing regulations on clinical testing of infant formulas. However, the agency is soliciting public comment on the need for establishing a policy or regulation on clinical testing of infant formulas. Answers to the following questions are essential to the development of an agency policy, and comments thereon are requested: (1) What constitutes a new infant formula, and what constitutes major reformulations of existing formulas that would require clinical testing; (2) what constitutes adequate metabolic testing, growth and development studies, or acceptance and tolerance tests, and in what situations are each of these types of testing appropriate; and (3) what criteria should be used to evaluate the results of tests or to measure the effectiveness (performance) of an infant formula? Although responses to these specific questions are especially desired, comments on any aspect of clinical testing of infant formulas are welcomed. All comments received will be considered by FDA in determining its future course of action with respect to clinical testing of infant formulas.

FDA proposes that all affected products initially introduced into, or initially delivered for introduction into, interstate commerce or prepared from raw materials shipped in interstate commerce on or after 180 days after date of publication in the Federal Register of any final regulation adopted on the basis of this proposal, shall comply with that regulation.

The agency has determined under 21 CFR 25.24(d)(13) (proposed December 11, 1979 (44 FR 71742)) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 412, 701(a), 52 Stat. 1055 as amended, 94 Stat. 1190 (21 U.S.C. 350a, 371(a))), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 106 to read as follows:

PART 106—INFANT FORMULA QUALITY CONTROL PROCEDURES

Subpart A—General Provisions

Sec.

Subpart B—Quality Control Procedures for Assuring Nutrient Content of Infant Formulas

Subpart C—Records and Reports

Subpart D—Notification Requirements

Authority: Secs. 412, 701(a), 52 Stat. 1055 as amended, 94 Stat. 1190 (21 U.S.C. 350a, 371(a)).

Subpart A—General Provisions

§ 106.1 Status and applicability of the quality control procedure regulations.

(a) The criteria set forth in §§ 106.20, 106.25, 106.30, 106.90, and 106.100 shall apply in determining whether the controls used in the manufacturing, processing, and packing of infant formula products meet the requirements of section 412 of the act as to safety, quality, and nutritional composition.

(b) The failure to comply with any regulation set forth in §§ 106.20, 106.25, 106.30, 106.90, and 106.100 applicable to the manufacturing, processing, and packing of an infant formula shall render such formula adulterated under section 412(a)(1)(C) of the act, and such formula, as well as the person who is responsible for the failure to comply, may be subject to regulatory action.

(c) The requirements set forth in this part are to be implemented and followed by any person who is a manufacturer of an infant formula.

(d) If a person engages in only some operations subject to the regulations in this part and not others, that person need only comply with those regulations applicable to the operations in which he or she is engaged.

§ 106.3 Definitions.

The definitions and interpretations contained in section 201 of the act are applicable to such terms when used in this part. The following definitions shall also apply:

(a) *Filling batch.* A filling batch is one or more in-process batches combined in a holding tank(s) and standardized for filling into finished product containers over a prescribed filling time.

(b) *Ingredients.* Ingredients are all substances, including the required nutrients specified in section 412(g) of the act, which are necessary for the manufacture of an infant formula product.

(c) *Indicator nutrient.* An indicator nutrient is a nutrient, usually one ingredient of a premix, the concentration of which is measured at several stages during the manufacturing of the infant formula product to confirm one or both of the following characteristics or operations:

(1) Proper addition and proper distribution of premix in the in-process batch and in the holding tank; and

(2) Stability of labile nutrients during production, e.g., vitamin A, vitamic C.

(d) *In-process batch.* An in-process batch is a combination of ingredients, including the base blend, premixer and other nutrients in accordance with a manufacturing order at any point in the process prior to packaging.

(e) *Manufacturer.* A manufacturer is a person that prepares, reconstitutes, or otherwise changes the phycical or chemical characteristics of an infant formula as defined in section 201(aa) of the act and packages the product in a container for distribution.

(f) *Nutrient.* A nutrient is any vitamin, mineral, or other substance required by section 412(g) of the act.

(g) *Nutrient premix.* A nutrient premix is a combination of two or more nutrients which is added as a single ingredient during processing.

Subpart B—Quality Control Procedures For Assuring Nutrient Content of Infant Formulas

§ 106.20 Ingredients

(a) Manufacturers shall ensure that incoming ingredients are not used in the manufacture of infant formulas if they have visable shipping damage or other defects or their label does not comport with order specifications. An identifying number or code shall be used in recording the disposition of each nutrient ingredient.

(b) Ingredients, other than nutrient premixes, which are generally stable in shipping and storage, and which are received under a supplier's guarantee or certification, or are labeled as having compositions complying with specifications in the U.S. Pharmacopeia, the National Formulary, the Food Chemicals Codex, or other similar recognized standards, may be forwarded without analysis for manufacturer use.

(c) When the nutrient(s) in an ingredient is likely to be affected by shipping or storage conditions, it shall be sampled and analyzed by the manufacturer. The ingredients shall be sampled by taking statistically randomized subsamples and a composite of the subsamples shall be analyzed quantitatively for each such nutrient or nutrients.

(d) Nutrient premixes which have been guaranteed or certified by the supplier shall be sampled and analyzed by the manufacturer. Such a premix shall be sampled by taking statistically randomized subsamples, and a composite of the subsamples shall be analyzed quantitatively for an indicator nutrient.

(e) Where ingredients, including individual nutrients or nutrient premixes, are without a supplier's guarantee or certification, or are not labeled as complying with prescribed standards, each lot shall be sampled and analyzed by the manufacturer. Each lot shall be sampled by taking statistically randomized subsamples to give a composite sample for confirmatory quantitative analysis for each nutrient. The samples shall be analyzed by recognized methods, such as those in the current "Official Methods of Analysis of the Association of Official Analytical Chemists," including a chemical method for vitamin D unless otherwise specified in this regulation. If found to be within specifications, the ingredients may be forwarded for manufacturing use.

(f) Lots that are not within specifications shall be conspicuously marked by the manufacturer that they have been rejected and shall be removed to a restricted area pending disposition.

§ 106.25 In-process control.

(a) An appropriate formula based on the composition of the ingredients and prepared for each in-process batch shall be checked and signed by a quality control supervisor. Each ingredient of the batch, and the amount and place of entry of the ingredient into the process, shall be listed on a batch record. Operators shall initial each entry of an ingredient into the process and record nutrient ingredient identification numbers on the batch record. This record shall accompany the batch while in-process and each entry on it shall be initialed by a second person for verification of the kind and the amount of the ingredient. The batch record shall be filed with all processing control records associated with the batch.

(b) A base blend, prepared by mixing the appropriate ingredients, including sources of protein, fat, and carbohydrate with filtered, potable water of quality mandated by the local Public Health Agency shall be thoroughly mixed and sampled by the manufacturer. A proximate analysis for protein, fat, ash, moisture, and carbohydrate shall be performed by the manufacturer on samples from each base blend.

(c) A premix that is made from individual nutrients by the infant formula manufacturer shall be analyzed by such manufacturer for each nutrient prior to its addition to the base blend, unless analyses for each nutrient contributed by the premix are performed on the contents of the holding tank(s) as prescribed in paragraph (e) of this section.

(d) After the addition of the nutrient premixes to the base blend, and homogenization, when appropriate, the inprocess batch may be sampled and analyzed for the apropriate indicator nutrient of each premix (e.g., vitamin A for the oil-soluble premix, vitamin C for the water-soluble vitamin premix, and manganese for the mineral premix). If a

nutrient is not suitable for use in the preparation of a uniform, stable premix, or if the composition of the nutrient is altered significantly with ensuing processing, it may be added separately at the most advantageous point in the manufacturing process to ensure its presence in prescribed amounts in the finished product. After the addition of such nutrient, the in-process batch may be analyzed for each individual added nutrient. Unless specified nutrient analyses are performed in-process, they shall be performed on the contents of the holding tank(s) as prescribed in paragraph (e) of this section.

(e) The manufacturer shall accumulate in-process batches in the holding tank(s) from which each filling batch is to be drawn. Each filling batch shall be held in storage until the nutrient composition of the contents of each holding tank is verified. After mixing, samples from each holding tank shall be analyzed by the manufacturer for the following physical attributes and nutrients:

(1) Solids, homogeneity, osmolality, and sedimentation.

(2) Protein, fat, and carbohydrate.

(3) Indicator nutrient(s) for premixes.

(4) Each nutrient in a premix made from individual nutrent components by the infant formula manufacturer and not analyzed in the in-process batch.

(5) Nutrients added independently of premixes during formulation of the product if not analyzed in the in-process batch.

(f) If the formula product in each holding tank conforms to its specifications, it may be released for heat sterilization or dehydration and packaging; otherwise it shall be adjusted as required and reanalyzed to verify the efficacy of standardization.

§ 106.30 Finished product evaluation.

(a) The manufacturer shall take random samples of the finished formula product from each packaging line after heat sterilization or dehydration and packaging, to represent the entire filling batch (i.e., from the start of the first holding tank to the end of the last holding tank).

(b) A sufficient number of containers shall be taken by the manufacturer to provide adequate product for the following types of testing:

(1) *Immediate analysis.* A composite sample of three containers taken randomly over each 2-hour period at each packaging line for each filling batch shall be analyzed before shipping for:

(i) Solids, homogeneity, osmolality, and sedimentation.

(ii) Indicator nutrients to assess process damage, such as vitamin A, vitamin B_1, vitamin B_6, and vitamin C.

(2) *Extended analysis.* Replicate samples of containers for the immediate analyses, as described in paragraph (b)(1) of this section, are to be taken from the first of every 10 filling batches or taken semi-monthly, whichever comes first. These samples shall be analyzed for the content of reducing sugar and all nutrients specified in section 412(g) of the act and declared on the label, except linoleic acid, vitamin D, vitamin K, choline, inositol, biotin, tryptophan (if necessary as part of the declaration of niacin equivalents), and those which were tested in the immediate analyses.

(3) *Progressive analysis.* Using replicates of the samples collected from one filling batch as specified in paragraph (b)(2) of this section, and beginning 3 months after their packaging, progressive analysis shall be initiated on a new filling batch every 3 months. These samples shall be analyzed every 3 months throughout the shelf life of the product for physical attributes (i.e., solids, homogeneity, osmolality, and sedimentation), and for all nutrients declared on the label. Vitamin D may be determined by chemical methods, except that it and the protein efficiency ration (PER) shall be determined by the appropriate AOAC bioassay method of analysis once every 6 months throughout the shelf life of the product.

(i) The rat bioassay method for determining vitamin D shall be the method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980), secs. 43.195–43.208 "Vitamin D (30)—Official Final Action,"[1] which is incorporated by reference.

(ii) The method for determining biological quality of protein in terms of PER shall be the method prescribed "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th ed. (1980), sections 43.212–43.216 "Biological Evaluation of Protein Quality (Protein Efficiency Ratio) (32)—Official Final Action,"[1] which is incorporated by reference.

(c) Solids, homogeneity, osmolality, and sedimentation shall conform to release ranges established by the manufacturer. Ranges of the nutrient composition in the finished product shall be such that their lower limits do not fall below, and their upper limits do not exceed, the minimum and maximum levels, respectively, specified in section 412(g) of the act, and the composition shall be consistent with label declarations.

(d) To ensure that the infant formula product contains those nutrients and levels of nutrients set forth in section 412(g) of the act, the manufacturer shall establish controls which shall include the implementation of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures based upon the design and capability of the manufacturing process. The manufacturer shall also establish acceptance criteria for sampling and testing to ensure that batches of infant formula meet nutrient specifications and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance, warning, and rejection ranges.

(1) The acceptance ranges lie within the upper and lower control limits of a statistical process average having two standard deviations as the limit boundaries. Where a nutrient level is between the second and third standard deviation, corrective measures shall be taken to bring the product into the acceptance range.

(2) If in any composite sample, any nutrient level lies below the three standard deviation limit, or the level of any nutrient having a maximum allowable concentration specified in section 412(g) of the act is above the three standard deviation limit, the filling batch shall be rejected and disposed of unless it is reconditioned and brought within specifications.

(3) When the results of testing three consecutive filling batchs show a trend in deviations from specified ranges in one or more nutrients, the product shall be evaluated to ascertain the steps needed to be taken to maintain the product in conformity with section 412(g) of the act.

(e) The manufacturer shall perform analyses for evaluation of the effect of changes in ingredients or processing conditions which could affect the physical attributes or nutrient levels as indicated in paragraph (e)(1) and (2) of this section. Three samples (each consisting of a composite sample representing the beginning, the middle, and the end of the filling batch) shall be taken from each of the first 10 filling batches for evaluation prior to shipment of finished products to determine the effects of such changes which include, but are not limited to:

(1) Minor changes in ingredients (e.g., changing one or more ingredient levels

[1] Copies may be obtained from the Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, DC 20044, or examined at the Office of the Federal Register Library.

to bring the ranges of nutrient concentration more closely within prescribed release limits; changing ingredients from one supplier to another whose products differ only in minor aspects from those previously used; changing the water source). The composite samples from the first and tenth filling batches and from two additional filling batches chosen from filling batches two through nine shall be analyzed by the manufacturer for all nutrients changed and those affected by the change.

(2) Major changes of ingredients more significant than those described in paragraph (e)(1) if this section, or changes in processes involving equipment or conditions such that physical attributes will be affected or labile nutrients will degrade beyond previously experienced ranges (e.g., changing type of ingredients, such as soy flour to soy isolate; replacing a heat exchanger with a steam injector-vapor tank system; changing time-temperature conditions of preheating during formulation of product; changing mixing times or mixing temperatures; or changing holding times and temperatures of sterilization). A complete analysis of all nutrients required by section 412(g) of the act and of PER shall be performed by the manufacturer on the composite samples from the first and tenth filling batches; analyses of all such nutrients and PER also shall be made on the composite samples from two additional filling batches chosen from filling batches two through nine, except that analyses for linoleic acid, vitamin D, vitamin K, choline, inositol, biotin, PER, and tryptophan (if necessary as part of the requirement of niacin) need not be made if they are within specification in filling batches 1 and 10.

§ 106.90 Coding.

The manufacturer shall mark each container of a finished infant formula with a conspicuous, permanent, and legible identifying code. Code marks shall be visible to purchasers on unopened packages. The required code shall identify the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall not extend over a period of more than one personnel shift.

Subpart C—Records and Reports

§ 106.100 Records.

(a) Records of results of examinations and copies of suppliers' guarantees or certifications that verify compliance with FDA regulations, guidelines, or action levels for raw materials, food-packaging materials, and infant formulas shall be maintained by the manufacturer.

(b) Quality control procedure records necessary to ensure nutrient content of infant formulas, including periodic nutrient testing, shall be maintained by the manufacturer and shall contain sufficient information to permit a public health evaluation of any batch of infant formula.

(c) The records required by paragraphs (a) and (b) of this section shall be retained for a period of time that meets or exceeds the shelf life of the infant formula.

Subpart D—Notification Requirements

§ 106.120 New formulations.

The manufacturer shall notify FDA, not later than the 90th day before the first processing of any new infant formula for commercial or charitable distribution for human consumption, that the new infant formula provides the nutrients required by section 412(g) of the act and that the processing meets the quality control procedure requirements prescribed by the Food and Drug Administration and that the infant formula is not adulterated or misbranded within the meaning of the act.

§ 106.122 Reformulations.

The manufacturer, before the first processing of any infant formula produced for commercial or charitable distribution for human consumption, when the manufacturer determines that a change in its formulation or a change (as described in section 412(b)(3) of the act) may affect whether the formula is adulterated, shall notify FDA of such changes, including a description of the changes, and that the reformulated formula provides the nutrients required by section 412(g) of the act.

§ 106.130 Notification format.

(a) The notification requirements prescribed in §§ 106.120 and 106.122 of this subpart are to be submitted to FDA in the following format:

Please Type or Print all Entries

1. Enter the name of the product:

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2. Check whether the identified infant formula is a "new formulation" _____ or a "reformulation"

If the identified formula is a reformulation, provide: a. A description of the change(s) in the formulation and/or processing.

b. How this (these) change(s) may affect whether the formula is adulterated.

3. Enter establishment name and address.

Name:_____

Address: _____

(City) (State) (Zip Code)

4. If establishment has a parent company, enter parent company name and address. If not applicable, check N/A.

Name:_____

Address: _____

(city) (State) (Zip Code)

N/A: _____

5. Notification Statement of the Quality of the Identified Infant Formula:

"I hereby notify FDA that the infant formula identified above meets the nutritional requirements of section 412(g) of the Federal Food, Drug, and Cosmetic Act, that the processing of the infant formula meets the quality control procedure requirements prescribed by the Food and Drug Administration and that the infant formula is not adulterated or misbranded within the meaning of said act.

Signed: _____

Date: _____

(This notification shall be signed and dated by a responsible official.)

(b) The notification requirements prescribed in paragraph (a) of this section shall be submitted to Chief, Regulatory Affairs Staff (HFF–204), Bureau of Foods, Food and Drug Administration, 200 C St., SW., Washington, D.C. 20204.

(c)(1) The manufacturer should submit to FDA one label for each infant formula produced for commercial or charitable distribution for human consumption with its submission for new formulations and reformulations.

(2) All labels are to be submitted to Chief, Regulatory Affairs Staff (HFF–204), and in accordance with the due dates established in §§ 106.120 and 106.122.

(d) The manufacturer shall promptly notify FDA when there is an infant formula in the marketplace which may not provide the nutrients required by section 412(g) of the act or when there is an infant formula otherwise adulterated or misbranded within the meaning of the act and presents a risk to human health. Descriptions of the known or suspected adulteration or misbranding must be provided. This notification shall be made, by telephone, either to the Director of the appropriate FDA district office specified in 21 CFR 5.115 or to FDA's Emergency and Epidemiological Operations Branch at 301–443–4667. After normal business hours (8 a.m. to 4:30 p.m.) the FDA emergency number, 202–737–0448, shall be used. This telephone notification shall be followed promptly by written confirmation which is to be sent to the Division of Regulatory Guidance (HFA—310), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, and to the

appropriate FDA district office specified in 21 CFR 5.115.

Interested persons may, on or before March 2, 1981, submit to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Orders 12044, as amended by Executive Order 12221, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Dockets Management Branch, Food and Drug Administration.

Dated: December 22, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–40507 Filed 12–29–80; 8:45 am]

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federal register

Tuesday
December 30, 1980

Part XII

Department of Education

Pre-College Teacher Development in Science Program

DEPARTMENT OF EDUCATION

34 CFR Part 797

Pre-College Teacher Development in Science Program

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary issues final regulations for the Pre-College Teacher Development in Science Program. This program provides support to colleges and universities and certain nonprofit institutions for the continuing education of preschool and elementary school teachers in mathematics, engineering, and the natural and social sciences.

