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Thursday
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Briefings on How To Use the Federal Register—
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WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 2 1/2 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: November 18 at 9:30 a.m.

WHERE: National Archives Theater, 8th and Pennsylvania Avenue NW., Washington, DC

RESERVATIONS: Laurice Clark, 202–523–3419.

NEW YORK, NY

WHEN: December 5 at 10:00 a.m.,

WHERE: Room 305A, 26 Federal Plaza, New York, NY

RESERVATIONS: Arlene Shapiro or Stephen Colon, New York Federal Information Center, 212–264–4810.

PITTSBURGH, PA

WHEN: December 8 at 1:30 p.m.,

WHERE: Room 2212, William S. Moorehead Federal Building, 1000 Liberty Avenue, Pittsburgh, PA

RESERVATIONS: Kenneth Jones or Lydia Shaw
Pittsburgh: 412–644–INFO
Philadelphia: 215–597–1707, 1709

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Presidential Documents

Title 3—

The President

Presidential Determination No. 87–3 of October 27, 1986

Determination Pursuant to Section 620E(e) of the Foreign Assistance Act of 1961, as Amended

Memorandum for the Honorable George P. Shultz, the Secretary of State

Pursuant to section 620E(e) of the Foreign Assistance Act of 1961, as amended, 22 U.S.C. 2375(e), I hereby certify that Pakistan does not possess a nuclear explosive device and that the proposed United States assistance program will reduce significantly the risk that Pakistan will possess a nuclear explosive device.

You or your delegatee are authorized and directed to publish this determination and certification in the **Federal Register.**

Ronald Reagan

THE WHITE HOUSE,
Washington, October 27, 1986.

[FR Doc. 86–25250
Filed 11–4–86; 4:05 pm]
Billing code 3195–01–M

Rules and Regulations

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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 51

Domestic Licensing of Production and Utilization Facilities; Communications Procedures Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations that establish the procedures for submitting correspondence, reports, applications, or other written communications pertaining to the domestic licensing of production and utilization facilities. The amendments indicate the correct mailing address for delivery of the communications and specify the number of copies required to facilitate action by the NRC. The proposed amendments will resolve a number of problems that have developed during the past several years regarding the submission of applications and reports. In addition to clarifying the procedures, these amendments will result in a reduction in reproduction and postage costs for the affected licensees.

EFFECTIVE DATE: January 5, 1987.

FOR FURTHER INFORMATION CONTACT: Steve Scott, Information and Records Management Branch, Division of Technical Information and Document Control, Office of Administration, Nuclear Regulatory Commission, Washington, DC 20555, Telephone: (301) 492–8585.

SUPPLEMENTARY INFORMATION: Because of varying and sometimes conflicting requirements for the submittal of information by applicants and licensees, confusion has arisen with regard to copy requirements and proper submittal procedures. In an effort to clarify these matters, the NRC issued Regulatory Guide 10.1 (Revision 4) "Compilation of Reporting Requirements for Persons Subject to NRC Regulations" and on August 8, 1982 the Director, Division of Licensing, Office of Nuclear Reactor Regulation, issued Generic Letter 82–14 "Submittal of Documents to the Nuclear Regulatory Commission." While these efforts at clarification resolved much of the confusion, these guidance documents contain outdated information and in many cases conflict with requirements in regulations or individual licenses. Therefore, the NRC is issuing this rule to specify copy requirements and provide mailing instructions. The rule also clarifies the current requirement in § 50.30 for making an updated copy of the application available at an appropriate office near the site for inspection by the public.

This rule supersedes all existing requirements and guidance with respect to the number of copies and mailing procedures. The Commission's guidance documents dealing with communications procedures will be revised to conform with the rule. Licensees whose technical specifications contain conflicting submittal directions are authorized by this rule to delete the conflicting directions by pen-and-ink changes to their technical specifications. The Commission does not expect formal applications for amendment of license to result from ths rulemaking.

This rule codifies NRC actions to reduce copy requirements. With few exceptions, copy requirements for licensee reports and applications are reduced to three. By reducing the number of copies transmitted to the Commission, the rule will result in reduced reproduction and postage costs for licensees.

Undesignated paragraphs in the amended text have been designated and obsolete titles of NRC personnel have been updated to reflect current NRC titles.

Proposed Rule

On March 26, 1985, the Commission published a proposed rule in the **Federal Register** (50 FR 11884) that would: (1) Clarify and standardize, to the extent practical, the procedures for making Part 50 submittals to the NRC; (2) reduce overall the number of copies of Part 50 submittals that applicants and licensees are required to send to the Commission; and (3) facilitate the flow of written communications from the affected licensees to NRC staff by eliminating the need for NRC to re-transmit Part 50 submittals between NRC Headquarters and the Regional Offices. After consideration of the public comments received, the Commission has modified the proposed rule as discussed in the following section. In addition, conforming amendments to 10 CFR Part 51 have been included to eliminate conflicting submittal directions.

Comments on Proposed Rule

The Commission received fifteen letters commenting on the proposed rule. Copies of those letters are available for public inspection and copying for a fee at the NRC Public Document Room, 1717 H Street NW., Washington, DC. Thirteen letters were from utilities, one from a major nuclear vendor and one from a national organization representing non-power nuclear reactors. There was a total of 53 individual comments that are discussed by subject below.

Copy Requirements

Comments: Eight commenters responded that the rule should go further in reducing the number of copies of submittals required by the Commission. The commenters recommended that NRC reduce the requirements for the following types of submittals: (1) Applications for license amendments; (2) various descriptive material, such as analyses of hydrogen control systems, analyses to ensure safe plant operation pending completion of equipment qualification, information demonostrating compliance with requirements for reduction of risk from anticipated transients without scram (ATWS) events, and information concerning modification of structures, systems or components of a facility; and (3) submittals required of non-power nuclear reactors.

Response: The Commission is reducing its copy requirements as suggested by the commenters. The Commission found that in many cases NRC did not fully utilize copies of the submittals named by the commenters when multiple copies were furnished by licensees. As as result, the copy requirements for the submittals named by the commenters were reduced to avoid unnecessary copying and postage costs for licensees.

Citation of Regulatory Requirement

Comment: Eight commenters addressed the section of the proposed rule that requires applicants and licensees to cite in the upper right corner of the first page of each Part 50 submittal, the specific regulation requiring the submission of the communication. The comments ranged from supportive to strongly opposed. Several commenters stated that a single submittal may be governed by several regulations. In addition, many licensee communications are in direct response to NRC requests for information, such as generic letters, inspection and enforcement bulletins, and Commission orders. For these responses, identifying the governing regulation would be burdensome to the licensee and a subjective decision open to interpretation.

Response: The Commission has revised this section to make citing the governing regulation on the upper right corner of the first page of the submittal a recommendation rather than a requirement for licensees and applicants. Standardizing the method of citing the regulation governing a submittal will help NRC administrative staff quickly and accurately sort (for distribution purposes) the large volume of correspondence, reports, applications, etc., received at NRC. The quick and proper handling of submittals that results from citing the basis for the submittal is in the best interest of the respondent as well as the NRC. However, as the commenters have pointed out, establishing this procedure as a requirement can cause various interpretive problems for licensees and the Commission has revised the rule accordingly.

Apparent Conflict in Proposed Rule

Comment: Three commenters responded that the proposed rule contained conflicting directions for submitting information concerning the modification of structures, systems, or components of a facility pursuant to § 50.109. This submittal type is listed in both § 50.4(b)(1) and § 50.4(b)(2). These sections have different copy requirements.

Response: The conflicting language in the proposed rule was the result of a drafting error. In the final rule, format changes were made that removed the sections containing the conflicting language noted by the commenters.

Additional Submittal Types for Inclusion in Rule

Comment: Three commenters recommended that the rule be modified to add several types of submittals. Two of these commenters cumulatively suggested expanding the coverage of the rule to 10 CFR Parts 2, 20, 21, 55, 70, and 73. The one other commenter suggested providing general guidance on submittal procedures for the types of written communications that are not specifically mentioned in the regulations, but frequently occur in the communication process with applicants and licensees.

Response: The Commission is presently working to standardize the communication procedures in the other parts of Title 10. However, those efforts will be reflected in different rulemakings and are beyond the scope of this particular rule. In response to the third commenter, language was added to § 50.4(b)(1) to identify types of written communications made pursuant to 10 CFR Part 50, not specifically mentioned in the regulations.

Waiver of Fee for License Amendments Resulting from Rule

Comment: Three commenters responded that applications for amendment of license technical specifications, which may result from promulgation of the rule, should not be subject to fees since they only address administrative matters.

Response: Since the rule does address only administrative matters and it clearly supersedes any conflicting submittal directions which may be found in an individual licensee's technical specifications or license conditions, licensees are not required to submit formal applications to amend their licenses to conform with the revised communications procedures. The Commission authorizes 10 CFR Part 50 licensees to delete any conflicting submittal requirements from their licenses or technical specifications by pen-and-ink changes. The Office of Inspection and Enforcement, through the NRC inspectors, will work with individual licensees to see that their procedures are updated.

Address Requirements

Comment: Three comments were made regarding the change in the address requirements contained in the proposed rule. Two commenters questioned whether communications would actually be addressed to the Document Control Desk or whether they would be addressed to the current NRC recipient and *mailed* to the Document Control Desk. The third commenter asked why other NRC organizations, such as the Office of Inspection and Enforcement, were not identified to receive separately mailed copies.

Response: The address requirements in the rule specify that the signed original of 10 CFR Part 50 communications must be addressed to the "U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555." The purpose of this rule is to establish one primary addressee for 10 CFR Part 50 submittals. Applicants and licensees will no longer be required to determine which NRC organization is the correct primary or secondary recipient. Nonetheless, it is required that *copies* of submittals be sent to the appropriate Regional Office and NRC Resident Inspector. No other NRC organizations were identified in the rule as receipients because the NRC internal distribution system will service them.

Elevation of Administrative Matters to Regulatory Requirements

Comments: Two commenters responded that the administrative requirements such as those contained in the rule (i.e. address requirements, distribution requirements, forms of communication, and delivery of communications) would be more appropriately issued in a guidance document (e.g. a regulatory guide or a generic letter) rather than placed in the regulations. One commenter stated that it would be too cumbersome to change the regulations every time NRC's administrative needs change. The other commenter considered the proposed rule to be divergent from the directives of the Atomic Energy Act of 1954 because administrative matters, such as photocopying, do not impact the health and safety of the public and as such should not be managed by rule, regulation or order. The commenter also felt that the rule is diametrically opposed to the spirit of the Paperwork Reduction Act of 1980 since licensees will have to develop strict procedures to assure compliance with administrative guidelines that have been elevated to regulatory requirements.