EFFECTIVE DATE: These final regulations are expected to take effect 45 days after they are transmitted to Congress. Regulations are usually transmitted to Congress several days before they are published in the **Federal Register**. The effective date is changed if Congress takes certain adjournments. If you want to know the effective dates of these final regulations, call or write the Department of Education contact person.

FOR FURTHER INFORMATION CONTACT: Mary G. Lewis, Pre-College Teacher Development in Science Program, U.S. Department of Education, 1832 M Street, N.W. (Room 819 Riviere Building, Washington, D.C. 20236. Telephone (202) 653–5839.

SUPPLEMENTARY INFORMATION: This program was transferred from the National Science Foundation to the Education Department by the Department of Education Organization Act of 1979, Pub. L. 96–88, Section 304. The current Education Department Program was part of the National Science Foundation's Pre-College Teacher Development in Science Program, which also included training opportunities for secondary school teachers. This NSF program was reestablished in fiscal year 1977 by Congress through Public Law 94–378. With the transfer of the preschool and elementary school portion of the program to the Education Department on May 4, 1980, the program for these grades is now subject to the General Education Provisions Act which requires publication of regulations in the **Federal Register**. (20 U.S.C. 3474(b))

The final rule, like the proposed regulations, essentially implement the operational guidelines of the program as administered by the National Science Foundation. For the initial administration of the program by the Education Department, no major changes have been made in accordance with the Congressional intent that the science education programs be transferred intact. S. Rep. No. 96–49, 96th Cong., 1st Sess. 50 (1979)

The provisions of these final regulations are substantially the same as the provisions of the notice of proposed rulemaking (NPRM) published in the **Federal Register** on August 13, 1980. Interest persons were given 30 days to comment on the NPRM. Seven persons submitted comments which generally supported the provisions established in the notice.

The paragraphs below summarize the comments and the Secretary's response to them. The comments and responses are presented in the order of the sections to which they pertain. Changes have been made in the final regulations in response to the comments, in addition to the corrections of minor technical and typographical errors.

§ 797.2 Eligible institutions.

Comment. Several commenters recommended expanding eligibility to receive grants under the program to include State educational agencies (SEAs), local educational agencies (LEAs), junior and community colleges, and teacher associations. One commenter suggested that the regulations be more specific on the rule of the LEAs in project planning.

Response. No change has been made. While the Secretary recognizes the effectiveness of SEAs, LEAs and other organizations in providing inservice teacher training, the Secretary views this program as an alternate form of continuing education for teachers which supplements other inservice efforts. During its initial administration by the Education Department, the program will retain the same general operating procedures which governed it previously at the National Science Foundation. No change is made to expand the eligible applicants to include LEAs, SEAs, and two-year colleges.

Many four year colleges and universities are active in pre-service teacher training. Their eligibility under this program stengthens the link between pre-service teacher training activities and the inservice training sponsored by this program. In addition, four year colleges and universities, but not two year institutions, can offer graduate credit to teachers, thereby providing an incentive for their participation. Since a further objective of the program is part to encourage cooperative relationships between scientists at colleges, universities and other eligible scientific institutions and preschool and elementary teachers. These institutions are essential to involve in the program.

With respect to the role of LEAs in project planning, § 797.31(f) stipulates that teachers and other appropriate individuals be consulted during the needs assessment phase of the project development. LEAs are encouraged to participate with eligible institutions in project planning. Local school systems may, and often do, initiate a project developed in conjunction with and sponsored by an eligible college or university, so the role of LEAs in the program is an important one.

§ 797.4 Definitions that apply to the Pre-College Teacher Development in Science Program.

Comment. One commenter suggested that a definition of "elementary school teacher" be included in the regulations, while two other commenters requested clarification as to whether middle schools are considered part of elementary education.

Response. No change has been made. The provisions of the Education Division General Administrative Regulations (EDGAR) are applicable to the program. Section 77.1(c) of EDGAR allows each State to determine the scope of the term elementary education. This decision was considered preferable to imposing an inflexible Federal limitation on the eligible participants in the program. It is therefore impossible to provide a uniform definition of an elementary school teacher, or to determine whether middle schools fall within the scope of elementary education since grade levels of elementary education may vary from State to State. Applicants with questions concerning this issue are urged to contact the appropriate State educational agency for guidance.

A clarification has been made in the final regulations by adding preschool teachers to provisions regarding program scope and participants. While the proposed rule referred only to elementary school teachers, ED had no intention to exclude teachers of educational levels below the elementary level. Since Congress transferred responsibility for both the preschool and elementary school portion of the program to the Education Department, the final rule clarifies the full range of activities and participants under the program. (S. Rept. No. 96–326, 96th Cong. 1st Sess. 50 (1979).

§ 797.10 What is the purpose of the program?

Comment. One commenter expressed concern that the regulations placed too much emphasis on knowledge of subject matter and instructional strategies, thereby ignoring the development of

science process and critical thinking skills.

Response. No change is needed. A broad definition of subject matter of science and mathematics is intended, including science processes and associated critical thinking skills, as well as science concepts and theories.

§ 797.31 What selection criteria does the Secretary use?

Comment. A commenter noted that while the preamble to the regulations stated that participating teachers are expected to carry out further inservice training of teacher colleagues in order to multiply the effect of the project, no provision for this was included in the regulations.

Response. No change has been made. While the Secretary encourages participating teachers to carry out further inservice training of their colleagues, the Secretary realizes the difficulty of evaluating the likelihood of achieving this objective. Therefore, while applicants are encouraged to develop plans to further the impact of the project, they will not be required to document these plans in their proposal. Further, the failure to include provisions for this in an application will not adversely affect the evaluation of an application.

Comment. One commenter suggested that the values assigned to the selection criteria be revised in order to emphasize the importance of training teachers to increase the participation of women, minorities, and the handicapped in science.

Response. No change has been made. Equal access and treatment for eligible project participants who are members of groups that have been traditionally underrepresented in science is considered in Section 797.31 (a) and (b).

The purpose of the program, as stated in Section 797.10, is to promote the offering of quality science, mathematics, and social studies instruction to the Nation's elementary school students through inservice teacher training. To change the values of the selection criteria to emphasize the participation of traditionally underrepresented groups would be inconsistent with the purpose of the program, which is to serve all teachers.

Comment. One commenter asked whether the needs assessment requirement in Section 797.31(f) referred exclusively to surveys or whether surveys are given preference over other methods of identifying needs. The commenter suggested that if a survey must be used in order to receive maximum points under the criterion, this should be specified in the regulations.

Response. No change has been made. In order to provide applicants with maximum flexibility in meeting the requirements of the regulations, no single method of conducting a needs assessment is stipulated in the regulations.

Applicants may satisfy the requirements of this section in a variety of ways including but not limited to a formal survey of teachers and/or administrators, meeting with teachers and other school personnel, a review of the literature, etc.

A new section has been added to Subpart E—What Conditions Must Be Met by a Grantee?—to clarify the applicable provisions governing costs under this program. Section 797.41 references the section of the Education Division General Administration Regulations (EDGAR) which apply to the Pre-College Teacher Development in Science Program. The statement in the Guide for Preparation of Proposals and Project and Award Management concerning use of the indirect cost rate for educational training projects has been revised in accordance with this new section to permit use of the negotiated rate for projects funded under this program.

CITATION OF LEGAL AUTHORITY: A citation of statutory or other legal authority has been placed in parentheses on the line following each provision.

Dated: December 22, 1980.

(Catalog of Federal Domestic Assistance No. 84119, Pre-College Teacher Development in Science Program)

Shirley M. Hufstedler,

Secretary of Education.

The Secretary adds a new Part 797 to Title 34 of the Code of Federal Regulations as follows:

PART 797—PRE-COLLEGE TEACHER DEVELOPMENT IN SCIENCE PROGRAM

Subpart A—General

Sec.

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

Subpart C—How Does One Apply for a Grant? [Reserved]

Subpart D—How Is a Grant Made?

Subpart E—What Conditions Must Be Met by a Grantee?

Authority: Pub. L. 81–507; Pub. L. 94–378; Pub. L. 96–88; 42 U.S.C. 1862; 20 U.S.C. 3444.

Subpart A—General

§ 797.1 Description of Pre-College Teacher Development in Science Program.

The Pre-College Teacher Development in Science Program offers continuing education in science, to provide in-service training for preschool and elementary school teachers.

(42 U.S.C. 1862)

§ 797.2 Eligible institutions.

The following institutions are eligible to receive grants:

(a) Institutions of higher education that offer at least a baccalaureate degree in science.

(b) Nonprofit private, non-academic institutions having both the scientific research staff and the facilities necessary to provide a quality science education program for pre-college teachers. This may include institutions such as, scientific research laboratories, field stations, museums, or planetariums.

(42 U.S.C. 1862)

§ 797.3 Regulations that apply to the Pre-College Teacher Development in Science Program.

The following regulations apply to the Pre-College Teacher Development in Science Program:

(a) The Education Division General Administrative Regulations (EDGAR) in 34 CFR Part 75 (Direct Grant Programs) and 34 CFR Part 77 (General).

(b) The regulations in this Part 797.

(42 U.S.C. 1862; 20 U.S.C. 3444)

§ 797.4 Definitions that apply to the Pre-College Teacher Development in Science Program.

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR Part 77:

Applicant	Fiscal year
Application	Nonprofit
Award	Preschool
Department	Project
Elementary school	Secretary

(20 U.S.C. 1221e-3(a)(1))

(b) *Definitions that apply to this Part.* The following definitions apply to this part:

"Science" means the mathematical, biological, physical, engineering, and social sciences.

(42 U.S.C. 1862)

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

§ 797.10 What is the purpose of the program?

The major objective of the Pre-College Teacher Development in Science Program is to promote the offering of quality science, social sciences, mathematics, and engineering instruction to the Nation's preschool and elementary school students. This is accomplished by—

(a) Improving preschool and elementary school teachers' knowledge of the subject matter of science and mathematics and their awareness of accompanying appropriate instructional strategies;

(b) Developing and maintaining cooperation and communication between preschool and elementary school teachers and scientists at institutions of higher education and certain other scientific institutions.

(c) Aiding teachers in the identification and use of resources which are appropriate to their level of instruction, and which will aid in their teaching of scientific concepts.

(42 U.S.C. 1862)

§ 797.11 What are the general characteristics of the projects?

(a) Projects supported in this program may involve a group of preschool and elementary school teachers engaged in a learning experience sponsored by the grantee institution and staffed by its faculty members or others selected for their expertise.

(b) Project staff site visits for individual consultation, with participants and group meetings devoted to classroom teaching strategies may be used to augment the instructional phase.

(c) Consistent with the needs of an identified group of teachers, projects provide: (1) instruction on general concepts of science and mathematics, (2) instruction on basic elements and concepts of a particular discipline, or (3) more advanced training in specific disciplines. The instruction may also illustrate appropriate materials and instructional teaching strategies for classroom use, as well as local resources that are applicable to classroom instruction.

(42 U.S.C. 1862)

§ 797.12 What types of projects are supported?

The types of projects supported under this program include but are not limited to:

(a) Academic Year Seminars—Part-time study offered at a central location for teachers within commuting distance, with sessions during the academic year.

(b) Summer Seminars—Part-time study offered during the summer at a central location for teachers within commuting distance with follow-up sessions during the academic year.

(c) Summer Workshops—Full-time projects offered during the summer, generally for 1 to 4 weeks. These projects normally will be regional and intended for more advanced training in specific disciplines. A limited follow-up activity may take place during the academic year.

(42 U.S.C. 1862)

Subpart C—How Does One Apply for a Grant? [Reserved]

Subpart D—How Is a Grant Made?

§ 797.30 How does the Secretary evaluate an application?

(a) The Secretary evaluates each application on the basis of the criteria in § 797.31.

(b) The Secretary assigns a maximum of 70 points that an application may receive under all the criteria.

(c) Each criterion is evaluated using a scale of 1–7.

(d) The weight assigned to each complete criterion is indicated in parenthesis following each criterion.

(e) For applications of substantially equal quality, the Secretary gives priority to projects that, nationwide, contribute to achieving overall balance among projects funded under this program in the following categories:

(1) Grade level.

(2) Academic discipline.

(3) Institutional type.

(4) Geographic location.

(42 U.S.C. 1862; 20 U.S.C. 1221e-3(a)(1))

§ 797.31 What selection criteria does the Secretary use?

(a) *Plan of operation.* (10 percent)

(1) The Secretary reviews each application for information that shows the quality of the plan of operation for the project.

(2) The Secretary looks for information that shows—

(i) High quality in the design of the project;

(ii) An effective plan of management that insures proper and efficient administration of the project;

(iii) A clear description of how the objectives of the project relate to the purpose of the program;

(iv) The way the applicant plans to use its resources and personnel to achieve each objective;

(v) A clear description of how the applicant will provide equal access and treatment for eligible project participants who are members of groups that have been traditionally underrepresented, such as—

(A) Members of racial or ethnic minority groups;

(B) Women;

(C) Handicapped persons; and

(D) The elderly.

(b) *Quality of key personnel.* (10 percent)

(1) The Secretary reviews each application for information that shows the quality of the key personnel the applicant plans to use on the project.

(2) The Secretary looks for information that shows—

(i) The qualifications of the project director (if one is to be used);

(ii) The qualifications of each of the other key personnel to be used in the project;

(iii) The time that each person referred to in paragraphs (b)(2)(i) and (ii) of this section plans to commit to the project; and

(iv) The extent to which the applicant, as part of its nondiscriminatory employment practices, encourages applications for employment from persons who are members of groups that have been traditionally underrepresented, such as members of racial or ethnic minority groups, women, and handicapped persons.

(3) To determine the qualifications of a person, the Secretary considers evidence of past experience and training, in fields related to the objectives of the project, as well as other information that the applicant provides.

(c) *Budget and cost effectiveness.* (5 percent)

(1) The Secretary reviews each application for information that shows that the project has an adequate budget and is cost effective.

(2) The Secretary looks for information that shows—

(i) The budget for the project is adequate to support the project activities; and

(ii) Costs are reasonable in relation to be objectives of the project.

(d) *Evaluation plan.* (5 percent)

(1) The Secretary reviews each application for information that shows

the quality of the evaluation plan for the project. (See 34 CFR 75.590—Evaluation by the grantee.)

(2) The Secretary looks for information that shows methods of evaluation that are appropriate for the project and, to the extent possible, are objective and produce data that are quantifiable.

(e) *Adequacy of resources.* (10 percent)

(1) The Secretary reviews each application for information that shows that the applicant plans to devote adequate resources to the project.

(2) The Secretary looks for information that shows—

(i) The facilities that the applicant plans to use are adequate; and

(ii) The equipment and supplies that the applicant plans to use are adequate.

(iii) Evidence is presented of long term support and institutional commitment to pre-college science education from the host institution. (20 U.S.C. 1221(e)–3(a)(1))

(f) *Need for the project.* (20 percent)

(1) The Secretary reviews each application for information that shows a well-established need for the project.

(2) The Secretary looks for information that shows—

(i) An adequate needs assessment has been carried out;

(ii) Appropriate individuals, especially representative teachers, have been consulted in the needs assessment; and

(iii) Instructional needs have been clearly identified and stated.

(g) *Cooperative relationships.* (10 percent)

(1) The Secretary reviews each application for information that shows the extent to which cooperative teaching relationships will be established between preschool and elementary teachers and college and university faculty or other scientists.

(2) The Secretary looks for information that shows the extent to which the project will advance the long-term program objective of promoting useful relationships between preschool and elementary science teachers and college and university or other scientists beyond the term of the grant.

(h) *Subject matter emphasis.* (20 percent)

(1) The Secretary reviews each application for information that shows the extent to which subject matter in science is emphasized.

(2) The Secretary looks for information that shows—

(i) The extent to which a central focus on science curriculum is intergrated with appropriate teaching strategies; and

(ii) The appropriateness of the content for the designated teacher group.

(i) *Participant selection.* (10 percent)

(1) The Secretary reviews each application for information that shows the appropriateness of the participant selection process.

(2) The Secretary looks for information that shows—

(i) Adequacy of plans to recruit participants; and

(ii) Suitability of participant evaluation and selection procedures.

(42 U.S.C. 1862)

Subpart E—What Conditions Must Be Met by a Grantee?

§ 797.40. Who may participate in the projects?

(a) The program is designed for the continuing education of preschool and elementary school teachers.

(b) Other school leaders such as principals, assistant superintendents, or resource teachers, may team with one or two teachers to represent a school or system.

(42 U.S.C. 1862)

§ 797.41 What cost principles apply to this program?

(a) The general principles to be used in determining costs for projects supported by this program are referenced in Subpart E of the Education Division General Administration Regulations (EDGAR) in 34 CFR Part 75 §§ 75.530–568.

(b) The section governing indirect cost rates for educational training projects contained in § 75.562 of EDGAR does not apply to this program.

(20 U.S.C. 1221e–3(a)(1))

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Tuesday
December 30, 1980

Part XIII

Department of Education

Rehabilitation Training; Final Rules With Invitation To Comment

DEPARTMENT OF EDUCATION

34 CFR Parts 385, 386, 387, 388, 389, and 390

Rehabilitation Training: Final Regulations With Invitation To Comment

AGENCY: Department of Education.

ACTION: Final regulations with invitation to comment.

SUMMARY: The Secretary adopts regulations for the purpose of implementing the Rehabilitation Act of 1973, as amended by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Pub. L. 95–602). These regulations include the requirements for Rehabilitation Long-Term Training, Experimental and Innovative Training, State Vocational Rehabilitation Unit In-Service Training, Rehabilitation Continuing Education Programs, and Rehabilitation Short-Term Training.

DATE: These regulations are expected to be effective forty-five days after they are transmitted to Congress. Regulations are usually transmitted to Congress several days before they are published in the **Federal Register.** The effective date is changed if the Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person.

DATES: Comments must be received on or before March 2, 1981.

ADDRESS: Comments should be addressed to Harold F. Shay, Director, Division of Manpower Development, Rehabilitation Services Administration, Office of Special Education and Rehabilitative Services, Department of Education, Room 3321, Mary E. Switzer Building, 330 C Street, SW., Washington, D.C. 20201, Telephone: (202) 245–0079 or TTY (202) 245–0591.

SUPPLEMENTARY INFORMATION:

Waiver of Proposed Rulemaking Procedures Affecting Selection Criteria

The Secretary of Health, Education, and Welfare published a Notice of Proposed Rulemaking in the **Federal Register** on November 29, 1979 that covered all new vocational rehabilitation and independent living rehabilitation authorities contained in the Rehabilitation, Comprehensive Services and Developmental Disabilities Amendments of 1978 (Pub. L. 95–602). Proposed regulations for the Rehabilitation Training Program were included in this Notice of Proposed Rulemaking.