Response: The Commission recognizes its responsibilities to minimize the number of administrative requirements placed in the regulations. It is also understood that administrative requirements are usually minor in nature when viewed within the full scope of NRC's programs for protecting the public health and safety. However, some administrative requirements are necessary to effectively implement these programs and therefore must be based in regulation. During the development of this rulemaking, compliance with the intent of the Paperwork Reduction Act of 1980, i.e. minimizing the Federal

paperwork burden for individuals, small businesses, State and local governments and other persons, was a prime consideration. Based on a determination of actual NRC needs, the Commission, through this rulemaking, is reducing the administrative burden placed on licensees especially with respect to copying requirements. The Commission has also, in response to commenters' concerns, revised the final rule to make citing the governing regulation on the upper right corner of the first page of the submittal, a recommendation rather than a requirement for applicants and licensees.

The administrative requirements which are contained in the rule are similar to those requirements which were previously found in 10 CFR Part 50. This rule has compiled and to a great extent standardized those earlier requirements. The Commission has determined that the Communications rule will actually *reduce* burden on licensees and is in full compliance with the Atomic Energy Act and Paperwork Reduction Act.

Clarify Subsection of Rule Regarding Reports Pursuant to § 50.71(b)

Comment: Two commenters recommended that § 50.4(b)(2)(xviii) of the proposed rule be clarified to better define what types of reports are covered by this subsection.

Response: Section 50.4(b)(2)(xviii) of the proposed rule was removed from the final rule. However, in response to the commenter's suggestion language was added to § 50.4(b)(1) to specifically identify additional types of written communications covered by the rulemaking.

Distribution Requirements to Resident Inspector

Comment: Two commenters responded that the Commission should clarify what is meant by the requirement to send one copy of certain 10 CFR Part 50 submittals to the "appropriate NRC Resident Inspector, if applicable."

Response: The Commission intends that licensees and applicants, with NRC Resident Inspectors stationed onsite, send copies of certain 10 CFR Part 50 submittals to the Resident Inspector. This has been clarified in the final rule.

Procedures for Proprietary Information

Comment: One commenter recommended that special procedures be established to protect submittals containing proprietary information. The commenter suggested that proprietary information, along with the appropriate application for withholding from public disclosure, be submitted to the responsible NRC management person and a copy (minus the proprietary information) sent to the Document Control Desk.

Response: NRC's internal document control procedures provide specifically for the proper handling and distribution of proprietary information. Currently, the Document Control Desk is responsible for receiving and disseminating proprietary 10 CFR Part 50 submittals sent to NRC Headquarters. Adopting the commenter's suggestion to send proprietary information directly to the responsible NRC management person would unnecessarily impede NRC's dissemination process and would not improve NRC control of proprietary information. Licensees and applicants who wish to have proprietary information withheld from public disclosure should submit the information in accordance with 10 CFR 2.790. When submitted, the proprietary information should be clearly identified and accompanied by a request containing detailed reasons and justifications that the proprietary information be withheld from public disclosure. A nonproprietary summary describing the general content of the proprietary information should also be provided.

Submission to Project Manager

Comment: One commenter suggested that it would speed up the processing of submittals if the NRC licensing project manager was specified as the primary addressee with a copy or copies sent to the Document Control Desk. The commenter stated that this method of addressing communications is encouraged in Generic Letter 82–30 "Filings Relating to 10 CFR Part 50 Production and Utilization Facilities" dated December 28, 1982.

Response: In actual practice, the Document Control Desk is the direct recipient of all 10 CFR Part 50 submittals mailed to NRC Headquarters. This includes those submittals addressed in the manner described in Generic Letter 82–30. This rule designates the Document Control Desk as the official addressee so that (1) the regulations more accurately reflect NRC's internal procedures and (2) correspondence procedures are made simpler for applicants and licensees. It is true that some licensees have arranged or have been requested to mail informal or courtesy copies directly to key NRC personnel and this practice will likely continue after issuance of the communications rule. However, licensees should note that in general, courtesy copies are not regarded by NRC as substitutes for formal submittals.

Clarify Submittal Due Dates

Comment: One commenter recommended that the rule formally clarify how submittal due dates are adjusted should the date occur on a weekend or holiday.

Response: Provisions for adjusting due dates were added to the rule in § 50.4 paragraph (d).

Implementation Schedule

Comment: On commenter recommended that the rule include an implementation schedule in view of the extensive changes to internal procedures and technical specifications that will be needed to implement the new requirements.

Response: The effective date of the rule is 60 days after publication in the **Federal Register.** This will allow those affected by the rule sufficient time to revise their internal procedures accordingly. As mentioned in a response to a previous comment, it will not be necessary for licensees to formally apply for changes to their technical specifications. Instead, the Commission authorizes licensees to make pen-and-ink changes to correct conflicting procedures in individual licenses and technical specifications.

Submittals in Media Other Than Paper

Comment: One commenter objected to the provision requiring applicants and licensees to contact the Division of Technical Information and Document Control before making submittals in other than paper form. The commenter stated that this requirement would unnecessarily impede the timely flow of information to the NRC.

Response: The Commission recognizes the need to keep the flow of information to the NRC as timely as is reasonably achievable. This is the primary reason the rule contains provisions for submissions in alternative media. The requirement to contact the Division of Technical Information and Document Control before making alternative media submissions is included to ensure that a submittal is in a form usable by NRC, i.e., compatible with NRC equipment.

Exemptions to the Copy Requirements

Comment: Two commenters recommended modifying the provisions in the rule regarding requests for exemptions to the copy requirements. One commenter objected to the requirement for specific exemption under 10 CFR 50.12 in order to submit other than the number of copies

specified in the proposed rule. The commenter questioned whether the Commission really wants to tie up the exemption process with such trivial matters. The other commenter suggested that the rule include provisions allowing licenses to negotiate copy requirements with the NRC project manager. The commenter states that this would codify an existing desirable practice.

Response: The Commission has modified the section to allow licensees to request case specific exceptions to the communications procedures through the NRC's Division of Technical Information and Document Control.

Determination of Receipt Date

Comment: One commenter recommended that the rule be changed to specifically state that the NRC Document Control Desk is the official NRC organization responsible for determining whether submittals have been filed within the required time period.

Response: For the past several years, the Document Control Desk has served as the receipt point for 10 CFR Part 50 submittals mailed to NRC Headquarters. After submittals are received, they are entered, or accessioned, in the NRC's document control system. It is at this point that 10 CFR Part 50 submittals are generally regarded as being formally filed with NRC Headquarters. This practice will continue under the provisions of the revised communications procedures. In parallel with NRC Headquarters, the Regional Offices serve as the official receipt determination point for 10 CFR submittals mailed to them.

Drafting Changes

Comment: There were numerous other comments that suggested minor editorial changes in the rule.

Response: These suggestions were evaluated in light of the revised structure of the rule and changes were made when they improved the rule.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(3). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

Paperwork Reduction Act Statement

This final rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget approval number 3150–0011.

Regulatory Analysis

The Commission has prepared a regulatory analysis on this final regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. Interested persons may examine a copy of the regulatory analysis at the NRC Public Document Room, 1717 H Street NW., Washington, DC. Single copies of the analysis may be obtained from Steve Scott, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555: telephone 301–492–8585.

Regulatory Flexibility Certification Statement

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule does not have a significant economic impact upon a substantial number of small entities. This rule amends 10 CFR 50 by specifying submittal procedures which facilitate NRC processing. This rule affects nuclear generating facilities by reducing the overall regulatory burden of reproducing and transmitting submittals to the Commission. Therefore, it is not expected to have a significant economic impact on any licensee.

Application of Backfit Rule

The Commission has determined that the backfit rule, 10 CFR 50.109, does not apply to the final rule. The final rule is purely administrative in nature, and therefore does not result in the "modification of or addition to systems, structures, components, or design of a facility . . . or the procedures or organization required to design, construct, or operate a facility. . ." See 10 CFR 50.109(a)(1).

List of Subjects

10 CFR Part 50

Antitrust, Classified information, Fire prevention, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Penalty, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statement, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is adopting the following amendments to 10 CFR Parts 50 and 51.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION OF FACILITIES

1. The authority citation for Part 50 continues to read as follows:

Authority: Secs. 103, 104, 161, 182, 183, 189, 68 Stat. 936, 937, 948, 953, 954, 955, 956, as amended, Sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2134, 2201, 2232, 2233, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1248 (42 U.S.C. 5841, 5842, 5846), unless otherwise noted.

Section 50.7 also issued under Pub. L. 95–601, Sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Sections 50.57(d), 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2071, 2073 (42 U.S.C. 2133, 2239). Sec. 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Secs. 50.80–50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Secs. 50.100–50.102 issued under sec. 188, 68 Stat. 955 (42 U.S.C. 2236).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273), §§ 50.10 (a), (b), and (c), 50.44, 50.46, 50.48, 50.54, and 50.80(a) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§50.10 (b) and (c) and 50.54 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§50.55(e), 50.59(b), 50.70, 50.71, 50.72, 50.73 and 50.78 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. Section 50.4 is revised to read as follows:

§ 50.4 Written communications.

(a) *Address requirements.* The signed original of all correspondence, reports, applications, and other written communications from the applicant or licensee to the Nuclear Regulatory Commission concerning the regulations in this part or individual license conditions must be addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555.

(b) *Distribution requirements.* Copies of all correspondence, reports, and other written communications concerning the regulations in this part or individual license conditions must be submitted to the Nuclear Regulatory Commission at the locations and in the quantities set forth below (addresses for the NRC Regional Offices are listed in Appendix D of Part 20 of this chapter).

(1) *Applications for amendment of permits and licenses; reports; and other communications.* All written communications (including responses to: generic letters, bulletins, information notices, inspection reports, and

miscellaneous requests for additional information), that are required of holders of operating licenses or construction permits issued pursuant to this part, must be submitted as follows, except as otherwise specified in paragraphs (b)(2) through (b)(7) of this section: the signed original to the Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, one copy to the appropriate Regional Office, and one copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility.

2. *Applications for permits and licenses, and amendments to applications.* Applications for construction permits, applications for operating licenses and amendments to either type of application must be submitted as follows, except as otherwise specified in paragraphs (b)(3) through (b)(7) of this section.

(i) Applications for licenses for facilities described in § 50.21 (a) and (c) and amendments to these applications: The signed original must be sent to the Nuclear Regulatory Commission. Document Control Desk, Washington, DC 20555 and one copy to the appropriate Regional Office.

(ii) Applications for permits and licenses for facilities described in § 50.21(b) or § 50.22, and amendments to these applications: the signed original and 37 copies must be sent to the Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, one copy to the appropriate Regional Office, and one copy to the appropriate NRC Resident Inspector, if one has been assigned to the site of the facility.