On May 4, 1980, the Department of Education was established and the Rehabilitation Services Administration became part of the Office of Special Education and Rehabilitative Services within this new Department. As a result, the publication of regulations under the Rehabilitation Act of 1973, as amended, is now subject to the provisions of Section 431 of the General Education Provisions Act and other requirements in effect in the Department of Education. It has become necessary therefore to revise the proposed regulations for the Rehabilitation Training Program in order to make them conform with requirements affecting Department of Education programs, including the selection criteria to be used in the evaluation of applications submitted for grant assistance. These selection criteria had not been included in the previously published Notice of Proposed Rulemaking.

In accordance with Section 431(b)(2)(A) of the General Education Provisions Act (20 U.S.C. 1232(b)(2)(A)), it is the practice of the Department of Education to offer interested parties the opportunity to comment on all proposed regulations, including the selection criteria to be used in discretionary grant programs such as the Rehabilitation Training Program. The publication of an additional proposed rulemaking covering the selection criteria for this program would be impracticable and contrary to the public interest under 5 U.S.C. 553(b) if grants are to be made in a timely manner in FY 1981, however, and the selection criteria are therefore being published as final regulations in this document.

Although the selection criteria for the Rehabilitation Training Program have been previously identified in Application Notices published in the **Federal Register,** it is recognized that there has not been an opportunity for the public to comment specifically on their appropriateness for these programs. Interested parties are invited therefore to submit comments and suggestions on the selection criteria to be used in the awarding of grants in future fiscal years. All comments and suggestions must be received no later than March 2, 1981.

Summary of Changes

Some comments were received in response to the Notice of Proposed Rulemaking provisions covering the Rehabilitation Training Program and changes are also being made in these revised regulations in response to these comments. A Summary of Comments and Responses to the proposed regulations is included in Appendix A.

The Notice of Proposed Rulemaking had included proposed regulations for the Rehabilitation Research Fellowship Program. Regulations for the Rehabilitation Research Fellowship Program are not included in these interim regulations since the National Institute of Handicapped Research has announced that it will be administering a Rehabilitation Research Fellowship Program in the future and, as a result, the Rehabilitation Services Administration will no longer be awarding Rehabilitation Research Fellowships.

References to EDGAR

Readers will note that reference to the Education Division General Administrative Regulations (EDGAR) cite Title 34 of the Code of Federal Regulations. EDGAR was transferred to Title 34 through final regulations published in the **Federal Register** on November 21, 1980 (45 FR 77368).

However, EDGAR was initially published in the **Federal Register** on April 3, 1980 (45 FR 22494) under Title 45 of the Code of Federal Regulations (CFR). For readers wishing to refer to that EDGAR document, the following cross-references will be helpful:

—45 CFR Part 74 is now 34 CFR Part 74.
—45 CFR Part 100a is now 34 CFR Part 75.
—45 CFR Part 100b is now 34 CFR Part 76.
—45 CFR Part 100c is now 34 CFR Part 77.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding these regulations. Written comments and recommendations may be sent to the address given at the beginning of this preamble. All comments received on or before March 2, 1981 will be considered in any future revisions of the final regulations.

All comments submitted in response to these final regulations will be available for public inspection during and after the comment period in Room 3321, Mary E. Switzer Building, 330 C Street, S.W., Washington, D.C. between 8:30 a.m. and 4:00 p.m., Monday through Friday, except Federal holidays.

The Department also requests comments on whether the regulations in this document would require submission of information that is already being gathered by or is available from any other agency or authority of the United States.

Citation of Legal Authority

A citation of statutory authority is placed in parentheses on the line following each substantive provision of the interim regulations. The first citation

is the appropriate section of the Rehabilitation Act of 1973, as amended, and it is followed by a citation to the same provision in the United States Code.

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

(Catalog of Federal Domestic Assistance Program Number 84.129 Rehabilitation Training)

Accordingly, the Secretary amends Title 34 of the Code of Federal Regulations by adding 34 Part 385 to read as follows:

PART 385—REHABILITATION TRAINING

Subpart A—General

Sec.

Subpart B—[Reserved]

Subpart C—How Does One Apply For a Grant?

Subpart D—How Does the Secretary Make a Grant?

Subpart E—What Conditions Must Be Met by a Grantee?

Authority: Secs. 12(c), 304 and 306, Rehabilitation Act of 1973, as amended (29 U.S.C. 711(c), 744 and 776)

Subpart A—General

§ 385.1 What is the Rehabilitation Training Program?

(a) The Rehabilitation Training Program is designed to—

(1) Increase the supply of personnel available for employment in public and private agencies and institutions involved in the vocational rehabilitation and independent living rehabilitation of physically and mentally handicapped individuals, especially those individuals with the most severe handicaps; and

(2) Maintain and upgrade basic skills and knowledge of personnel employed as providers of vocational, medical, social or psychological rehabilitation services.

(b) The Secretary awards financial assistance through five categories of training programs—

(1) Rehabilitation Long-Term Training (Part 386);

(2) Experimental and Innovative Training (Part 387);

(3) State Vocational Rehabilitation Unit In-Service Training (Part 388);

(4) Rehabilitation Continuing Education Programs (Part 389); and

(5) Rehabilitation Short-Term Training (Part 390).

(Section 304 of the Act; 29 U.S.C. 774)

§ 385.2 Who is eligible for assistance under these programs?

State agencies and other public or nonprofit agencies and organizations, including institutions of higher education, are eligible for assistance under the Rehabilitation Training Program.

(Section 304 of the Act; 29 U.S.C. 774)

§ 385.3 What regulations apply to these programs?

The following regulations apply to the Rehabilitation Training Program—

(a) The Education Division General Administrative Regulations (EDGAR) in 34 CFR Part 75 (Direct Grant Programs);

(b) The regulations in EDGAR, 34 CFR Part 77 (General);

(c) The regulations in this Part 385; and

(d) The regulations in Parts 386, 387, 388, 389, and 390, as appropriate.

(Sections 12(c) and 304 of the Act; 29 U.S.C. 711(c) and 774)

§ 385.4 What definitions apply to these programs?

(a) The following definitions in 34 CFR Part 77 apply to the programs under the Rehabilitation Training Program—

"Applicant"
"Application"
"Award"
"Budget Period"
"Department"
"EDGAR"
"Nonprofit"
"Private"
"Project"
"Project Period"
"Public"
"Secretary"

(Section 12(c) of the Act; 29 U.S.C. 711(c))

(b) The following definitions also apply to programs under the Rehabilitation Training program—

"Act" means the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.) as amended by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Pub. L. 95–602).

(Section 12(c) of the Act; 29 U.S.C. 711(c))

"Handicapped individual" means an individual—

(1) Who has a physical or mental disability which for that individual constitutes or results in a substantial handicap to employment; and

(2) Who can reasonably be expected to benefit in terms of employability from the provision of vocational rehabilitation services, or for whom an extended evaluation of vocational rehabilitation potential is necessary to determine whether he or she might reasonably be expected to benefit in terms of employability from the provision of vocational rehabilitation services.

(Section 7(7)(A) of the Act; 29 U.S.C. 706(7)(A))

"Independent living rehabilitation services" or "independent living services means."

(1) Counseling services, including psychological counseling, psychotherapeutic counseling, peer counseling, advocacy services and related services;

(2) Housing incidental to the provision of any independent living rehabilitation services, and including appropriate accommodations to, and modifications of any space utilized to serve severely handicapped individuals;

(3) Physical and mental restoration services;

(4) Attendant care;

(5) Transportation;

(6) Interpreter services for deaf individuals, including tactile interpretation for deaf-blind individuals;

(7) Reading services, rehabilitation teaching services, and orientation and mobility services for blind individuals;

(8) Recreational activities;

(9) Services to members of a severely handicapped individual's family when necessary for improving the individual's ability to engage or continue in employment;

(10) Vocational and other training services, including personal and vocational adjustment when necessary for improving a severely handicapped individual's ability to live and function more independently, or to engage or continue in employment;

(11) Job placement services;

(12) Referral services;
(13) Telecommunications, sensory and other technological aids and devices;
(14) Services for children of pre-school age including physical therapy, development of language and communication skills, and child development services;
(15) Any other vocational rehabilitation services available under the State plan for vocational rehabilitation services which are appropriate to the independent living rehabilitation needs of a severely handicapped individual; and
(16) Any appropriate preventive services necessary to decrease the future needs of a severely handicapped individual.

(Section 702(b) of the Act; 29 U.S.C. 796(b))

"Physical or mental disability" means a physical or mental condition which materially limits, contributes to limiting or, if not corrected, will probably result in limiting an individual's employment activities or vocational functioning.

(Section 7(7)(a)(i) of the Act; 29 U.S.C. 706(7)(A)(i))

"Physical and mental restoration services means—
(1) Medical or corrective surgical treatment;
(2) Diagnosis and treatment for mental or emotional disorders by a physician skilled in the diagnosis and treatment of such disorders or by a pyschologist licensed or certified in accordance with State laws and regulations;
(3) Dentistry;
(4) Nursing services;
(5) Necessary hospitalization (either inpatient or outpatient care) in connection with surgery or treatment and clinic services;
(6) Convalescent or nursing home care;
(7) Drugs and supplies;
(8) Prosthetic, orthotic or other assistive devices including hearing aids, essential to obtaining or retaining employment;
(9) Eyeglasses and visual services, including visual training, and the examination and services necessary for the prescription and provision of eyeglasses, contact lenses, microscopic lenses, telescopic lenses, and other special visual aids, prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select;
(10) Podiatry;
(11) Physical therapy;
(12) Speech or hearing therapy;
(13) Psychological services;
(14) Therapeutic recreation services;
(15) Medical or medically related social work services;
(16) Treatment of either acute or chronic medical complications and emergencies which are associated with or arise out of the provision of physical and mental restoration services; or which are inherent in the condition under treatment;
(17) Special services for the treatment of individuals suffering from end-stage renal disease, including transplantation, dialysis, artificial kidneys, and supplies; and
(18) Other medical or medically related rehabilitation services including art therapy, dance therapy, music therapy and psychodrama.

(Section 103(a)(4) of the Act; 29 U.S.C. 723(a)(4))

"State agency" means the sole State agency designated to administer (or supervise local administration of) the State plan for vocational rehabilitation services. The term includes the State agency for the blind, if designated as the sole State agency with respect to that part of the plan relating to the vocational rehabilitation of blind individuals.

(Section 101(a)(1)(A) of the Act; 29 U.S.C. 721(a)(1)(A))

"State unit" or "State vocational rehabilitation unit" means either—
(1) The State agency vocational rehabilitation bureau, division, or other organizational unit which is primarily concerned with vocational rehabilitation or vocational and other rehabilitation of handicapped individuals and which is responsible for the administration of the vocational rehabilitation program of the State agency; or
(2) The independent State commission, board, or other agency which has vocational rehabilitation, or vocational and other rehabilitation as its primary function.

(Section 7(3) of the Act; 29 U.S.C. 706(3))

"Stipend" means financial assistance on behalf of individuals in support of their training, as opposed to salary payment for services provided within the project.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

"Vocational rehabilitation services" means—
(1) Evaluation of vocational rehabilitation potential, including diagnostic and related services incidental to the determination of eligibility for, and the nature and scope of services to be provided;
(2) Counseling and guidance, including personal adjustment counseling, to maintain a counseling relationship throughout a handicapped individual's program of services, and referral necessary to help handicapped individuals secure needed services from other agencies;
(3) Physical and mental restoration services; necessary to correct or substantially modify a physical or mental condition which is stable or slowly progressive;
(4) Vocational and other training services, including personal and vocational adjustment, books, tools, and other training materials;
(5) Maintenance;
(6) Transportation;
(7) Services to members of a handicapped individual's family when necessary to the vocational rehabilitation of the handicapped individual;
(8) Interpreter services for the deaf, including tactile interpreting for deaf-blind individuals;
(9) Reader services, rehabilitation teaching services, and orientation and mobility services for the blind;
(10) Telecommunications, sensory and other technological aids and devices;
(11) Recruitment and training services to provide new employment opportunities in the fields of rehabilitation, health, welfare, public safety, law enforcement and other appropriate public service employment;
(12) Placement in suitable employment;
(13) Post-employment services necessary to maintain suitable employment;
(14) Occupational licenses; and
(15) Other goods and services which can reasonably be expected to benefit a handicapped individual in terms of employability.

(Section 103(a) of the Act; 29 U.S.C. 723(a))

Subpart B—[Reserved]

Subpart C—How Does One Apply for a Grant?

§ 385.20 What are the application procedures for these programs?

The Secretary gives the State vocational rehabilitation unit an opportunity to review and comment on applications submitted from within the State that it serves. The procedures to be followed by the applicant and the State are in EDGAR §§ 75.155–75.159.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

Subpart D—How Does the Secretary Make a Grant?

§ 385.30 [Reserved]

§ 385.31 How does the Secretary evaluate an application?

(a) The Secretary evaluates each application on the basis of general

selection criteria identified in § 385.32 and specific selection criteria identified in Parts 386, 387, 388, 389 and 390. The maximum possible score for each complete criterion under each category of training is stated in parentheses in § 386.31, § 387.31, § 388.31, § 389.31, and § 390.31. The number of points awarded each criterion depends on how well the application meets all the elements under that criterion.

(b) The Secretary awards up to 100 possible points for these selection criteria.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

§ 385.32 What general selection criteria does the Secretary use in reviewing an application?

(a) *Plan of operation.* (1) The Secretary reviews each application for information that shows the quality of the plan of operation for the project.

(2) The Secretary looks for information that shows—

(i) High quality in the design of the project;

(ii) An effective plan of management that insures proper and efficient administration of the project;

(iii) A clear description of how the objectives of the project relate to the purpose of the program;

(iv) The way the applicant plans to use its resources and personnel to achieve each objective;

(v) A clear description of how the applicant will provide equal access and treatment for eligible project participants who are members of groups that have been traditionally underrepresented, such as—

(A) Handicapped persons;

(B) The elderly;

(C) Women; and

(D) Members of racial or ethnic minority groups.

(b) *Quality of key personnel.* (1) The Secretary reviews each application for information that shows the quality of key personnel proposed for the project.

(2) The Secretary looks for information that shows—

(i) The qualifications of the project director;

(ii) The qualifications of each of the other key personnel to be used in the project;

(iii) The time that each person referred to in paragraphs (2)(i) and (ii) of this section will commit to the project; and

(iv) The extent to which the applicant, as part of its nondiscriminatory employment practices, encourages applications for employment from persons who are members of groups that have been traditionally underrepresented, such as—

(A) Handicapped persons;

(B) The elderly;

(C) Women; and

(D) Members of racial or ethnic minority groups.

(3) To determine personnel qualifications, the Secretary considers experience and training, in fields related to the objectives of the project, as well as other information that the applicant provides.

(c) *Budget and cost effectiveness.* (1) The Secretary reviews each application for information that shows that the project has an adequate budget and is cost effective.

(2) The Secretary looks for information that shows—

(i) The budget for the project is adequate to support the project activities;

(ii) Costs are reasonable in relation to the objectives of the project.

(d) *Evaluation plan. (1) The Secretary reviews each application for information that shows the quality of the evaluation plan for the project.*

(2) The Secretary looks for information that shows methods of evaluation that are appropriate for the project, and to the extent possible, are objective, and produce data that are quantifiable.

(e) *Adequacy of resources.* (1) The Secretary reviews each application for information that shows that the applicant plans to devote adequate resources to the project.

(2) The Secretary looks for information that shows—

(i) The facilities that the application plans to use are adequate; and

(ii) The equipment and supplies that the applicant plans to use are adequate.

(Sections 12(c) and 304 of the Act; 29 U.S.C. 711(c) and 774)

§ 385.33 What other factors does the Secretary consider in reviewing an application?

In addition to the selection criteria listed in § 385.32 and Parts 386 through 390, the Secretary, in making awards under this program, considers such factors as—

(a) The geographical distribution of projects in each Rehabilitation Training Program category throughout the country; and

(b) The past performance of the applicant in carrying out similar training activities under previously awarded grants, as indicated by such factors as compliance with grant conditions, soundness of programmatic and financial management practices and attainment of established project objectives.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

Subpart E—What Conditions Must Be Met by a Grantee?

§ 385.40 What are the requirements pertaining to the membership of a project advisory committee?

When a project funded under Parts 386 through 390 establishes an advisory committee, its membership must include handicapped persons or other representatives of handicapped individuals, trainees, and providers of vocational rehabilitation and independent living rehabilitation services.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

§ 385.41 What are the requirements affecting the collection of data from State agencies?

When the collection of data is necessary from handicapped individuals being served by two or more State agencies or from employees of two or more of these agencies, the project director must submit requests for the data to appropriate representatives of the affected agencies, as determined by the Secretary. This requirement also applies to employed project staff and individuals enrolled in courses of study supported under these programs.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

§ 385.42 What are the requirements affecting the dissemination of training materials?

A set of any training materials developed under the Rehabilitation Training Program must be submitted to any information clearinghouse designated by the Secretary.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

The Secretary amends Title 34 of the Code of Federal Regulations by redesignating Subpart E of Part 362 as 34 CFR Part 386 and revises the regulations to read as follows:

PART 386—REHABILITATION TRAINING: REHABILITATION LONG-TERM TRAINING

Subpart A—General

Sec.

Supart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

Authority: Secs. 12(c) and 304, Rehabilitation Act of 1973 (29 U.S.C. 711(c) and 774).

Subpart A—General

§ 386.1 What is the Rehabilitation Long-Term Training Program?

This program is designed to provide a balanced program of academic and non-academic training activities in the fields of—

(a) rehabilitation medicine;
(b) rehabilitation nursing;
(c) rehabilitation counseling;
(d) rehabilitation social work;
(e) rehabilitation psychiatry;
(f) rehabilitation psychology;
(g) physical therapy;
(h) occupational therapy;
(i) speech-language pathology and audiology;
(j) rehabilitation facility administration;
(k) vocational evaluation and work adjustment;
(l) prosthetics and orthotic;
(m) rehabilitation of the blind;
(n) rehabilitation of the deaf;
(o) rehabilitation of the mentally ill;
(p) rehabilitation job placement and job development;
(q) therapeutic recreation;
(r) undergraduate education in the rehabilitation services;
(s) rehabilitation administration;
(t) rehabilitation dentistry; and
(u) other fields that contribute to the rehabilitation of handicapped individuals, including homebound and institutionalized individuals and individuals with limited English-speaking ability.