(3) *Acceptance review application.* Written communications required for an application for determination of suitability for docketing pursuant to § 50.30(a)(6) must be submitted as follows: the signed original and 13 copies to the Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555 and one copy to the appropriate Regional Office.

(4) *Security plan and related submittals.* Written communications, as defined in paragraphs (b)(4)(i) through (iv) of this section must be submitted as follows: The signed original and three copies to the Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, and two copies to the appropriate Regional Office;

(i) Physical security plan pursuant to § 50.34;

(ii) Safeguards contingency plan pursuant to § 50.34;

(iii) Change to security plan, guard training and qualification plan, or safeguards contingency plan made without prior Commission approval pursuant to § 50.54(p);

(iv) Application for amendment of physical security plan, guard training and qualification plan, or safeguards contingency plan pursuant to § 50.90.

(5) *Emergency plan and related submittals.* Written communications as defined in paragraphs (b)(5)(i) through (iii) in this section, must be submitted as follows: the signed original to the Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, two copies to the appropriate Regional Office, and one copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility.

(i) Emergency plan pursuant to § 50.34;

(ii) Change to an emergency plan pursuant to § 50.54(q);

(iii) Emergency implementing procedures pursuant to Appendix E.V of this part.

(6) *Updated FSAR.* An updated Final Safety Analysis Report (FSAR) or replacement pages, pursuant to § 50.71(e) must be submitted as follows: the signed original and 10 copies to the Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, one copy to the appropriate Regional Office, and one copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility.

(7) *Quality assurance related submittals.* (i) A change to the Safety Analysis Report quality assurance program description pursuant to § 50.54(a)(3) or § 50.55(f)(3), or a change to a licensee's NRC-accepted quality assurance topical report pursuant to § 50.54(a)(3) or § 50.55(f)(3), must be submitted as follows: the signed original to the Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, one copy to the appropriate Regional Office, and one copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility.

(ii) A change to an NRC-accepted quality assurance topical report from nonlicensees (i.e., architect/engineers, NSSS suppliers, fuel suppliers, constructors, etc.) must be submitted as follows: one signed original to the Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555.

(c) *Form of communications.* All copies submitted to meet the requirements set forth in paragraph (b) of this section must be typewritten, printed or otherwise reproduced in permanent form on unglazed paper. Exceptions to these requirements may be granted for the submittal of micrographic, photographic, or electronic forms. Prior to making any submittal in other than paper form, the applicant or licensee must contact the Division of Technical Information and Document Control, Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492–8585, to obtain specifications, copy requirements, and prior approval.

(d) *Delivery of communications.* Written communications may be delivered to the Document Control Desk at 7920 Norfolk Avenue, Bethesda, MD, between the hours of 8:15 a.m. and 4:00 p.m. Eastern Time. If a submittal due date falls on a Saturday, Sunday, or Federal holiday, the next Federal working day becomes the official due date.

(e) *Regulation governing submission.* Licensees and applicants submitting correspondence, reports, and other written communications pursuant to the regulations of this part are requested but not required to cite whenever practical, in the upper right corner of the first page of the submittal, the specific regulation or other basis, requiring submission.

(f) *Conflicting requirements.* The communications requirements contained in this section and §§ 50.12, 50.30, 50.36, 50.36a. 50.44, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.62, 50.71, 50.73, 50.82, 50.90, and 50.91 supersede and replace all existing requirements in any license conditions or technical specifications in effect on January 5, 1987. Exceptions to these requirements must be approved by the Division of Technical Information and Document Control, Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 492–8585.

3. In § 50.30, paragraphs (a) and (b) are revised to read as follows and paragraph (c) is removed.

§ 50.30 Filing of application for licenses; oath or affirmation.

(a) *Serving of applications.* (1) Each filing of an application for a license to construct and/or operate a production or utilization facility (including amendments to the applications) must be submitted to the U.S. Nuclear Regulatory Commission in accordance with § 50.4.

(2) An additional 10 copies of the general information and 30 copies of the safety analysis report, or part thereof or amendment thereto, must be retained by the applicant for distribution in accordance with the written instructions of the Director, Office of Nuclear Reactor Regulation, or the Director, Office of Nuclear Material Safety and Safeguards, as appropriate.

(3) Each applicant shall, upon notification by the Atomic Safety and Licensing Board appointed to conduct the public hearing required by the Atomic Energy Act for the issuance of a construction permit, update the application and serve the updated copies of the application or parts of it, eliminating all superseded information, together with an index of the updated application, as directed by the Atomic Safety and Licensing Board. In addition, at that time the applicant shall serve a copy of the updated application on the Atomic Safety and Licensing Appeal Panel. Any subsequent amendment to the application must be served on those served copies of the application and must be submitted to the U.S. Nuclear Regulatory Commission as specified in § 50.4.

(4) The applicant must make a copy of the updated application available at the public hearing for the use of any other parties to the proceeding, and shall certify that the updated copies of the application contain the current contents of the application submitted in accordance with the requirements of this part.

(5) At the time of filing an application, the Commission will establish a Local Public Document Room near the site of the proposed facility, for the use of the public, where a copy of the application, subsequent amendments, and other records pertinent to the facility will be available for public inspection and copying.

(6) The serving of copies required by this section must not occur until the application has been docketed pursuant to § 2.101(a) of this chapter. Copies must be submitted to the Commission, as specified in § 50.4, to enable the Director, Office of Nuclear Reactor Regulation, or the Director, Office of Nuclear Material Safety and Safeguards, as appropriate, to determine whether the application is sufficiently complete to permit docketing.