(Section 304(b) of the Act; 29 U.S.C. 774(b))

§ 386.2 Who is eligible for assistance under this program?

Those agencies and organizations eligible for assistance under this program are described in 34 CFR § 385.2.

(Section 304(a) of the Act; 29 U.S.C. 774(a))

§ 386.3 What regulations apply to this program?

The following regulations apply to this program:

(a) 34 CFR Part 385 (Rehabilitation Training); and

(b) The regulations in this Part 386.

(Section 304 of the Act; 29 U.S.C. 774)

§ 386.4 What definitions apply to this program?

The definitions in 34 CFR Part 385 apply to this program.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

§ 386.10 What types of projects are authorized under this program?

The Rehabilitation Long-Term Training Program provides financial assistance for—

(a) Projects that provide basic or advanced training leading to an academic degree in one of those fields of study identified in § 386.1.

(b) Projects that provide a number of interrelated training activities designed to improve the professional competence of employed rehabilitation workers in one of those fields of study indentified in § 386.1 but not directly related to the awarding of an academic degree.

(c) Projects that provide undergraduate medical students an orientation to the concepts and techniques of rehabilitation medicine.

(d) Projects that provide support for medical residents enrolled in residency training programs in the specialty of physical medicine and rehabilitation.

(Section 304(b) of the Act; 29 U.S.C. 774(b))

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make A Grant?

§ 386.30 What selection criteria are used under this program?

(a) *Plan of operation.* (30 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(a).

(b) *Quality of key personnel.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(b).

(c) *Budget and cost effectiveness.* (10 points)

The Secretary evaluates each application on the baisis of the criterion in § 385.32(c).

(d) *Evaluation plan.* (5 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(d).

(e) *Adequacy of resources.* (5 points)

The Secretary evaluates each application on the basis of criterion in § 385.32(e).

(f) *Evidence of need.* (10 points)

(1) The Secretary reviews each application for information that shows that the need for the training project has been adequately justified.

(2) The Secretary looks for information that shows that the need for the training project has been established in terms of rehabilitation manpower supply and demand and includes an assessment of the potential of existing programs within the geographical area to meet the employment needs in the specific rehabilitation field for which grant support is sought.

(g) *Relevance to State-Federal rehabilitation service program.* (10 points)

(1) The Secretary reviews each application for information that shows that the proposed project appropriately relates to the mission of the State/Federal rehabilitation service program.

(2) The Secretary looks for information that shows that the project can be expected either to increase the supply of trained personnel available to State and other public or nonprofit agencies involved in the rehabilitation of physically or mentally handicapped individuals, or to maintain and improve the skills and quality of professional personnel in the rehabilitation fieled in which the training is to be provided.

(h) *Nature and scope of curriculum.* (20 points)

(1) The Secretary reviews each application for information that demonstrates the adequacy of the proposed curriculum.

(2) The Secretary looks for information that shows—

(i) The scope and nature of the coursework reflect content that can be expected to enable the achievement of the established project objectives;

(ii) The curriculum and teaching methods provide for an integration of theory and practice relevant to the educational objectives of the program;

(iii) There is evidence of educationally focused practical and other field experiences in settings that assure student involvement in the provision of vocational rehabilitation or independent living rehabilitation services to physically and mentally handicapped persons, especially those who are severely handicapped;

(iv) The didactic coursework includes student exposure to vocational rehabilitation or independent living rehabilitation processes, concepts, programs, and services; and

(v) There is evidence of current professional accreditation by the designated accrediting agency in the professional field in which grant support is being requested.

(Sections 12(c) and 304 of the Act; 29 U.S.C. 711(c) and 774)

Subpart E—What Conditions Must Be Met by a Grantee?

§ 386.40 What are the matching requirements?

(a) A grantee must contribute to the cost of a project under this program in an amount satisfactory to the Secretary. The part of the costs to be borne by the grantee is determined by the Secretary at the time of the award.

(b) The grantee is expected to furnish as large a part of the total project cost as possible. In the case of academic training projects with a multi-year project period, the grantee's share of the teaching costs is expected to increase progressively in each succeeding year so that total personnel costs are fully absorbed by the grantee at the termination of the project period.

(Sec. 12(c) and 304 of the Act; 29 U.S.C. 711(c) and 774 (a))

§ 386.41 What are allowable costs?

In addition to those allowable costs established in EDGAR §§ 75.530–75.562, the following items are allowable under long-term training projects.

(a) Student stipends;

(b) Tuition and fees; and

(c) Student travel in conjunction with training assignments.

(Sec. 12(c) and 304(a) of the Act; 29 U.S.C. 711(c) and 774 (a))

§ 386.42 What are the special requirements affecting the awarding of traineeships?

(a) A candidate for a rehabilitation traineeship must—

(1) Be a citizen of the United States or a foreign national lawfully admitted to the United States for permanent residence;

(2) Take the training at the educational institution or agency designated in the traineeship award;

(3) Not be an employee of the Federal government;

(4) Not concurrently receiving educational allowances from any other Federal, State or local public or voluntary agency when that allowance is conditioned on a conflicting employment obligation incurred by the trainee, except for federally assisted student loans, or educational allowances or benefits payable under Chapters 34, 35 and 36 of Title 38, U.S.C. as limited by Section 213 of the Veterans Educational and Training Amendments Act of 1972, or educational allowances or benefits payable under any State or local program;

(5) Be enrolled for non-academic study in the grantee institution;

(6) Express interest in a career in clinical practice, administration, supervision, teaching, or research in the vocational rehabilitation or independent living rehabiliation of physically or mentally handicapped persons, especially those with the most severe handicaps; and

(7) Indicate an expectation to seek employment in a State vocational rehabilitation agency or in another rehabilitation agency or facility from which the State agency secures services.

(b) No training or instruction may be provided to an individual for any one course of study extending for a period in excess of four years.

(Sections 12(c) and 304(b) of the Act; 29 U.S.C. 711(c) and 774 (b))

The Secretary amends Title 34 of the Code of Federal Regulations by adding 34 CFR Part 387 to read as follows:

PART 387—EXPERIMENTAL AND INNOVATIVE TRAINING

Subpart A—General

Sec.

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

Subpart E—What Conditions Must Be Met by a Grantee?

Authority: Sections 12(c) and 304 of the Rehabilitation Act of 1973 (29 U.S.C. 711(c) and 774).

Subpart A—General

§ 387.1 What is the Experimental and Innovative Training Program?

This program is designed—

(a) To develop new types of rehabilitation personnel, and to demonstrate the effectiveness of these new types of personnel in providing rehabilitation services to severely handicapped persons; and

(b) To develop new and improved methods of training rehabilitation personnel so that there may be a more effective delivery of rehabilitation services by State and other rehabilitation agencies.

(Section 304 of the Act; 29 U.S.C. 774)

§ 387.2 Who is eligible for assistance under this program?

Those agencies and organizations eligible for assistance under this program are described in 34 CFR § 385.2.

(Section 304(a) of the Act; 29 U.S.C. 774(a))

§ 387.3 What regulations apply to this program?

(a) 34 CFR Part 385 (Rehabilitation Training); and

(b) The regulations in this Part 387.

(Section 304 of the Act; 29 U.S.C. 774)

§ 387.4 What definitions apply to this program?

The definitions in 34 CFR Part 385 apply to this program.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

§ 387.10 What types of projects are authorized under this program?

The Experimental and Innovative Training Program supports time-limited pilot projects through which new types of rehabilitation workers may be trained or through which innovative methods of training rehabilitation workers may be demonstrated.

(Section 304(b) of the Act; 29 U.S.C. 744(b))

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

§ 387.30 What selection criteria are used under this program?

(a) *Plan of operation.* (25 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(a).

(b) *Quality of key personnel.* (15 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(b).

(c) *Budget and cost effectiveness.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(c).

(d) *Evaluation plan.* (15 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(d).

(e) *Adequacy of resources.* (5 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(e).

(f) *Evidence of need.* (10 points)

The Secretary reviews each application for information that shows that the need for the training project has been adequately justified.

(2) The Secretary looks for information that shows that—

(i) The proposed project represents an experimental or innovative approach to the training of rehabilitation workers and provides for the training of new types of rehabilitation workers or the development of innovative training methodologies; and

(ii) The need for the training program has been justified and includes an assessment of the potential of existing training programs of a traditional nature to meet the personnel needs in the rehabilitation field for which support is sought.

(g) *Relevance to State-Federal rehabilitation service program.* (10 points)

(1) The Secretary reviews each application for information that shows that the proposed project appropriately relates to the mission of the State-Federal rehabilitation service program.

(2) The Secretary looks for information that shows that the project can be expected either to increase the supply of trained personnel available to public and private agencies involved in the rehabilitation of physically or mentally handicapped individuals or maintain and improve the skills and quality of rehabilitation workers.

(h) *Nature and scope of curriculum.* (10 points)

(1) The Secretary reviews each application for information that demonstrates the adequacy and scope of the proposed curriculum.

(2) The Secretary looks for information that shows that—

(i) The scope and nature of the training content can be expected to enable the achievement of the established project objectives of the training project;

(ii) The curriculum and teaching methods provide for an integration of theory and practice relevant to the educational objectives of the program;

(iii) There is evidence of educationally focused practicum or other field experiences in settings that assure student involvement in the provision of vocational rehabilitation or independent living rehabilitation services to physically and mentally handicapped persons, especially those who are severely handicapped; and

(iv) The didactic coursework includes student exposure to vocational rehabilitation or independent living rehabilitation processes, concepts, programs, and services.

(Section 12(c) and 304 of the Act; 29 U.S.C. 711(c) and 774)

Subpart E—What Conditions Must Be Met by a Grantee?

§ 387.40 What are the matching requirements?

A grantee must contribute to the cost of a project under this program in an amount satisfactory to the Secretary. The part of the costs to be borne by the grantee is determined by the Secretary at the time of the grant award.

(Section 12(c) and 304(a) of the Act; 29 U.S.C. 711(c) and 774(a))

§ 387.41 What are allowable costs?

In addition to those allowable costs established under EDGAR §§ 75.530–75.562, the following items are allowable under experimental and innovative training projects—

(a) Student stipends;

(b) Tuition and fees; and

(c) Student travel in conjunction with training assignments.

(Section 12(c) and 304(a) of the Act; 29 U.S.C. 711(c) and 774(a))

The Secretary amends Title 34 of the Code of Federal Regulations by adding 34 CFR 388 to read as follows:

Part 388—State Vocational Rehabilitation Unit In-Service Training

Subpart A—General

Sec.

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

Subpart E—What Conditions Must Be Met by a Grantee?

Authority: Sections 12(c) and 304 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 711(c) and 774)

Subpart A—General

§ 388.1 What is the State Vocational Rehabilitation Unit In-Service Training Program?

This program is designed to support special projects for training State vocational rehabilitation unit personnel in program areas essential to the effective management of the unit's program of vocational rehabilitation services or in skill areas which will enable staff personnel to improve their ability to provide vocational rehabilitation services to severely handicapped individuals.

(Section 304 of the Act; 29 U.S.C. 774)

§ 388.2 Who is eligible for assistance under this program?

Those agencies and organizations eligible for assistance under this program are described in 34 CFR § 385.2.

(Section 304(a) of the Act; 29 U.S.C. 744(a))

§ 388.3 What regulations apply to this program?

The following regulations apply to this program:

(a) 34 CFR Part 385 (Rehabilitation Training); and

(b) The regulations in this Part 388.

(Section 304 of the Act; 29 U.S.C. 744)

§ 388.4 What definitions apply to this program?

The definitions in 34 CFR Part 385 apply to this program.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

§ 388.10 What types of projects are authorized under this program?

State vocational rehabilitation unit in-service training projects are concerned with the staff development and training of State vocational rehabilitation unit personnel in order to assure an improved level of competence in serving State unit clients and to assist in expanding and improving vocational rehabilitation services for handicapped individuals, especially those with the most severe handicaps.

(Section 304(b) of the Act; 29 U.S.C. 774(b))

§ 388.11 What specific activities may be supported under this program?

(a) Training activities supported under a State vocational rehabilitation unit in-service training grant focus primarily on program areas that are essential to the State unit's operation, or on skill areas that will enable staff personnel to improve their ability to function on their job, or prepare for positions of greater

responsibility within the unit, or to correct deficiencies identified in the State program.

(b) Training methods may include—

(1) The development of State unit training institutes concerned with special aspects of State unit administration or service provision;

(2) Attendance for individual employees or groups of employees at special courses conducted in cooperation with an educational institution;

(3) Individualized directed study in priority areas of State unit service or practice; and

(4) Maintenance of agency instructional library resources for books, films, tapes and other resources.

(Section 304(b) of the Act; 29 U.S.C. 744(b))

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

§ 388.30 What selection criteria does the Secretary use in this program?

(a) *Plan of operation.* (25 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(a).

(b) *Quality of key personnel.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(b).

(c) *Budget and cost effectiveness.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(c).

(d) *Evaluation plan.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(d).

(e) *Adequacy of resources.* (5 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(e).

(f) *Evidence of need.* (15 points)

(1) The Secretary reviews each application for information that shows the need for the in-service training has been adequately justified.

(2) The Secretary looks for information that shows—

(i) The State unit has conducted a needs assessment of the in-service training needs of State unit employees; and

(ii) The State unit in-service training plan responds to needs identified on the basis of the training needs assessment.

(g) *Relevance to State/Federal rehabilitation service program.* (10 points)

(1) The Secretary reviews each application for information that shows that the proposed project appropriately relates to the mission of the State/Federal rehabilitation service program.

(2) The Secretary looks for information that shows the proposed project can be expected to improve the competence of State vocational rehabilitation unit personnel in providing vocational rehabilitation services to handicapped individuals or in otherwise contributing to the more effective management of the State unit program.

(h) *Nature and scope of training program.* (15 points)

(1) The Secretary reviews each application for information that demonstrates the adequacy and scope of the proposed training program content.

(2) The Secretary looks for information that shows—

(i) The scope and nature of the training activities reflect content that can be expected to enable the achievement of the established project objectives;

(ii) The program primarily includes an integrated sequence of—

(a) workshops, seminars, and other special courses for counselors and other classes of State unit personnel concerned with State unit procedures;

(b) concentrated training activities focusing on improving State unit staff skills in working with specific groups of severely handicapped persons; and

(c) directed individualized or group staff development activities designed to enable selected staff to acquire special skills.

(Section 12(c) and 304 of the Act; 29 U.S.C. 711(c) and 774)

Subpart E—What Conditions Must Be Met by a Grantee?

§ 388.40 What are the matching requirements?

The Secretary may make grants for paying part of the costs of projects under this program. The grantee must provide at least 10 percent of the total costs of the project.

(Section 12(c) and 304(a) of the Act; 29 U.S.C. 711(c) and 744(a))

§ 388.41 What are the allowable costs?

In addition to those allowable costs established in EDGAR §§ 75.530–75.562, the following items are allowable under State vocational rehabilitation unit in-service training projects:

(a) Trainee per diem costs;

(b) Trainee travel in connection with a training course; and

(c) Trainee tuition and fees.

(Section 12(c) and 304(a) of the Act; 29 U.S.C. 711(c) and 774(a))

The Secretary amends Title 34 of the Code of Federal Regulations by adding 34 CFR Part 389 to read as follows:

Part 389—Rehabilitation Continuing Education Programs

Subpart A—General

Sec.

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

Subpart E—What Conditions Must Be Met by a Grantee?

Authority: Sections 12(c) and 304 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 711(c) and 774)

Subpart A—General

§ 389.1 What is the Rehabilitation Continuing Education Program?

This program is designed to support training centers that serve either a Federal region or another geographical area and provide for a broad integrated sequence of training activities that focus on meeting recurrent and common training needs of employed rehabilitation personnel throughout a multi-State geographical area.

(Section 304 of the Act; 29 U.S.C. 774)

§ 389.2 Who is eligible for assistance under this program?

Those agencies and organizations eligible for assistance under this program are described in 34 CFR § 385.2.

(Section 304(a) of the Act; 29 U.S.C. 774(a))

§ 389.3 What regulations apply to this program?

The following regulations apply to this program—

(a) 34 CFR Part 385 (Rehabilitation Training); and

(b) The regulations in this Part 389.

(Section 304 of the Act; 29 U.S.C. 774)

§ 389.4 What definitions apply to this program?

The definitions in 34 CFR Part 385 apply to this program.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

§ 389.10 What types of projects are authorized under this program?

Rehabilitation Continuing Education Programs—

(a) Train newly employed State agency staff at the administrative, supervisory, professional, subprofessional, or clerical levels in order to develop needs skills for effective agency performance;

(b) Provide training opportunities for experienced State agency personnel at all levels of State agency practice to upgrade their skills and to develop mastery of new program developments dealing with significant issues, priorities and legislative thrusts of the State/Federal vocational rehabilitation program; and

(c) Develop and conduct training programs for staff of private rehabilitation agencies and facilities which cooperate with State vocational rehabilitation units in providing vocational rehabilitation and other rehabilitation services.

(Section 304(b) of the Act; 29 U.S.C. 774(b))

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

§ 389.30 What selection criteria does the Secretary use in this program?

(a) *Plan of operation.* (25 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(a).

(b) *Quality of key personnel.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(b).

(c) *Budget and cost effectiveness.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(c).

(d) *Evaluation plan.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(d).

(e) *Adequacy of resources.* (5 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(e).

(f) *Evidence of need.* (15 points)

(1) The Secretary reviews each application for information that shows the need for the Rehabilitation Continuing Education Program has been adequately justified.

(2) The Secretary looks for information that shows the need for the training program has been justified and includes an assessment of the potential of existing programs within the geographical area (including State vocational rehabilitation unit in-service training) to meet the needs for which support is sought.

(g) *Relevance to State/Federal rehabilitation service program.* (10 points)

(1) The Secretary reviews each application for information that shows the proposed project appropriately relates to the mission of the State/Federal rehabilitation service program.

(2) The Secretary looks for information that the proposed project can be expected to improve the competence of professional and other personnel employed in the rehabilitation agencies serving severely physically and mentally disabled individuals.

(h) *Nature and scope of training program.* (15 points)

(1) The Secretary reviews each application for information that demonstrates the adequacy and scope of the proposed training program content.

(2) The Secretary looks for information that shows—

(i) The scope and nature of the training activities reflect content that can be expected to enable the achievement of the established project objectives of the training project.

(ii) The program and teaching methods provide for an integration of theory and practice relevant to the educational objectives of the program.

(iii) The program includes a broad intergrated sequence of training activities for employed rehabilitation workers.