(b) *Oath or affirmation.* Each application for a license, including whenever appropriate a construction permit, or amendment of it, and each amendment of each application must be executed in a signed original by the applicant or duly authorized officer thereof under oath or affirmation.

* * * * *

4. In § 50.36, paragraph (c)(5) is revised to read as follows:

§ 50.36 Technical specifications.

* * * * *

(c) * * *

(5) *Administrative controls.* Administrative controls are the provisions relating to organization and management, procedures, recordkeeping, review and audit, and reporting necessary to assure operation of the facility in a safe manner. Each licensee shall submit any reports to the Commission pursuant to approved technical specifications as specified in § 50.4.

* * * * *

5. In § 50.36a, paragraph (a)(2) is revised to read as follows:

§ 50.36a Technical specifications on effluents from nuclear power reactors.

(a) * * *

(2) Each licensee shall submit a report to the Commission within 60 days after January 1 and July 1 of each year, that specifies the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous effluents during the previous six months of operation, including any other information as may be required by the Commission to estimate maximum potential annual radiation doses to the public resulting from effluent releases. The report must be submitted as specified in § 50.4. If quantities of radioactive materials released during the reporting period are significantly above design objectives, the report must cover this specifically. On the basis of these reports and any additional information the Commission may obtain from the licensee or others, the Commission may require the licensee to take action as the Commission deems appropriate.

* * * * *

6. In § 50.44, paragraphs (c)(3)(vi)(A) and (c)(3)(vii)(A) are revised to read as follows:

§ 50.44 Standards for combustible gas control system in light water cooled power reactors.

* * * * *

(c) * * *

(3) * * *

(vi)(A) Each applicant for or holder of an operating license for a boiling light-water nulcear power reactor with a Mark III type of containment or for a pressurized light-water nuclear power reactor with an ice condenser type of containment issued a construction permit before March 28, 1979, shall submit an analysis to the Commission as specified in § 50.4.

* * * * *

(vii)(A) By June 25, 1985, each applicant for or holder of an operating license subject to the requirements of paragraphs(c)(3) (iv), (v) and (vi) of this section shall develop and submit to the Commission a proposed schedule for meeting these requirements. The schedule may be developed using integrated scheduling systems previously approved for the facility by the NRC.

* * * * *

7. In § 50.49, paragraph (h) and the introductory text of paragraph (i) are revised to read as follows:

§ 50.49 Environmental qualification of electric equipment important to safety for nuclear power plants.

* * * * *

(h) Each license shall notify the Commission as specified in § 50.4 of any significant equipment qualification problem that may require extension of the completion date provided in accordance with paragraph (g) of this section within 60 days of its discovery.

(i) Applicants for operating licenses granted after February 22, 1983, but prior to November 30, 1986, shall perform an analysis to ensure that the plant can be safely operated pending completion of equipment qualification required by this section. This analysis must be submitted, as specified in § 50.4, for consideration prior to the granting of an operating license and must include, where appropriate, consideration of:

* * * * *

8. In § 50.54, the introductory text of paragraphs (a)(3), (a)(3) (i), (f), and the introductory language of (p), (q), and (w)(4) are revised to read as follows:

§ 50.54 Conditions of licenses.

* * * * *

(a) * * *

(3) After March 11, 1983, each licensee described in paragraph (a)(1) of this section may make a change to a previously accepted quality assurance program description included or referenced in the Safety Analysis Report, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to the NRC at least annually in accordance with the requirements of § 50.71. Changed to the quality assurance program description that do reduce the commitments must be submitted to NRC and receive NRC approval prior to implementation, as follows:

(i) Changes made to the Safety Analysis Report must be submitted, as specified in § 50.4. Changes made to NRC-accepted quality assurance topical report descriptions must be submitted, as specified in § 50.4.

* * * * *

(f) The licensee shall at any time before expiration of the license, upon request of the Commission, submit, as

specified in § 50.4, written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked.

* * * * *

(p) The licensee shall prepare and maintain safeguards contingency plan procedures in accordance with Appendix C of Part 73 of this chapter for effecting the actions and decisions contained in the Responsibility Matrix of the safeguards contingency plan. The licensee may make no change which would decrease the effectiveness of a security plan prepared pursuant to § 50.34(c) or Part 73 of this chapter, or of the first four categories of information (Background, Generic Planning Base, Licensee Planning Base, Responsibility Matrix) contained in a licensee safeguards contingency plan prepared pursuant to § 50.34(d) or Part 73 of this chapter without prior approval of the Commission. A licensee desiring to make such a change shall submit an application for an amendment to a license pursuant to § 50.90. The licensee may make changes to the security plan or to the safeguards contingency plan without prior Commission approval if the changes do not decrease the safeguards effectiveness of the plan. The licensee shall maintain records of changes to the plans made without prior Commission approval for a period of two years from the date of the change, and shall submit, as specified in § 50.4, a report containing a description of each change within two months after the change is made. Prior to the safeguards contingency plan being put into effect, the licensee shall have:

* * * * *

(q) A licensee authorized to possess and/or operate a nuclear power reactor shall follow and maintain in effect emergency plans which meet the standards in § 50.47(b) and the requirements in Appendix E to this part. A licensee authorized to possess and/or operate a research reactor or a fuel facility shall follow and maintain in effect emergency plans which meet the requirements in Appendix E of this part. The nuclear power reactor licensee may make changes to these plans without Commission approval only if the changes do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the standards of § 50.47(b) and the requirements of Appendix E of this part. The research reactor licensee and/or the fuel facility licensee may make changes to these plans without Commission approval, only if these changes do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the requirements of Appendix E of this part. Proposed changes that decrease the effectiveness of the approved emergency plans shall not be implemented without application to and approval by the Commission. The licensee shall submit, as specified in § 50.4, a report of each proposed change for approval. If a change is made without approval, the licensee shall submit, as specified in § 50.4, a report of each change within 30 days after the change is made.

* * * * *

(w) * * *

(4) The licensee shall report, as specified in § 50.4, on April 1 of each year, the present levels of insurance or financial protection it maintains and the sources of the insurance or protection.

* * * * *

9. In § 50.55, paragraphs (e)(3), the introductory text of (f)(3), and (f)(3)(i) are revised to read as follows:

§ 50.55 Conditions of construction permits.

* * * * *

(e) * * *

(3)(i) The holder of a construction permit shall also submit, as specified in § 50.4, a written report on a reportable deficiency within 30 days.

(ii) The report must include a description of the deficiency, an analysis of the safety implications and the corrective action taken, and sufficient information to permit analysis and evaluation of the deficiency and of the corrective action. If sufficient information is not available for a definitive report to be submitted within 30 days, an interim report containing all available information shall be filed, as specified in § 50.4, together with a statement that indicates when a complete report will be filed.

* * * * *

(f) * * *

(3) After March 11, 1983, each construction permit holder described in paragraph (f)(1) of this section may make a change to a previously accepted quality assurance program description included or referenced in the Safety Analysis Report, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the quality assurance program description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the quality assurance program description that do reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(i) Changes to the Safety Analysis Report must be submitted for review as specified in § 50.4. Changes made to NRC-accepted quality assurance topical report descriptions must be submitted as specified in § 50.4.

* * * * *

10. In § 50.55a, paragraphs (g)(5)(ii) and (g)(5)(iii) are revised to read as follows:

§ 50.55a Codes and standards.

* * * * *

(g) *Inservice inspection requirements.*

* * * * *

(5) * * *

(ii) If a revised inservice inspection program for a facility conflicts with the technical specification for the facility, the licensee shall apply to the Commission for amendment of the technical specifications to conform the technical specification to the revised program. The licensee shall submit this application, as specified in § 50.4, at least six months before the start of the period during which the provisions become applicable, as determined by paragraph (g)(4) of this section.

(iii) If the licensee has determined that conformance with certain code requirements is impractical for its facility, the licensee shall notify the Commission and submit, as specified in § 50.4, information to support the determinations.

* * * * *

11. In § 50.59, paragraph (b) is revised to read as follows:

§ 50.59 Changes, tests, and experiments.

* * * * *

(b)(1) The licensee shall maintain records of changes in the facility and of changes in procedures made pursuant to this section, to the extent that these changes constitute changes in the facility as described in the safety analysis report or to the extent that they constitute changes in procedures as described in the safety analysis report. The licensee shall also maintain records of tests and experiments carried out pursuant to paragraph (a) of this section. These records must include a written safety evaluation which provides the bases for the determination that the change, test, or experiment does not involve an unreviewed safety question.

(2) The licensee shall submit, as specified in § 50.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the safety evaluation of each. The report must be submitted annually or at such shorter intervals as may be specified in the license.

(3) The records of changes in the facility shall be maintained until the date of termination of the license, and records of changes in procedures and records of tests and experiments shall be maintained for a period of five years.

* * * * *

12. In § 50.62, paragraphs (c)(6) and (d) are revised to read as follows:

§ 50.62 Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants.

* * * * *

(c) * * *

(6) Information sufficient to demonstrate to the Commission the adequacy of items in paragraphs (c)(1) through (c)(5) of this section shall be submitted to the Commission as specified in § 50.4.

(d) *Implementation.* By 180 days after the issuance of the QA guidance for non-safety related components, each licensee shall develop and submit to the Commission, as specified in § 50.4, a proposed schedule for meeting the requirements of paragraphs (c)(1) through (c)(5) of this section. Each shall include an explanation of the schedule along with a justification if the schedule calls for final implementation later than the second refueling outage after July 26, 1984, or the date of issuance of a license authorizing operation above 5 percent of full power. A final schedule shall then be mutually agreed upon by the Commission and licensee.

13. In § 50.71, paragraphs (a), (b) and (e)(1) are revised to read as follows:

§ 50.71 Maintenance of records, making of reports.

(a) Each licensee and each holder of a construction permit shall maintain all records and make all reports, in connection with the activity, as may be required by the conditions of the license or permit or by the rules, regulations, and orders of the Commission in effectuating the purposes of the Act, including section 105 of the Act. Reports must be submitted in accordance with § 50.4.

(b) With respect to any production or utilization facility of a type described in § 50.21(b) or 50.22, or a testing facility, each licensee and each holder of a construction permit shall submit its annual financial report, including the certified financial statements, to the Commission, as specified in § 50.4, upon issuance of the report.

* * * * *

(e) * * *

(1) The licensee shall submit revisions containing updated information to the Commission, as specified in § 50.4, on a replacement-page basis that is accompanied by a list which identifies the current pages of the FSAR following page replacement.

* * * * *

14. In § 50.73, paragraphs (c) and (d) are revised to read as follows:

§ 50.73 Licensee event report system.