(iv) The program primarily includes coursework which can be expected to be needed on a recurrent basis throughout the multi-State geographical area to be served.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

Subpart E—What Conditions Must Be Met by a Grantee?

§ 389.40 What are the matching requirements?

A grantee must contribute to the cost of a project under this program in an amount satisfactory to the Secretary. The part of the cost to be borne by the grantee is determined by the Secretary at the time of the grant award.

(Sections 12(c) and 304(a) of the Act; 29 U.S.C. 711(c) and 774(a))

§ 389.41 What are allowable costs?

In addition to those allowable costs established under EDGAR §§ 75.530–75.562, the following items are allowable under Rehabilitation Continuing Education programs—

(a) Trainee per diem costs;

(b) Trainee travel in connection with a training course;

(c) Trainee tuition and fees; and

(d) Special accommodations for handicapped trainees.

(Sections 12(c) and 304(a) of the Act; 29 U.S.C. 711(c) and 774(a))

The Secretary amends Title 34 of the Code of Federal Regulations by adding 34 CFR Part 390 to read as follows:

PART 390—REHABILITATION SHORT-TERM TRAINING

Subpart A—General

Sec.

Authority: Sections 12(c) and 304 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 711(c) and 774).

Subpart A—General

§ 390.1 What is the Rehabilitation Short-Term Training Program?

This program is designed for the support of special seminars, institutes, workshops and other short-term courses in technical matters relating to the delivery of vocational, medical, social, and psychological rehabilitation services.

(Sections 21(a)(2) and 304(a) of the Act; 29 U.S.C. 711(a)(2) and 774(a))

§ 390.2 Who is eligible for assistance under this program?

Those agencies and organizations eligible for assistance under this program are described in 34 CFR § 385.2.

(Section 304(a) of the Act; 29 U.S.C. 774(a))

§ 390.3 What regulations apply to this program?

(a) 34 CFR Part 385 (Rehabilitation Training); and

(b) The regulations in this Part 390.

(Section 304 of the Act; 29 U.S.C. 774)

§ 390.4 What definitions apply to this program?

The definitions in 34 CFR Part 385 apply to this program.

(Section 12(c) of the Act; 29 U.S.C. 711(c))

Subpart B—What Kinds of Projects Does the Department of Education Assist Under This Program?

§ 390.10 What types of projects are authorized under this program?

(a) Projects under this program are designed to provide short-term training and technical instruction in areas of special significance to the delivery of vocational, medical, social, and psychological rehabilitation services.

(b) Short-term training projects may be of regional or national scope.

(c) Conferences and meetings in which training is not the primary focus may not be supported under this program.

(Section 12(a)(2) and 304 of the Act; 29 U.S.C. 711(a)(2) and 774)

Subpart C—[Reserved]

Subpart D—How Does the Secretary Make a Grant?

§ 390.30 What selection criteria does the Secretary use in this program?

(a) *Plan of operation.* (25 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(a).

(b) *Quality of key personnel.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(b).

(c) *Budget and cost effectiveness.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(c).

(d) *Evaluation plan.* (5 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(d).

(e) *Adequacy of resources.* (10 points)

The Secretary evaluates each application on the basis of the criterion in § 385.32(e).

(f) *Evidence of need.* (15 points)

(1) The Secretary reviews each application for information that shows the need for the training project has been adequately justified.

(2) The Secretary looks for information that shows the need for the training project that has been established and validated in terms of its potential impact on the rehabilitation service delivery system.

(g) *Relevance to State/Federal rehabilitation service program.* (10 points)

(1) The Secretary reviews each application for information that shows the proposed project appropriately relates to the mission of the State/Federal rehabilitation service program.

(2) The Secretary looks for information that shows the proposed project relates to the mission of the State/Federal rehabilitation service program and can be expected to improve the skills and competence of personnel engaged in the administration or delivery of rehabilitation services, and others with an interest in the delivery of rehabilitation services.

(h) *Nature and scope of training program content.* (15 points)

(1) The Secretary reviews each application for information that demonstrates the adequacy and scope of the proposed training program content.

(2) The Secretary reviews each application for information that shows that—

(i) The educational objectives are clearly defined, measurable and achievable; and

(ii) The proposed course content and methodology to develop and implement the training can be expected to achieve the stated educational objectives.

Subpart E—What Conditions Must Be Met by a Grantee?

§ 390.40 What are the matching requirements?

A grantee must contribute to the cost of a project under this program in an amount satisfactory to the Secretary. The part of the costs to be borne by the grantee is determined by the Secretary at the time of the award.

(Sections 12(c) and 304(a) of the Act; 29 U.S.C. 711(c) and 774(a))

§ 390.41 What are allowable costs?

(a) In addition to those allowable costs established in EDGAR §§ 75.530–75.562, the following items are allowable under short-term training projects:

(1) Trainee per diem costs;

(2) Trainee travel in connection with a training course;

(3) Trainee registration fees; and

(4) Special accommodations for handicapped trainees.

(b) The preparation of training materials may not be supported under a short-term training grant unless the materials are essential for the conduct of the seminar, institute, workshop or other short course for which the grant support has been provided.

(Sections 12(c) and 304(a) of the Act; 29 U.S.C. 711(c) and 744(a))

Appendix A—Summary of Comments and Responses To Notice of Proposed Rulemaking Published in Federal Register of November 29, 1979

§ 385.40 What are the requirements pertaining to the membership of project advisory committees? (formerly 1362.10)

Comment. Under the previous proposed regulations, the membership of any advisory committee established in connection with a Rehabilitation Services Administration supported project was required to include "handicapped individuals." Since the term "handicapped individual" is a term defined under the Rehabilitation Act to refer generally to an individual who is eligible for vocational rehabilitation services and a client of a State vocational rehabilitation unit and since the scope of projects supported under the Rehabilitation Act may extend far beyond the provision of vocational rehabilitation services, it was suggested that the use of this term was not fully appropriate in this section.

Response. This section has been revised to ensure that advisory committees include "handicapped persons or other representatives of handicapped individuals" but not necessarily current clients of State units.

Comment. Some comments were received requesting that the majority of the members of any advisory committee established under this section be handicapped persons. It was suggested that at least 51 percent of the membership of any project advisory committee should themselves be handicapped.

Response. No change has been made in this section in this regard. The scope of discretionary projects authorized under the Rehabilitation Act includes service delivery, rehabilitation facility assistance, training of professional personnel, and other special purposes. The membership of any project advisory committee is based on the qualifications of each individual in terms of the purpose of the project. To require that an advisory committee have a majority of membership of physically or mentally handicapped persons might not only minimize the need for the most efficient and effective achievement of project objectives but might arbitrarily minimize the contribution of so very many other qualified persons in the rehabilitation community.

Comment. Comments associated with the specific learning disability issue under the overall Rehabilitation Act proposed regulations requested that the proposed section be revised to require that the membership of each project include "handicapped individuals" and in the case of projects which involve school-age students, representatives from educational agencies.

Response. No change has been made in this section in this regard. It is noted that the proposed section already required handicapped individuals and their representatives to be included in the membership of project advisory committees. Since vocational rehabilitation programs are intended for handicapped persons who are or near working age, parents are only one type of representative appropriate for participation in these advisory committees.

The suggestion that educational agency representation be required in project advisory committees was also not accepted. Projects funded under the Rehabilitation Act may cover a broad range of cooperative program service areas and to emphasize one area of cooperative programing at the expense of others would be inconsistent with the traditional flexibility of Rehabilitation Act programing. On the basis of experience it is clear that when an advisory committee is established for any special project which involves educational services, educational agencies are represented on the project advisory committee.

§ 386.1 What is the Rehabilitation Long-Term Training Program? (formerly 1362.70)

Comment. A few commenters suggested that this section be revised to include the area of rehabilitation administration within the scope of the long-term training program. Other commenters asked that the field of rehabilitation dentistry be similarly identified.

Response. A change has been made in this section. Training in the areas of rehabilitation administration and rehabilitation dentistry have long been supported under the rehabilitation long-term training program, but these areas have never been identified in either the Act or the regulations. The guidelines for the rehabilitation training grant program have reflected the full scope of the program, however, and have identified these areas within the scope of the rehabilitation training grant program.

Since training in rehabilitation administration and rehabilitation dentistry have both been supported for so very long a period of time, the section is being revised to include coverage of both general training for rehabilitation administrative personnel and the specialized training related to the provision of dental services to severely physically and mentally disabled individuals.

§ 390.10 What types of projects are authorized under this program? (formerly 1362.73)

Comment. As part of the comment received in connection with the specific learning disability issue under the State vocational rehabilitation service regulations, it was suggested that this section be revised to ensure special attention "to addressing the training needs of rehabilitation personnel in the area of development and implementation of cooperative activities with educational agencies, parents and clients."

Response. No change has been made in this section in this regard. It is noted that short-term training priorities under the rehabilitation short-term training program are identified each year and are included within an annual General Plan for Rehabilitation Short-Term Training. This General Plan is prepared with the advice of agencies and organizations knowlegeable about the training needs of employed rehabilitation personnel. Since short-term training needs fall into so many diverse areas and since short-term training needs change.

Response. No change has been made in this section in this regard. It is noted that short-term training priorities under the rehabilitation short-term training program are identified each year and are included within an annual General Plan for Rehabilitation Short-Term Training. This General Plan is prepared with the advice of agencies and organizations knowlegeable about the training needs of employed rehabilitation personnel. Since short-term training needs fall into so many diverse areas and since short-term training needs change extensively from year to year, it would not be appropriate to identify a single area of short-term training as a continuing priority under these regulations.

§ 390.41 What are allowable costs? (formerly 1362.73)

Comment. It was suggested that this section be revised to clarify that Federal grant funds may be used to provide special accommodations for handicapped persons attending short-term training seminars, institutes, and workshops conducted under the rehabilitation short-term training program.

Response. A change has been made in this section to specify that special accommodations for handicapped trainees may be included in grant costs to provide for such assistance as readers for blind persons, interpreters for deaf persons, attendants for trainees with severe mobility impairments and other accommodations which may be required to ensure the full participation of handicapped trainees in short-term training courses.

[FR Doc. 80-40417 Filed 12-29-80; 8:45 am]
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federal register

Tuesday
December 30, 1980

Part XIV

Department of Education

Federal Assistance to States for Education of Handicapped Children

DEPARTMENT OF EDUCATION

Office of Special Education

Office for Civil Rights

34 CFR Part 104 and 300

Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance; and Assistance to States for Education of Handicapped Children

AGENCY: Department of Education.

ACTION: Notice of Interpretation.

SUMMARY: The Secretary of Education interprets Part B of the Education of the Handicapped Act, as amended, and Section 504 of the Rehabilitation Act of 1973, as amended, concerning the use of parents' insurance proceeds to pay for required services. It is the Secretary's interpretation that these statutes and their implementing regulations do not permit an educational agency responsible for the education of a handicapped child to require the parents of that child to use private insurance proceeds to pay for required services where the parents would incur financial loss. This interpretation is issued in response to public inquiries regarding Departmental policy on the matter.

EFFECTIVE DATE: This interpretation is expected to take effect 45 days after it is transmitted to Congress. Interpretations are usually transmitted to Congress several days before they are published in the **Federal Register.** The effective date of interpretations that are subject to the transmittal requirement is changed if Congress takes certain adjournments. Although the interpretation of Section 504 is not subject to this requirement, the Secretary has decided to set its effective date for the same day that the interpretation of Part B of the Education of the Handicapped Act becomes effective. If you want to know the effective date of this interpretation, call or write the Department of Education contact persons.

FOR FURTHER INFORMATION CONTACT:

Ms. Shirley A. Jones, Office of Special Education, Department of Education, Donohoe Building, Room 4030, 400 Maryland Ave. S.W., Washington, D.C. 20202, telephone: (202) 472–7921. Mr. Edward A. Stutman, Office for Civil Rights, Department of Education, Switzer Building, Room 5430, 300 C St., S.W., Washington, D.C. 20202, telephone: (202) 245–0781.

SUPPLEMENTARY INFORMATION:

The Issue

The issue is whether Part B of the Education of the Handicapped Act, as amended, ("Part B"; 20 U.S.C. 1411–1420) and its regulations (34 CFR Part 300; formerly 45 CFR Part 121a) and Section 504 of the Rehabilitation Act of 1973, as amended ("Section 504"; 29 U.S.C. 794) and its regulations (34 CFR Part 104; formerly 45 CFR Part 84) permit an educational agency responsible for the education of a handicapped child to require the child's parents to file insurance claims and use the proceeds to pay for services that must be provided to the child under Part B and Section 504.

The Interpretation

Both Part B and Section 504 prohibit a public agency from requiring parents, where they would incur a financial cost, to use insurance proceeds to pay for services that must be provided to a handicapped child under the "free appropriate public education" requirements of those statutes. The use of parents' insurance proceeds to pay for services in these circumstances must be voluntary on the part of the parents.

Discussion

Under Section 612(2)(B) of Part B (20 U.S.C. 1412(2)(B)), each participating State must make available to all handicapped children within specified ages a free appropriate public education. "Free appropriate public education" is defined in Section 602(18) of the Education of the Handicapped Act, as amended, (20 U.S.C. 1401(18)) as "special education and related services which are provided at public expense, under public supervision and direction, and without charge. . . ." The requirement to provide these services is implemented in 34 CFR 300.300 *et seq.*

Similarly, the Department's regulations implementing Section 504 require any recipient of Federal financial assistance that operates a public elementary or secondary education program to "provide a free appropriate public education to each qualified handicapped person who is in the recipient's jurisdiction, regardless of the nature or severity of the person's handicap." 34 CFR 104.33(a). The provision of a free education is defined as "the provision of educational and related services without cost to the handicapped person or to his or her parents or guardian, except for those fees that are imposed on non-handicapped persons or their parents or guardian." 34 CFR 104.33(c).

The Secretary interprets the requirements that a free appropriate public education be provided "without charge" or "without cost" to mean that an agency may not compel parents to file an insurance claim when filing the claim would pose a realistic threat that the parents of handicapped children would suffer a finanial loss not incurred by similarly situated parents of non-handicapped children. Financial losses include, but are not limited to, the following:

(1) A decrease in available lifetime coverage or any other benefit under an insurance policy;

(2) An increase in premiums or the discontinuation of the policy; or

(3) An out-of-pocket expense such as the payment of a deductible amount incurred in filing a claim.

Financial losses do not include incidental costs such as the time needed to file an insurance claim or the postage needed to mail the claim.

The statutory and regulatory provisions relating to a free appropriate public education guarantee freedom only from financial loss as described above. Therefore, when the educational agency pays the financial costs related to filing a claim and no other cost (such as those listed above) is imposed, the parent suffers no financial loss. In addition, an agency may insist that parents file a claim when they would incur only minor incidental costs such as the time required to complete the form. The agency may require the parents to file a claim if it ensures that parents do not have to bear even a short-term financial loss. For example, if benefits begin only after a $50.00 deductible, the agency may insist that the parents file a claim if it pays for the services and the deductible in advance.

(20 U.S.C. 1401, 1411–1420; 29 U.S.C. 794)

The responsibility to make available a free appropriate public education does not mean that a public educational agency must use only its own funds for that purpose. An agency may use whatever State, local, Federal, and private sources of support are available to pay for required services. See 34 CFR 300.301(a) and 34 CFR 104.33(c)(1). Moreover, nothing in the Part B or Section 504 regulations relieves an insuror or similar third party from an otherwise valid obligation to provide or pay for services to a handicapped child. See 34 CFR 300.301(b) and 34 CFR 104.33(c).

Call for Public Comment

The Secretary is interested in receiving public comments on the extent to which the Department should provide further guidance on the use of insurance proceeds or other sources of funds to pay for services to handicapped children, and on the relationship between educational agencies and insurance carriers. These comments may be sent at any time to the Department contact persons identified in the beginning of this document.

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

[FR Doc. 80-40418 Filed 12-29-80; 8:45 am]

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federal register

Tuesday
December 30, 1980

Part XV

Department of Education

Pell Grant Program; Final Rules With Comments Invited

DEPARTMENT OF EDUCATION

34 CFR Part 690

Pell Grant Program

AGENCY: Department of Education.

ACTION: Final regulations with comments invited.

SUMMARY: The Secretary is issuing regulations for the Pell Grant Program (formerly the Basic Educational Opportunity Grant Program). These regulations are being amended to implement the statutory changes contained in the Education Amendments of 1980, Pub. L. 96–374.

DATES: These regulations are expected to take effect 45 days after they are transmitted to Congress. Regulations are usually transmitted to the Congress several days before they are published in the **Federal Register.** The effective date is changed by statute if Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person.

Comments must be received on or before March 2, 1981.

ADDRESSES: Comments should be addressed to William L. Moran, Office of Postsecondary Education, Office of Student Financial Assistance, U.S. Department of Education, (Room 4318, ROB–3) 400 Maryland Avenue, S.W., Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: William L. Moran, Telephone (202) 472–4300.

SUPPLEMENTARY INFORMATION: On October 3, 1980, the Education Amendments of 1980, Pub. L. 96–374, were enacted into law reauthorizing the Pell Grant Program (formerly the Basic Educational Opportunity Grant Program) through the 1985–86 award year.

Most of the statutory changes contained in the new law which affect the administration of the Pell Grant Program are primarily minor or technical in nature. Therefore, in order to facilitate the administration of the program, regulations implementing these changes are being issued in final form.

The Education Amendments of 1980 repealed the existing statutory provisions concerning calculation of a student's cost of attendance for the Pell Grant program. The new law revised the definition of "cost of attendance" and made it applicable to all student financial assistance programs authorized by Title IV of the Higher Education Act. Therefore, the changes to be made to the "cost of attendance" portion of the Pell Grant regulation, Subpart E, will be published separately as a notice of proposed rulemaking.

The Education Amendments of 1980 also mandate a common need analysis system for the Pell Grant and campus-based programs, Supplemental Educational Opportunity Grant, College Work-Study and National Direct Student Loan, begining with the 1982–83 award year. The new law provides that a separate notice of proposed rulemaking for this system will be published in the **Federal Register** and submitted to Congress for review by July 1, 1981.

The changes required by the new law are outlined in the following summary. In addition to these changes, terminology in these regulations is being updated to reflect the creation of the Department of Education and the change in the name of the Basic Educational Opportunity Grant Program to the Pell Grant Program. Also, other minor technical changes were made to facilitate program administration.

1. The Education Amendments of 1980 increase the maximum Pell grant amount in steps from $1,900 in the 1981–82 award year to $2,600 in 1985–86. In addition, the previous limitation of a student's Pell Grant to 50 percent of his or her cost of attendance has been modified in the new law so that the maximum cost of attendance percentage that may be covered by a Pell Grant in future years increases as the size of the maximum grant increases.

2. Under previous legislation, student eligibility was limited to four years (in some cases, five years) of full-time Basic Grant assistance. The new law provides that a student is eligible to receive Pell Grants during the period required to complete his or her first undergraduate baccalaureate course of study.

Although the four-year eligibility limitation is no longer applicable, the definition of "undergraduate student" in § 690.2 retains the concept that an undergraduate course of study for purposes of the Pell Grant Program is one which usually does not exceed four academic years or is a five academic year program designed to lead to a first degree. A student enrolled in any other length program is considered to be an undergraduate only while taking the academic requirements to complete the first four academic years of the program. This concept does *not* restrict a student to only four Pell Grant awards since it is possible for a student to take longer than four academic years to complete the academic requirements of his or her undergraduate program or undergraduate portion of the program.

3. The source of the administrative cost allowance of $10 per year for each student who receives a Pell Grant at an institution in an award year was changed in the new law from a separate appropriation to a reserve from the program appropriation. This allowance must be used to offset the institution's costs of administering the Pell Grant and campus-based programs. The priority for expenditure of this allowance for student consumer information which was contained in the previous legislation has been deleted.

4. The schedule of Pell Grant reductions provided in the new law for use at less-than-full funding gives the maximum protection to the lowest income students. For example, no reduction is required for a student whose expected family contribution is less than $601.

For the first time, the reduction schedule appears in the text of the regulations. Previously, the regulations referenced the appropriate section of the law. The inclusion of the reduction schedule in these regulations is an attempt to provide a more complete, self-contained set of procedural regulations from which institutions can administer the Pell Grant Program.

Several provisions have been deleted from the previous program regulations because they have been codified in the Student Assistance General Provisions. These include, for example, the definition of an institution of higher education in the former § 190.2a, as well as other terms defined in that section, plus the definition of a recognized equivalent of a high school diploma.

Waiver of Notice of Proposed Rulemaking

The regulatory changes merely reflect the statutory changes made by the Education Amendments of 1980 and a few minor programmatic revisions. In addition, the Secretary wishes to give the higher education community as much advance notice as possible of these changes.

Accordingly, the Secretary finds that the publication of a proposed rule in this instance would be unnecessary, impracticable and contrary to the public interest within the meaning of 5 U.S.C. 553(b), and is publishing these rules as final regulations.

Invitation to Comment

Although notice and comment is not required, the Secretary believes that public comment may be valuable both on the changes made to reflect statutory changes and on other changes that could be made to improve the regulations. The public is particularly invited to comment on the following:

(1) The definitions of undergraduate student, full-time student and of half-time student in § 690.2.

(2) Ways of reducing any regulatory burdens imposed by these regulations.

(3) Whether a comprehensive general part should be prepared containing common provisions from all student aid programs.

Educational Assessment Impact

On November 14, 1980, the Secretary published a notice in the **Federal Register** of the Department's intent to publish regulations necessary to implement the Education Amendments of 1980. In that notice, the Department listed the existing regulations affected by the new law and requested comments whether those regulations required information that is already being gathered by or is available from any other agency or authority of the United States. The regulations in this document are based on regulations listed in the November 14, 1980 notice. Based on any comments received and the Department's own review, it has been determined that the regulations in this document do not require information that is already being gathered by or is available from any other agency or authority of the United States.

Interested persons are invited to submit comments and recommendations regarding these regulations. Written comments and recommendations may be sent to the address given at the beginning of this preamble.

All comments submitted in response to these regulations will be available for public inspection, during and after the comment period, in Room 4318, ROB-3, 7th and D Streets, SW., Washington, D.C. between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

CITATION OF LEGAL AUTHORITY: A citation of statutory or other legal authority is placed in parentheses on the line following each substantive provision of these regulations.

(Catalogue of Federal Domestic Assistance Numbers: Pell Grant Program, 84.063)

Dated: December 22, 1980.

Shirley M. Hufstedler,

Secretary of Education.

Part 690 of Title 34 of the Code of Federal Regulations is amended as follows:

PART 690—PELL GRANT PROGRAM

Subpart A—Scope, Purpose and General Definitions

Sec.

Subpart B—Application Procedures for Determining Expected Family Contribution

Subpart C—Expected Family Contribution

Subpart D—Expected Family Contribution for Independent Students

Subpart E—Cost of Attendance

Subpart F—Determination of Pell Grant Awards

Subpart G—Administration of Grant Payments—Regular Disbursement System

Subpart H—Administration of Grant Payments—Alternate Disbursement System

Authority: Section 411 of the Higher Education Act of 1965 as added by Section 131(b) of Public Law 92-318, 86 Stat. 247-251 as amended (20 U.S.C. 1070a), unless otherwise noted.

1. Subpart A is revised to read as follows:

Subpart A—Scope, Purpose and General Definitions

§ 690.1 Scope and purpose.

The Pell Grant Program awards grants to help financially needy students meet their costs of postsecondary education.

(20 U.S.C. 1070a)

§ 690.2 General definitions.

The following definitions are set forth in Subpart A of the Student Assistance General Provisions, 34 CFR Part 668, Subpart A:

Ability to Benefit; Institution of higher education (including Public or Private nonprofit institution of higher education, proprietary institution of higher education, and postsecondary vocational institution); one-year training program; recognized equivalent of a high school diploma; and six-month training program.

Other definitions used in this part are:

Academic year: (1) A period of time in which a full-time student is expected to complete the equivalent of at least 2 semesters, 2 trimesters or 3 quarters at institutions using credit hours; or

(2) At least 900 clock hours of training for each program at institutions using clock hours.

(20 U.S.C. 1088)

Act: Title IV-A-1 of the Higher Education Act (HEA) of 1965, as amended.

Award year: The period of time between July 1 of one year and June 30 of the following year.

Clock hour: The equivalent of—

(1) A 50 to 60 minute class, lecture or recitation; or

(2) A 50 to 60 minute faculty supervised laboratory, shop training, or internship.

College Work-Study (CW-S) Program: The program of part-time employment authorized by Title IV-C of the Higher Education Act.

Eligibility index: Expected family contribution.

Enrolled: Completion of registration requirements at the institution a student is attending.

Enrollment status: At those institutions using semesters, trimesters, quarters, or other academic terms and measuring progress by credit hours, enrollment status equals a student's credit hour work load categorized as either full-time, three-quarter-time, or half-time.

Full-time student: An enrolled student who is carrying a full-time academic work load (other than by correspondence) as determined by the institution and which is applicable to all students enrolled in a particular program. However, the institution's full-time standard must equal or exceed one of the following minimum requirements:

(1) 12 semester hours or 12 quarter hours per academic term in those institutions using standard semester, trimester or quarter hour systems;

(2) 24 semester hours or 36 quarter hours per academic year for institutions using credit hours to measure progress but not using semester, trimester or quarter systems, or the prorated equivalent for programs of less than one academic year;

(3) 24 clock hours per week for institutions using clock hours;

(4) In those institutions using both credit and clock hours, if the sum of the following fractions is equal to or greater than one:

number of credit hours per term divided by 12 plus number of clock hours per week divided by 24

(5) A series of courses or seminars which equals 12 semester hours or 12 quarter hours in a maximum of 18 weeks; or

(6) The work portion of a cooperative education program in which the amount of work performed is equivalent to the academic work-load of a full-time student.

(20 U.S.C. 1088(c)(2))

Guaranteed Student Loan (GSL) Program: The student loan program authorized by title IV–B of the Higher Education Act.

Half-time student. (1) An enrolled student who is carrying a half-time academic work load—as determined by the institution—which amounts to at least half the work load of the appropriate minimum requirement outlined in the definition of a full-time student. (See definition of full-time student.)

(2) A student enrolled solely in a program of study by correspondence who is carrying a work load of at least 12 hours or preparation of work per week. However, regardless of the work load, no student enrolled solely in correspondence study will be considered more than a half-time student.

National Defense Student Loan (NDSL) Program: The student loan program authorized by Title II of the National Defense Education Act.

National Direct Student Loan (NDSL) Program: The student loan program authorized by Title IV–E of the Higher Education Act.

Parent Loans for Undergraduate Students (PLUS): The Parent Loan Program authorized by Title IV–B of the Higher Education Act.

Payment schedule: (1) A table showing a full-time student's Scheduled Pell Grant for a given award year. This table, published by the Secretary, is based on—

(i) The Expected Family Contribution.

(ii) Attendance costs as defined in Subpart E; and

(iii) The amount of funds available for making Pell Grants.

(2) The Payment Schedule also includes the Disbursement Schedules which are tables showing the grant amounts three-quarter and half-time students would receive for an academic year.

Scheduled Pell Grant: The amount of a Pell Grant which would be paid to a full-time student for a full academic year.

Secretary: The Secretary of the Department of Education or an official or employee of the Department acting for the Secretary under a delegation of authority.

State Student Incentive Grant (SSIG) Program: The grant program authorized by Title IV–A–3 of the Higher Education Act.

Student Eligibility Report (SER): A report provided to an applicant showing the amount of his or her expected family contribution.

Supplemental Educational Opportunity Grant (SEOG) Program: The grant program authorized by Title IV–A–2 of the Higher Education Act.

Three-quarter-time student: An enrolled student who is carrying a three-quarter-time academic work load—as determined by the institution—which amounts to at least three quarters of the work load of the appropriate minimum requirement outlined in the definition of a full-time student. (See defintion of full-time student.)

Undergraduate student: A student enrolled in an undergraduate course of study at an institution of higher education who:

(1) Has not been awarded a baccalaureate or first professional degree; and

(2) Is in an undergraduate course of study which usually does not exceed 4 academic years, or is enrolled in a 5 academic year program designed to lead to a first degree. A student enrolled in a program of any other length is considered an undergraduate student for only the first 4 academic years of that program.

(20 U.S.C. 1070a unless otherwise noted.)

§ 690.3 Special terms.

(a) Eligible program: An undergraduate program of education or training which—

(1) Admits as regular students only persons who—

(i) Have a high school diploma.

(ii) Have a General Education Development Certificate (G.E.D) or a State certificate received after passing a State-authorized examination which the State recognizes as the equivalent of a high school diploma, or

(iii) Are beyond the age of compulsory school attendance in the State in which the institution is located, and have the ability to benefit from the education or training offered; and

(2)(i) Leads to a bachelor, associate or undergraduate professional degree,

(ii) Is at least a two-year program which is acceptable for full credit toward a bachelor degree,

(iii) Is at least a 1 year program leading to a certificate or degree, which prepares students for gainful employment in a recognized occupation. (A 1-year program is defined in 34 CFR Part 668, Subpart A), or

(iv) Is, for a proprietary or postsecondary vocational institution, at least a six-month program leading to a certificate or degree, which prepares students for gainful employment in a recognized occupation. (A six-month program is defined in 34 CFR Part 668, Subpart A).

(b) *An eligible program of study by correspondence:* An undergraduate program of education or training which must be designed to require at least 12 hours of preparation a week.

(c) *Regular student:* A person who enrolls in an eligible program at an institution of higher education for the purpose of obtaining a degree or certificate.

(d) *Payment period for an institution that uses the Regular Disbursement System but does not use academic terms.*

(1) An institution participating in the Pell Grant program under the Regular Disbursement System (RDS institution) that does not use semesters, trimesters,

quarters, or other academic terms must have at least two payment periods for each academic year, or for each program which is less than an academic year.

(2) For a fulltime student whose educational program is one academic year—

(i) The first payment period is the period of time in which the student completes the first half of his or her academic year (in credit or clock hours), and

(ii) The second payment period is the period of time in which the student completes the second half of that academic year.

(3) For a full-time student whose educational program is more than one academic year, the first and second payment periods shall be calculated under paragraph (d)(2) of this section. For subsequent academic years, or fractions of academic years, each payment period shall be the period of time in which the student completes—

(i) One-half of the academic year, or

(ii) The remaining hours in the student's educational program, which ever is to be completed first.

(4) For a full-time student whose educational program is LESS than an academic year—

(i) The first payment period is the period of time in which the student completes the first half of his or her educational program (in credit or clock hours), and

(ii) The second payment period is the period of time in which the student completes the second half of that educational program.

(5) The payment period for an eligible part-time student shall be calculated as follows:

(i) Determine the length of time it would take a full-time student in the program to complete one academic year or a program of less than one academic year, as appropriate.

(ii) The first payment period is the period of time in which the part-time student completes half the work (in credit or clock hours) he or she is scheduled to complete in the period referred to in paragraph (d)(5)(i) of this section.

(iii) The second payment period begins when the first payment period ends and ends when the student completes the other half of the work that he or she was scheduled to complete in the period referred to in paragraph (d)(5)(i) of this section.

(iv) Each subsequent payment period begins when the previous period ends and ends when the part-time student completes—

(A) Half the work he or she is scheduled to complete during the period of time referred to in paragraph (d)(5)(i) of this section, or

(B) The remaining hours of his or her educational program whichever is completed first.

(6) If an RDS institution chooses to have more than two payment periods in an academic year or in a program of less than an academic year, the rules set forth in paragraphs (d)(2) through (d)(5) of this section shall be modified to reflect the number of payment periods. For example, if an institution chooses to have three payment periods for an academic year, each payment period shall correspond, for a full-time student, to one-third of the academic year.

(e) *Payment period for an institution using the Regular Disbursement System that uses academic terms.*

(1) For an RDS institution that uses semesters, trimesters, quarters or other academic terms, the payment period is the semester, trimester, quarter or other academic term.

(2) If a student's progress is measured in clock hours, a student may not be paid for a subsequent payment period until he or she finishes the hours of the previous payment period for which the student has already been paid.

(f) *Payment period for an institution using the Alternate Disbursement System.* A payment period for an institution participating in the Pell Grant program under the Alternate Disbursement System (ADS institution) shall be calculated as follows:

(1) If an ADS institution uses semesters, trimesters, quarters or other academic terms and measures progress in credit hours, the payment period is the semester, trimester, quarter or other academic term.

(2) If an ADS institution measures progress in clock hours, or measures progress in credit hours but does not use academic terms, it shall have at least two payment periods. The payment periods shall be calculated as follows:

(i) If the student's academic year is within one award year and the student's educational program is at least one academic year—

(A) The first payment period is the period of time in which the student completes the first half of his or her academic year, and

(B) The second payment period is the period of time in which the student completes the second half of his or her academic year.

(ii) If the student's academic year is NOT within one award year or the student's educational program is LESS than a full academic year—

(A) The first payment period is the period of time in which the student completes the first half of the hours he or she is scheduled to complete within the award year, and

(B) The second payment period begins when the first payment period ends and ends when the student completes all hours he or she was scheduled to complete between the beginning of the second payment period and June 30.

(iii) a student with incompleted hours for the second payment period of any award year may complete them during the following award year. In this case, if the student's educational program is more than an academic year, the first payment period of the new award year begins when the student finishes all carried over hours for which he or she was paid.

(20 U.S.C. 1070a)

§ 690.4 Eligible student.

(a) A student is eligible to receive a Pell Grant if the student—

(1) Is a regular student.

(2) Is enrolled as at least a half-time undergraduate student at an institution of higher education;

(3) Is enrolled in an eligible program as a regular student, as defined in § 690.3; and

(4)(i) Is a U.S. citizen or National,

(ii) Is a permanent resident of the U.S.,

(iii) Provides evidence from the Immigration and Naturalization Service that he or she is in the United States for other than a temporary purpose with the intention of becoming a citizen or permanent resident, or

(iv) Is a permanent resident of the Trust Territory of the Pacific Islands, or the Northern Mariana Islands.

(b) A member of a religious order, community, society, agency or organization who is pursuing a course of study in an institution of higher education will be considered as having an expected family contribution of at least $2,401 if that religious order—

(1) Has a primary objective the promotion of ideals and beliefs regarding a Supreme Being;

(2) Requires its members to forego monetary or other support substantially beyond the support it provides; and

(3)(i) Has directed the member to pursue the course of study, or

(ii) Provides subsistence support to its members.

(20 U.S.C. 1070a)

§ 690.5 Duration of student eligibility.

A student is eligible to receive a Pell Grant for the period of time required to complete the first undergraduate baccalaureate course of study being pursued by that student.

(20 U.S.C. 1070a.)

§ 690.6 Pell Grant payments from more than one institution.

A student will not be entitled to receive Pell Grant payments concurrently from more than one institution or from the Secretary and an institution.

(20 U.S.C. 1070a.)

§ 690.7 Institutional eligibility.

(a)(1) An institution of higher education is eligible to participate in the Pell Grant Program if it—

(i) Meets the appropriate definition set forth in 34 CFR 668, Subpart A,

(ii) Enters into a program participation agreement with the Secretary, and

(iii) Complies with that agreement and with the applicable provisions of 34 CFR Part 668 of this title, "Student Assistance General Provisions."

(2) If an institution becomes eligible during an award year, a student enrolled and attending that institution will be eligible to receive a Pell Grant for the payment period during which the institution became eligible and any subsequent payment period.

(b)(1) An institution of higher education becomes ineligible to participate in the Pell Grant Program if it no longer meets the applicable definition set forth in Part 668 of this title, or if its eligibility is terminated under the procedures set forth for terminating institutions in Part 668 of this title.

(2) If an institution becomes ineligible during an award year, an eligible student who was attending the institution and who submitted a valid SER to the institution, or to the Secretary if the institution participates under the Alternate Disbursement System (ADS), before the date the institution became ineligible, will be paid a Pell Grant for that award year for—

(i) The payment period that the student completed before the institution became ineligible, and

(ii) The payment period in which the institution became ineligible.

(c) An institution participating in the program under ADS which becomes ineligible must provide the Secretary with the name and enrollment status of each student who applied for and was determined eligible for a Pell Grant who was attending the institution when its eligibility was terminated.

(d) An institution participating in the program under the Regular Disbursement System which becomes ineligible must supply to the Secretary—

(1) The name and enrollment status of each eligible student who, during the award year, submitted a valid SER to the institution before it become ineligible.

(2) The amount of funds paid to each Pell Grant recipient for that award year.

(3) The amount due to each student eligible to receive a Pell Grant through the end of the payment period; and

(4) An accounting of the Pell Grant expenditures for that award year to the date of termination.

(20 U.S.C. 1070a.)

§ 690.8 Consortium Agreements.

(a) A consortium agreement is a written agreement between at least two institutions which enables an enrolled student in an eligible program at one institution to take courses at other institutions which apply towards his or her certificate or degree at the first institution.

(b) If two eligible institutions have entered into a consortium agreement, the institution at which the student is enrolled and expects to receive a degree or certificate calculates and pays the student's Pell Grant. However, if the student is attending an institution *other* than the institution at which he or she is enrolled and expects to receive a degree, the institution at which the student is actually in attendance may pay the student's Pell Grant if both institutions agree in writing to that arrangement.

(c) The institution which calculates and pays the student a Pell Grant must take into account courses taken by the student at both institutions in determining the student's enrollment status and cost of attendance.

(20 U.S.C. 1070a.)

§ 690.9 Determination of enrollment status under special circumstances.

(a) Non-credit remedial courses.

(1) When calculating a student's enrollment status, neither the institution nor the Secretary may count any course in a program of instruction leading to a high school diploma or the recognized equivalent of a high school diploma, even if the course is necessary to enable the student to complete the degree or certificate program.

(2) Except as provided in paragraph (a)(1) of this section, in determining a student's enrollment status, the institution and Secretary will include any non-credit remedial course in which the student is enrolled. If a non-credit remedial course is not measured by clock or credit hours, the institution must determine the equivalent number of clock or credit hours which should be included for that work. A non-credit remedial course is a course of study for which no credit is given toward a certificate or degree and which is designed to increase the ability of the student to pursue an undergraduate course of study leading to that certificate or degree.

(b) Combination of regular and correspondence study.

(1) If—in addition to regular coursework—an eligible student takes correspondence courses from either his or her own institution or another institution under a consortium agreement with the student's institution, the correspondence work may be included in determining the student's enrollment status.

(2) Except as noted in subparagraph (3), the correspondence work that will be included is that amount of work which—

(i) Applies toward the student's degree or certificate or is remedial work necessary for the student to proceed in his or her course of study;

(ii) Is completed within the period of time required for regular course work; and

(iii) Does not exceed the amount of the student's regular course work.

(3) Notwithstanding subparagraph (b)(2)(iii), a student who would be a half-time student based solely on his or her correspondence work will be considered a half-time student unless the calculation in subparagraph (b)(2) indicates a greater status.

(20 U.S.C. 1070a.)

§ 690.10 Administrative cost allowance to participating schools.

(a) The Secretary will pay to each participating institution an amount equal to $10 per award year for each student who receives a Pell Grant at that institution for that year.

(b) All funds an institution receives under this section must be used solely for the institution's costs of administering the Pell Grant, Supplemental Educational Opportunity Grant, College Work-Study and National Direct Student Loan programs.

(20 U.S.C. 1096)

2. Subpart B is revised to read as follows:

Subpart B—Application Procedures for Determining Expected Family Contribution

§ 690.11 Application.

(a) As the first step to receiving a Pell Grant, a student applies on an approved form to the Secretary to have his or her expected family contribution determined. Facsimile copies of this form are not acceptable.

(b) The student, and where relevant, the student's parents or spouse, must submit information that is accurate and

complete as of the date the application is signed.

(c) The address provided by the student must be his or her residence and not the address of the school, unless the student resides at the school.

(20 U.S.C. 1070a)

§ 690.12 Certification of information.

(a) The applicant, and where relevant the applicant's parents or spouse, must provide (if requested by either the Secretary or the school) information or documents, including a copy of Federal Income Tax Returns, necessary to verify the accuracy of the information provided.

(b) Failure to provide the requested documentation may make the applicant ineligible to receive a Pell Grant.

(20 U.S.C. 1070a)

§ 690.13 Deadline for filing applications.

For each award year the Secretary will establish application filing deadlines for determining expected family contributions.

(20 U.S.C. 1070a)

§ 690.14 Notification of expected family contribution.

The Secretary will send to each eligible applicant a "Student Eligibility Report" (SER) which states the amount of the applicant's expected family contribution and information used in that computation.

(20 U.S.C. 1070a)

§ 690.15 Applicant's request for recomputation of expected family contribution because of clerical or arithmetic error.

(a) An applicant may request a recomputation of his or her expected family contribution if he or she believes a clerical or arithmetic error has occurred, or if the information submitted was inaccurate when the application was signed.

(b) A request for recomputation must be made on an approved form and must be received by the Secretary no later than the annual deadline unless the recomputation is necessary because of a request made by the Secretary to verify information.

(20 U.S.C. 1070a)

§ 690.16 Request for recomputation of expected family contribution because of extraordinary circumstances.

In filing an application to have an expected family contribution determined, an applicant may provide financial information relating to the tax year immediately following the base year if the conditions in §§ 690.39 or 690.48 apply.

(20 U.S.C. 1070a)

3. Subpart F is amended to read as follows:

Subpart F—Determination of Pell Grant Awards

§ 690.61 Submission process and deadline for student eligibility report.

(a)(1) A student applies for a Pell Grant by submitting a valid "Student Eligibility Report" (SER) to his or her institution or to the Secretary, if that institution is participating in the Pell Grant Program under the Alternate Disbursement System (ADS).

(2) The SER is considered valid only if all information used in the calculation of the eligibility index is complete and accurate when the application was signed. Institutions are entitled to rely on SER information except under conditions set forth in § 690.77.

(b) Except as noted in § 690.77, to receive a Pell Grant, a student who enrolls before May 1 of an award year must submit the SER to his or her institution on or before May 31 of that award year.

A student who enrolls for the first time in the award year on or after May 1 of that award year may submit the SER to the institution on or before June 30 of that award year.

(c) A student attending an institution participating in the Pell Grant Program under the ADS has an additional ten days to submit the SER to the Secretary: June 10 for those who enroll before May 1, and July 10 for those who enroll on or after May 1.

(d) A student who submits an SER to an institution when he or she is no longer enrolled and eligible for payment at that institution may not be paid a Pell Grant.

(20 U.S.C. 1070a)

§ 690.62 Calculation of a Scheduled Pell Grant at full-funding.

(a) When funds are available to satisfy all payments, the Secretary will pay each eligible, full-time student for a complete academic year a Scheduled Pell Grant which is the lowest of:

(1) In award year 1981–82,

(i) the difference between $1,900 and the expected family contribution stated on his or her SER; or

(ii) 50 percent of his or her cost of attendance; or

(iii) the difference between his or her cost of attendance and expected family contribution.

(2) In award year 1982–83,

(i) the difference between $2,100 and the expected family contribution stated on his or her SER; or

(ii) 60 percent of his or her cost of attendance; or

(iii) the difference between his or her cost of attendance and expected family contribution.

(3) In award year 1983–84,

(i) the difference between $2,300 and the expected family contribution stated on his or her SER; or

(ii) 65 percent of his or her cost of attendance; or

(iii) the difference between his or her cost of attendance and expected family contribution.

(4) In award year 1984–85,

(i) the difference between $2,500 and his or her expected family contribution stated on his or her SER; or

(ii) 65 percent of his or her cost of attendance; or

(iii) the difference between his or her cost of attendance and expected family contribution.

(5) In award year 1985–86,

(i) the difference between $2,600 and the expected family contribution stated on his or her SER; or

(ii) 70 percent of his or her cost of attendance; or

(iii) the difference between his or her cost of attendance and expected family contribution.

(b) Notwithstanding paragraph (a) of this section, no payment will be made if the student's Scheduled Pell Grant is less than $200.

(20 U.S.C. 1070a(a)(2).)

§ 690.63 Calculation of a Scheduled Pell Grant at less than full funding.

(a) When funds are not available to satisfy all payments, the Secretary calculates a Scheduled Pell Grant at less than full funding by—

(1) Determining the maximum grant award at full funding for that award year. The maximum grant award is the maximum Pell Grant authorized for the award year without regard to an applicant's expected family contribution or cost of attendance;

(2) Subtracting from that amount, the applicant's expected family contribution; and

(3) Reducing the remainder, based on the applicant's expected family contribution, according to the table in paragraph (b) of this section.

(b) If the applicant's expected family contribution is:	The amount calculated in paragraph (a) of this section is reduced by:
$0 to $600	0
$601 to $800	10
$801 to $1,000	20
$1,001 to $1,200	30
$1,201 to $1,600	40
$1,601 or more	50

(c) If the amount appropriated for an award year exceeds the amount needed for making payments under paragraph (a) of this section, the Secretary shall pay the excess to each eligible student in proportion to the degree that the student's award was reduced in accordance with paragraph (b) of this section.

(d) If the amount appropriated for an award year is less than the amount needed for making grants under paragraph (a) of this section, the Secretary shall reduce each amount determined under paragraph (a) of this section according to the following formula:

Scheduled Pell Grant at Pro-Rata Reduction equals amount determined in paragraph (a) of this section times appropriations available for Pell Grants divided by appropriation needed to fund Pell Grants under paragraph (a) of this section.

(e) At less than full funding, the Secretary will pay a Pell Grant to a full time student for a full academic year in an amount which is the lowest of:

(1) The amount calculated in paragraph (a), (c) or (d) of this section, as appropriate;

(2) The appropriate cost of attendance limitation; or

(3) The difference between the student's cost of attendance and expected family contribution.

(f) Notwithstanding paragraph (e) of this section, no payment may be made if

(1) The student's award is less than $50; or

(2) The student's Scheduled Pell Grant at full funding is less than $200.

(20 U.S.C. 1070a)

§ 690.64 Maximum Pell Grant as percentage of cost of attendance.

Notwithstanding § 690.62 and § 690.63, in any award year—

(a) If the maximum grant for that award year is $1,900 or less, no grant may exceed 50 percent of the recipient's cost of attendance;

(b) If the maximum grant for that award year is at least $1,901 but not more than $2,099, no grant may exceed 55 percent of the recipient's cost of attendance;

(c) If the maximum grant for that award year is at least $2,100 but not more than $2,299, no grant may exceed 60 percent of the recipient's cost of attendance; and

(d) If the maximum grant for any award year is at least $2,300 but not more than $2,599, no grant may exceed 65 percent of the recipient's cost of attendance.

(20 U.S.C. 1070a)

§ 690.65 Calculation of a Pell Grant for a payment period.

(a) At those institutions using semesters, trimesters, quarters, or other academic terms and measuring progress by credit hours, a student's Pell Grant for each payment period is calculated as follows:

(1) Determine his or her enrollment status for the term.

(2) Based upon that enrollment status, determine his or her annual award from the Payment Schedule (full-time students), or one of the Disbursement Schedules (part-time students), as appropriate.

(3) Divide the amount determined in subparagraph (2) by the number of terms in an academic year if those terms are of equal length.

(4) If those terms are not of equal length, determine that portion of the award derived in subparagraph (2) which reflects the proportion of the academic year represented by that term. However, a payment for any term may not exceed 50 percent of the award determined in subparagraph (2). To insure this, payments for unequal terms must be adjusted if necessary.

(b) At those institutions which measure progress by clock hours or which measure progress by credit hours or units but do not use semesters, trimesters, quarters or other academic terms, a student's Pell Grant for each payment period is calculated by:

(1) Determining the student's Scheduled Pell Grant; and

(2) Multiplying the Scheduled Pell Grant by:

The number of credit or clock hours the student is expected to take in a payment period divided by the number of credit or clock hours that a full-time student would take in an academic year.

(b) Notwithstanding paragraphs (a) and (b) of this section—

(1) A student may not receive a Pell Grant if the amount which the student would receive, projected on the basis of a full academic year, would be less than either $200 at full funding or $50 at less than full funding; and

(2) The amount of a student's award for an award period may not exceed his or her Scheduled Pell Grant award for that award year.

(20 U.S.C. 1070a)

§ 690.66 Calculation of a Pell Grant for a payment period which occurs in two award periods.

A student who enrolls in a payment period which is scheduled to occur in two award years shall be paid in accordance with the following rules—

(a)(1) The entire payment period will be considered to occur within one award year.

(2) The institution will determine the award year in which the payment period will be placed.

(3) The determination made in paragraph (a)(2) of this section must be the same for all Pell Grant recipients for all payment periods (in a program) which begin on the same day.

(4) If the institution places the payment period in the first award year, it must pay the student with funds from the first award year.

(5) If the institution places the payment period in the second award year, it must pay the student with funds from the second award year.

(b) The institution may not make a payment which will result in the student receiving more than his or her Scheduled Pell Grant award for that award year.

(c)(1) If a term-based institution offers a series of mini-sessions which occurs in two award years, the combined sessions will be treated as one term. A student may not receive more than one term's award for completing any combination of these sessions.

(2) For such mini-sessions, a term-based institution must determine the student's enrollment status for the entire term. That enrollment status will be based upon—

(i) The total number of credits enrolled for in all sessions if that number is known when the award is calculated, or

(ii) A projected number of credits based upon the credits enrolled for in the first session, if the number of credits to be taken in subsequent sessions is unknown when the award is calculated.

(20 U.S.C. 1070a)

§ 690.67 Transfer student: attendance at more than one institution during an award period.

(a) If a Pell Grant recipient withdraws from one institution and enrolls at a

second in the same award year, the student must submit an SER to the second institution or to the Secretary for an institution participating in the program under ADS.

(b) The second institution (or the Secretary for ADS schools) calculates the student's award according to § 690.65.

(c) The second institution (or the Secretary for ADS schools) pays a Pell Grant for only that portion of the award year in which the student is enrolled at that institution. The grant must be adjusted to ensure that the student does not exceed the Scheduled Pell Grant for that award year.

(d) A transfer student must repay any amount received in an award year which exceeds the Scheduled Pell Grant.

(20 U.S.C. 1070a)

§ 690.68 Correspondence study.

A student, enrolled in a program of study by correspondence will be paid according to the following procedures:

(a) The institution prepares a written schedule for submission of lessons. This schedule must reflect a work load of at least 12 hours of preparation per week. It is used to determine the length of the program.

(b) The student's Pell Grant for an award year is calculated by:

(1) Determining the Scheduled Pell Grant according to §§ 690.62 or 690.63, whichever is appropriate, taking into account § 690.64, and

(2) Multiplying the Scheduled Pell Grant by the lesser of the following fractions:

½ or the hours of preparation in the award year divided by the hours of preparation in the academic year.

(This procedure insures that students in a program of study by correspondence are paid as half-time students.)

(d) A student will receive two equal payments for an award year. The first payment will be made after the student has submitted 25 percent of the lessons scheduled for the award year.

(e) The final payment will be made after the student has submitted 75 percent of the lessons scheduled for the award year.

(20 U.S.C. 1070a)

4. Subpart G is amended to read as follows:

Subpart G—Administration of Grant Payments—Regular Disbursement System

§ 690.71 Scope.

This subpart deals with program administration by an institution of higher education that has entered into an agreement with the Secretary to calculate and pay Pell Grant awards.

(20 U.S.C. 1070a)

§ 690.72 Institutional agreement—regular disbursement system (RDS).

(a) The Secretary may enter into an agreement with an institution of higher education under which the institution will calculate and pay Pell Grants to its students. The agreement will be on a standard form provided by the Secretary and will contain the necessary terms to carry out this part.

(b) The Secretary will send a Payment Schedule for each award year to an institution that has entered into an agreement under paragraph (a) of this section.

(20 U.S.C. 1070a)

§ 690.73 Termination of agreement—regular disbursement system.

(a) Termination by the Secretary. The Secretary may terminate the agreement with an institution by giving—

(1) 30 days written notice; or

(2) Less than 30 days written notice if it is necessary to prevent the likelihood of a substantial loss of funds to the Federal government or to students.

(b) Information provided. The institution must provide the following information to the Secretary if the Secretary terminates the agreement:

(1) The name and enrollment status of each eligible student who submitted a valid SER to the institution before the termination date;

(2) The amount of funds the institution paid to Pell Grant recipients for the award year in which the agreement is terminated;

(3) The amount due to each student eligible to receive a Pell Grant through the end of the award year; and

(4) An accounting of Pell Grant expenditures to the date of termination.

(c) Termination by the institution. The institution may terminate the agreement by giving the Secretary written notice. The termination becomes effective on June 30 of that award year. The institution must carry out the agreement for the remainder of the award year.

(d) Termination because of a change in ownership which results in a change of control. The agreement automatically terminates when an institution changes ownership which results in a change of control. The Secretary will enter into an agreement with the new owner if the institution complies with requirements set forth in Subpart B of the Student Assistance General Provisions (34 CFR Part 668).

(e) If an agreement is terminated, the institution's eligibility as discussed in § 690.7 is not terminated but the Secretary will pay and institution's students ONLY if the institution enters into an ADS agreement (See § 690.92.).

(20 U.S.C. 1070a)

§ 690.74 Advancement of funds to institutions.

The Secretary will advance funds for each award year, from time to time, to RDS institutions, based on his or her estimate of the institution's need for funds to pay Pell Grants to its students.

(20 U.S.C. 1070a)

§ 690.75 Determination of eligibility for payment.

(a) An institution may pay a Pell Grant to a student only after it determines that the student—

(1) Meets the eligibility requirements set forth in § 690.4;

(2) Is maintaining satisfactory progress in his or her course of study;

(3) Is not in default on any National Defense/Direct Student Loan made by that institution or on any Guaranteed Student Loan or Parent Loan for Undergraduate Students (PLUS) received to meet the cost of attendance at that institution; and

(4) Does not owe a refund on a Pell Grant, a Supplemental Grant or a State Student Incentive Grant received to meet the cost of attending that institution.

(b)(1) Before making any payment to a student, the institution must confirm that he or she continues to meet the criteria set forth in paragraph (a) of this section.

(2) However, if an eligible student submits an SER to the institution and becomes ineligible before receiving a payment, the institution must pay the student only the amount which it determines could have been used for educational purposes before the student became ineligible.

(c) If an institution determines at the beginning of a payment period that a student is not maintaining satisfactory progress, but reverses itself BEFORE the end of the payment period, the institution may pay a Pell Grant to the student for the entire payment period.

(d) If an institution determines at the beginning of a payment period that a student is not maintaining satisfactory progress, but reverses itself AFTER the end of the payment period, the institution may neither pay the student a Pell Grant for that payment period nor make adjustments in subsequent Pell Grant payments to compensate for the loss of aid for that period.

(e) Conditions under which students who are overpaid grants may continue to receive Pell Grants are are follows:

(1) Overpayment of a Pell Grant. If an institution makes an overpayment of a

Pell Grant to a student, it may continue to make Pell Grant payments to that student if (i) the student is otherwise eligible; and (ii) it can eliminate the overpayment in the award year in which it occurred by adjusting the subsequent Pell Grant payments for that award year.

(2) Overpayment of a Pell Grant due to institutional error. In addition to the exception provided in paragraph (e)(1) of this section, if the institution makes an overpayment of Pell Grant to a student as a result of its own error, it may continue to make payments to that student if;

(i) The student is otherwise eligible, and

(ii) The student acknowledges in writing the amount of overpayment and agrees to repay it in a reasonable period of time.

(3) Overpayment on a Supplemental Grant. An institution may continue to make Pell Grant payments to a student who receives an overpayment on a Supplemental Grant if:

(i) The student is otherwise eligible, and

(ii) It can eliminate the overpayment by adjusting subsequent financial aid payments (other than Pell Grants) in the same award year in which it occurred.

(f) An institution, in determining whether a student is in default on a loan made under the Guaranteed Student Loan Program or the PLUS Program, may rely upon the student's written statement that he or she is not in default unless the institution has information to the contrary.

(g) Conditions under which students who are in default on loans made for attendance at that institution may receive Pell Grants are as follows:

(1) Guaranteed Student Loans and Parent Loans for Undergraduate Student (PLUS). An institution may pay a Pell Grant to a student who is in default on a Guaranteed Student Loan or a PLUS Loan if the Secretary (for federally insured loans) or a guaranteed agency (for a loan insured by that guarantee agency) determines that the student has made satisfactory arrangements to repay the defaulted loan.

(2) National Defense/Direct Student Loan. An institution may pay a Pell Grant to a student who is in default on a National Defense/Direct Student Loan made at that institution, if the student has made arrangements, satisfactory to the institution, to repay the loan.

(3) The Secretary considers a National Defense Student Loan, a National Direct Student Loan, a Guaranteed Student Loan, or a PLUS Loan which is discharged in bankruptcy to be in default for purposes of this section.

(h) For purposes of this section, an overpayment of a grant means that a student received payment of a grant greater than the amount he or she was entitled to receive.

(20 U.S.C. 1070a)

§ 690.76 Frequency of payment.

(a) In each payment period, an institution may pay a student at such times and in such installments as it determines will best meet the student's needs.

(b) Only one payment is required if a portion of an academic year occurring within one award year is less than three months.

(c) The institution may pay funds due a student for any completed period in one lump sum. The student's enrollment status will be determined according to work already completed.

(20 U.S.C. 1070a)

§ 690.77 Verification of information on the SER—withholding of payments.

(a)(1) The Secretary may require that a student verify the information submitted on the application and included on the SER, by submitting appropriate documentation to the institution or to the Secretary.

(2) The Secretary may also require that the institution withhold payment of a student's grant until the institution or the Secretary determines that the student has supplied the correct information.

(b) If an institution believes that any information on the SER used in calculating the student's expected family contribution is inaccurate, or if the application is chosen by the Secretary for verification, the institution must request that the student verify the information on the SER.

(c) The Secretary will establish and publish—

(1) Procedures to be used in verifying information for selected students ("Validation Procedures"), and

(2) The conditions under which payments will be made for these students.

(d)(1) If a student makes a correction which results in a change in his or her expected family contribution, the student must submit the SER to the institution, and the institution must recalculate the student's award based on the verified SER. Any overpayment must be repaid by the student.

(2) If the documentation requested by the institution under this section does not verify the information on the SER, or if the student does not correct the SER, the institution must forward the student's name, social security number and other relevant information to the Secretary in accordance with the procedures referenced in paragraph (c) of this section.

(e) A student corrects an SER by—

(1) Providing accurate information on the SER;

(2) Getting the appropriate signatures on the SER; and

(3) Re-submitting the SER to the Secretary.

(f) If an institution has documentation which indicates that the information used to calculate the student's expected family contribution on the SER is inaccurate, it may not pay a Pell Grant for any award year until the student corrects the error or verifies the data.

(g) If an institution believes, but cannot document, that inaccuracies exist on the SER, it may not withhold payments unless authorized by the Secretary. These cases must be forwarded to the Secretary.

(h)(1) If the Secretary requests documentation, the student must comply within a time period set by the Secretary.

(2)(i) If the student provides the requested documentation on time, he or she will be eligible for Pell Grant payments based upon the verified SER.

(ii) If the verified SER is submitted to the institution after the appropriate deadline as specified in § 690.61, but within an established time period to be determined by the Secretary, the student may be paid only up to the amount withheld because of the verification process.

(3) If the student does not provide the requested documentation within the established time period—

(i) The student will forfeit the Pell Grant for the award year,

(ii) Any grant payments received must be returned to the Secretary, and

(iii) No further Pell Grant applications will be processed for that student until documentation has been provided or the Secretary decides there is no longer need for documentation.

(20 U.S.C. 1070a.)

§ 690.78 Method of disbursement—by check or credit to student's account.

(a) The institution may pay a student either directly by check or by crediting his or her account with the institution. The institution must notify the student of the amount of money he or she can expect to receive, and how he or she will be paid.

(b)(1) The institution may not make a payment to a student for a payment period until the student is registered for that period.

(2) The earliest an institution can directly pay a registered student is 10

days before the first day of classes of a payment period.

(3) The earliest an institution can credit a registered student's account is 3 weeks before the first day of classes of a payment period.

(c) The institution must return to the Pell Grant account any funds paid to a student who, before the first day of classes—

(1) Officially or unofficially withdraws, or

(2) Is expelled.

(d)(1) If an institution pays a student directly, it must notify him or her when it will pay the Pell Grant award.

(2) If the student has not picked up the check at the end of the 15 day period, the institution may credit the student's account for any amount owed to it for the award year.

(3) If a student does not pick up the check on time, the institution must keep that check for 15 days after the date the student's enrollment for that award year ends.

(4) A student forfeits the right to receive the proceeds of the check if he or she does not pick up the check by the end of the 15 day period.

(5) Notwithstanding paragraph (d)(4) of this section, the institution may, if it chooses, pay a student who did not pick up the check, through the next payment period.

(20 U.S.C. 1070a.)

§ 690.79 Educational purpose statement.

(a) An institution may not pay a Pell Grant unless the student files a statement of educational purpose with the institution in which the student declares that he or she will use Pell Grant funds solely for educational expenses connected with attendance at the institution.

(b) The Secretary considers the following statement as satisfying this requirement.

Statement of Educational Purpose

I declare that I will use any funds I receive under the Pell Grant program solely for expenses connected with attendance at

_____
(Name of Institution)
(Date)_____
(Signature) _____

(20 U.S.C. 1090)

§ 690.80 Recovery of overpayments.

(a)(1) The student is liable for any overpayment made to him or her.

(2) Also, the institution is liable for an overpayment it makes to a student if the regulations indicate that the payment should not have been made. The institution must restore those funds to the Pell Grant account even if it cannot collect the overpayment from the student.

(b) If an institution makes an overpayment for which it is not liable, it must help the Secretary recover the overpayment by—

(1) Making a reasonable effort to contact the student and recover the overpayment; and, if successful,

(2) Providing the Secretary with the student's name, social security number, amount of overpayment, and other relevant information.

(20 U.S.C. 1070a.)

§ 690.81 Recalculation of a Pell Grant award.

(a) Change in expected family contribution. (1) If the student's expected family contribution changes the institution must recalculate the Pell Grant Award.

(2) Except as provided in § 690.77(h)(ii), the institution must adjust the award and pay the student the amount he or she is entitled to for the award year if the expected family contribution is recalculated because of—

(i) A clerical or arithemetic error under § 690.15, or

(ii) Extraordinary circumstances which affect the expected family contribution under § 690.39 and § 690.48.

(3) If a student's expected family contribution is recalculated because of a correction of the information requested under § 690.12 or § 690.77, the student's Pell Grant for the award year must be adjusted. Where possible, the adjustment must be made within the same award year.

(4) If the recalculation takes place in a subsequent award year, the student will be

(i) Eligible to receive payment unless prohibited under the provisions of § 690.77(h) and

(ii) Required to return any overpayment at the time of recalculation.

(b) Change in enrollment status.

(1) If an institution decides that a student's enrollment status has changed during a payment period, it may (but is not required to) establish a policy under which the student's award may be recalculated.

(2) If such a policy is established, it must apply to all students.

(3) If a student's award is recalculated, the institution determines the total amount the student is entitled to for the entire payment period by taking into account—

(i) The portion of the payment period at the original enrollment status;

(ii) The portion of the payment period at the new enrollment status; and

(iii) Any change in the student's cost of attendance.

(20 U.S.C. 1070a.)

§ 690.82 Fiscal control and fund accounting procedures.

(a)(1)(i) An institution must receive and process all Pell Grant funds through one identifiable bank account.

(ii) This account may be an existing one (preferably one maintained for Federal funds) if the institution maintains adequate accounting records to account for the Pell Grants funds separately from the other funds in that account.

(iii) At no time may the Pell Grant funds in this bank account be less than the balance indicated in the institution's accounting records for these funds.

(2) The institution must account for the receipt and expenditure of Pell Grant funds in accordance with generally accepted accounting principles.

(b) A separate bank account for Pell Grant funds is not required. However, the institution must notify any bank in which it deposits Pell Grant funds of all accounts in that bank in which it deposits Federal funds. This notice can be given by either:

(i) Including in the name of the account the fact that Federal funds are deposited therein; or

(ii) Sending a letter to the bank listing the accounts in which Federal funds will be deposited. A copy of this letter must be retained in the institution's files.

(c) Except for funds received under § 690.10, funds received by an institution under this part are held in trust for the intended student beneficiaries and may not be used or hypothecated for any other purpose.

(20 U.S.C. 1070a.)

§ 690.83 Maintenance and retention of records.

(a) Each institution must maintain adequate records which include the fiscal and accounting records that are required under § 690.82 and records indicating—

(1) The eligibility of all enrolled students who have submitted a valid SER to the institution;

(2) The name, social security number, and amount paid to each recipient;

(3) The amount and date of each payment;

(4) The amount and date of any overpayment that has been restored to the program account;

(5) The "Student Eligibility Report" for each student;

(6) The student's cost of attendance;

(7) How the student's full or part-time enrollment status was determined; and

(8) The student's enrollment period.

(b)(1) The institution must make the records listed in paragraph (a) available for inspection by the Secretary's authorized representative at any reasonable time in the institution's offices. It must keep these records for five years after it submits an accounting of each award year's funds to the Secretary.

(2) An accounting of each award year's funds occurs when the institution submits to the Secretary the June 30 Progress Report for that award year. The June 30 Progress Report (ED Form 255–3) is the report on which an institution reports to the Secretary the total amount of money it has expended in the Pell Grant Program during an award year and the total number of Basic Grant recipients at that institution during that award year.

(c) The institution must keep records involved in any claim or expenditure questioned by Federal audit until resolution of any audit questions.

(d) An institution may substitute microfilm copies in lieu of original records in meeting the requirements of this section.

(20 U.S.C. 1070a)

§ 690.84 Submission of reports.

The institution must submit the reports and information the Secretary requires in connection with the funds advanced to it and must comply with the procedures the Secretary finds necessary to ensure that the reports are correct.

(20 U.S.C. 1070a)

§ 690.85 Audit and examination.

(a) Federal audits. The institution must give the Secretary, the Comptroller General of the United States, or their duly authorized representatives, access to the records specified in § 690.82 and § 690.83 and to any other pertinent books, documents, papers, and records.

(b) Non-Federal audits. The institution must audit or have audited under its direction all Pell Grant Program transactions to determine at a minimum—

(1) The fiscal integrity of financial transactions and reports; and

(2) If such transactions are in compliance with the applicable laws and regulations. Such audits will be performed in accordance with the Department of Education's "Audit Guide" for the Pell Grant Program.

(3) The institution must have an audit performed at least once every two years.

(c) The institution must submit audit reports to the institution's local regional office of the Department of Education's Audit Agency. It must give the Audit Agency and the Secretary access to records or other documents necessary to the audit's review.

(20 U.S.C. 1070a.)

5. Subpart H is amended to read as follows:

Subpart H—Administration of Grant Payments—Alternate Disbursement System

§ 690.91 Scope.

This subpart deals with program administration by an institution of higher education under the Alternate Disbursement System (ADS). Under the ADS, the Secretary calculates and pays the Pell Grant awards.

(20 U.S.C. 1070a.)

§ 690.92 Institutional agreement—Alternate Disbursement System (ADS).

(a) Under ADS, the Secretary will calculate and pay Pell Grant awards to students enrolled in an institution which has entered into an agreement to carry out this subpart.

(b) Under this agreement, the institution agrees to:

(1) Complete ED Form 304 for each eligible student as specified in § 690.94; and

(2) Maintain and keep records as specified in § 690.90.

(20 U.S.C. 1070a.)

§ 690.93 Change in ownership and change to the Regular Disbursement System (RDS).

(a) Change to RDS. The Secretary may enter into an agreement with an ADS institution which wishes to participate in the program under the Regular Disbursement System. However, the agreement will go into effect July 1 of the succeeding award year.

(b) Termination because of a change in ownership that results in a change in control.

(1) An ADS agreement terminates when an institution changes ownership that results in a change in control.

(2) The Secretary may enter into an agreement with the new owner if the institution complies with the requirements set forth in Subpart B of the Student Assistance General Provisions (34 CFR Part 668).

(20 U.S.C. 1070a.)

§ 690.94 Calculation and disbursement of awards by the Secretary of Education.

(a) An eligible student enrolled in an institution participating in the Pell Grant Program under the ADS applies to the Secretary for a Pell Grant according to the following procedures:

(1) The student submits an SER to his or her institution and obtains an ED Form 304 from the institution;

(2) The student completes the ED Form 304, including the statement of educational purpose described in § 690.79, and submits it to the institution;

(3) On the ED Form 304 the institution certifies that the student—

(i) Meets eligibility requirements of § 690.4,

(ii) Is maintaining satisfactory progress in his or her course of study,

(iii) Does not owe a refund on grants received for attendance at that institution under the Pell Grant, the Supplemental Grant, or the State Student Incentive Grant Programs, and

(iv) Is not in default on any National Defense/Direct Student Loan made by the institution or on any Guaranteed Student Loan received for attendance at that institution. (In determining whether a student is in default on a GSL, the institution may rely on a written statement provided by the student unless the institution has information to the contrary); and

(4) The institution returns the SER and ED Form 304 to the student, who then submits these documents to the Secretary. Both documents must be received by the Secretary on or before the deadline dates described in § 690.61.

(b) If an institution believes that the information on an SER may be in error, the institution must notify the student and request documentation or correction. Any case not resolved by the institution should be reported to the Secretary.

(c) The Secretary will calculate a student's award in accordance with Subpart F of this part and will pay the student once every payment period.

(20 U.S.C. 1070a.)

§ 690.95 Termination of enrollment and refund.

(a) The institution must inform the Secretary of the date when a student officially or unofficially withdraws or is expelled during a payment period for which that student was paid.

(b) A student who officially or unofficially withdraws or is expelled from an institution before completion of 50 percent of a payment period for which he or she has been paid, will refund a prorated portion of the payment as determined by the Secretary.

(20 U.S.C. 1070a.)

§ 690.96 Maintenance and retention of records.

(a) An institution under the ADS must establish and maintain for each award year—

(1) Records relating to each Pell Grant recipient's enrollment status, and attendance costs at the institution; and

(2) Records showing when each recipient was enrolled.

(b) The institution must make these records available at the geographic location where the student will receive his or her degree or certificate of course completion, and must keep them for five years from the end of the award year.

(c) The institution will make available to the Secretary, the Comptroller General of the United States, and their authorized representatives, pertinent books, documents, papers, and records for audit and examination during the five year retention period.

(d) An institution may substitute microfilm copies in lieu of original records in meeting the requirements of this section.

(20 U.S.C. 1070)

6. Appendix A to Part 960 is removed.

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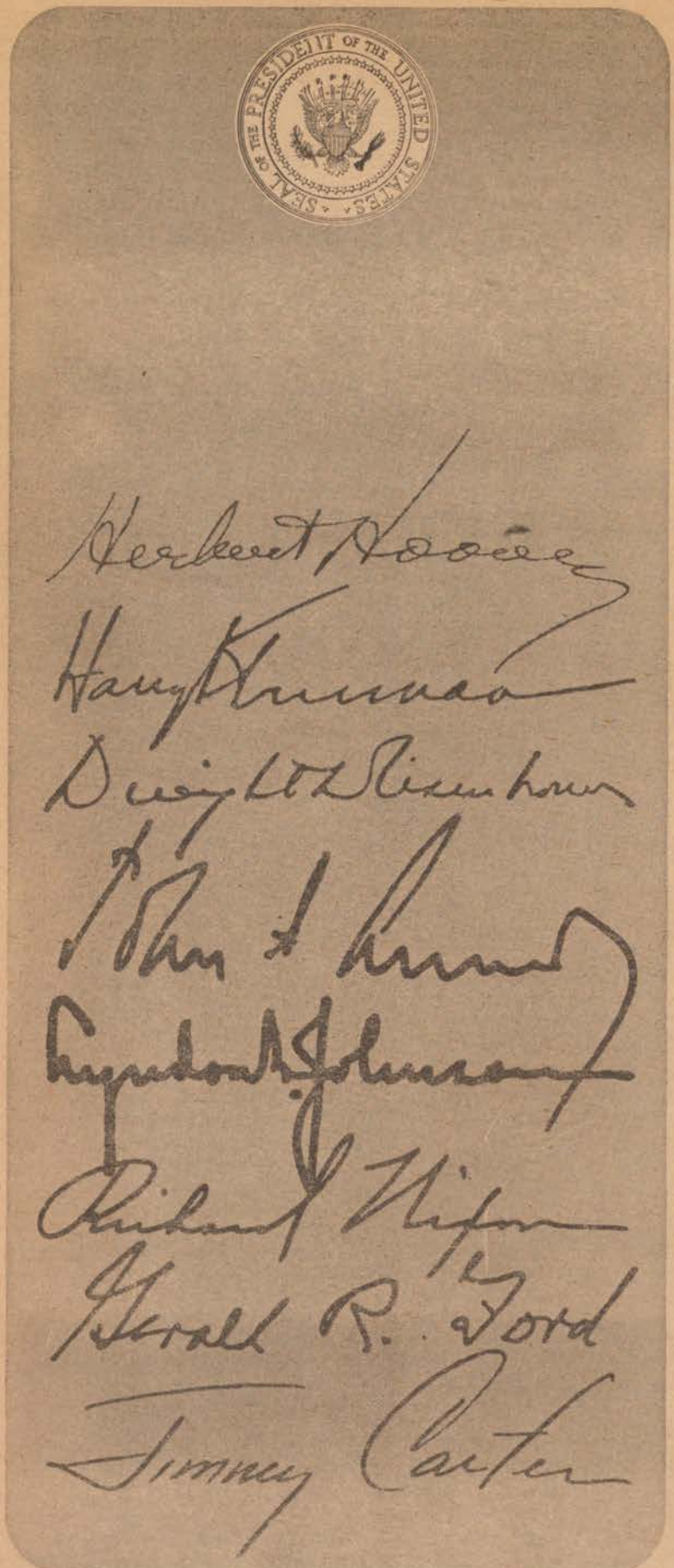

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