(c) *Supplemental information.* The Commission may require the licensee to submit specific additional information beyond that required by paragraph (b) of this section if the Commission finds that supplemental material is necessary for complete understanding of an unusually complex or significant event. These requests for supplemental information will be made in writing and the licensee shall submit, as specified in § 50.4, the requested information as a supplement to the initial LER.

(d) *Submission of reports.* Licensee Event Reports must be prepared on Form NRC 366 and submitted within 30 days of discovery of a reportable event or situation to the U.S. Nuclear Regulatory Commission, as specified in § 50.4.

* * * * *

15. In § 50.82, paragraph (a) is revised to read as follows:

§ 50.82 Application for termination of licenses.

(a) Any licensee may submit an application to the Commission, as specified in § 50.4, for authority to surrender a license voluntarily and to dismantle the facility and dispose of its component parts. The Commission may require information, including information as to proposed procedures for the disposal of radioactive material, decontamination of the site, and other procedures, to provide reasonable assurance that the dismantling of the facility and disposal of the component parts will be performed in accordance with the regulations in this chapter and will not be inimical to the common defense and security or to the health and safety of the public.

* * * * *

16. Section § 50.90 is revised to read as follows:

§ 50.90 Application for amendment of license or construction permit.

Whenever a holder of a license or construction permit desires to amend the license or permit, application for an amendment must be filed with the Commission, as specified in § 50.4, fully describing the changes desired, and following as far as applicable, the form prescribed for original applications.

17. In § 50.91 paragraph (a)(1) is revised to read as follows:

§ 50.91 Notice for public comment; State consultation.

* * * * *

(a) *Notice for public comment.* (1) At the time a licensee requests an amendment, it must provide to the Commission, in accordance with the distribution requirements specified in § 50.4, its analysis about the issue of no significant hazards consideration using the standards in § 50.92.

* * * * *

18. In Appendix E, section V is revised to read as follows:

Appendix E—Emergency Planning and Preparedness for Production and Utilization Facilities

* * * * *

V. Implementing Procedures

No less than 180 days prior to the scheduled issuance of an operating license for a nuclear power reactor or a license to possess nuclear material the applicant's detailed implementing procedures for its emergency plan shall be submitted to the Commission as specified in § 50.4. Licensees who are authorized to operate a nuclear power facility shall submit any changes to the emergency plan or procedures to the Commission, as specified in § 50.4, within 30 days of such changes.

19. In Appendix G, section V, paragraph E is revised to read as follows:

Appendix G—Fracture Toughness Requirements

* * * * *

V. Inservice Requirements—Reactor Vessel Beltline Material

* * * * *

E. The proposed programs for satisfying the requirements of sections V.C. and V.D. of this appendix must be submitted, as specified in § 50.4, for review and approval on an individual case basis at least three years prior to the date when the predicted fracture toughness levels will no longer satisfy the requirements of section V.B. of this appendix.

20. In Appendix H, section II, paragraph B.3 and section III, paragraph A are revised to read as follows:

Appendix H—Reactor Vessel Material Surveillance Program Requirements

* * * * *

II. Surveillance Program Criteria

B. * * *

3. A proposed withdrawal schedule must be submitted with a technical justification as specified in § 50.4. The proposed schedule must be approved prior to implementation.

* * * * *

III. Report of Test Results

A. Each capsule withdrawal and the test results must be the subject of a summary technical report to be submitted, as specified in § 50.4, within one year after capsule withdrawal unless an extension is granted by the Director, Office of Nuclear Reactor Regulation.

* * * * *

21. In Appendix I, section IV, paragraph A.3. and paragraph A.3.a of the "Concluding Statement on Position of the Regulatory Staff (Docket–RM–50–2)" are revised to read as follows:

Appendix I—Numerical Guides for Design Objectives and Limiting Conditions for Operation To Meet the Criterion "As Low as is Reasonably Achievable" for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents

* * * * *

Sec. IV. *Guides on technical specifications for limiting conditions for operation for light-water-cooled nuclear power reactors licensed under 10 CFR Part 50.*

* * * * *

A. * * *

3. Report these actions as specified in § 50.4, within 30 days from the end of the quarter during which the release occurred.

* * * * *

Concluding Statement on Position of the Regulatory Staff (Docket–RM–50–2)

A. * * *

3. * * *

a. The applicant submits, as specified in § 50.4, an evaluation of the potential for effects from long-term buildup on the environment in the vicinity of the site of radioactive material, with a radioactive half-life greater than one year, to be released; and

* * * * *

22. In Appendix J, section V, paragraph B.1. is revised to read as follows:

Appendix J—Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors

* * * * *

V. Inspection and Reporting of Tests

* * * * *

B. *Report of test results.* 1. The preoperational and periodic tests must be the subject of a summary technical report submitted to the Commission, as specified in § 50.4, approximately three months after the conduct of each test. The report must be titled "Reactor Containment Building Integrated Leak Rate Test."

* * * * *

23. In Appendix K, section II, paragraph 1.c. is revised to read as follows:

Appendix K—ECCS Evaluation Models

* * * * *

II. Required Documentation

1. * * *

c. The licensee shall submit to the Commission, as specified in § 50.4, a complete listing of each computer program, in the same form as used in the evaluation model.

* * * * *

24. In Appendix M, Paragraph 2 is revised to read as follows:

Appendix M—Standardization of Design; Manufacture of Nuclear Power Reactors; Construction and Operation of Nuclear Power Reactors Manufactured Pursuant to Commission License

* * * * *

2. An application for a manufacturing license pursuant to this Appendix M must be submitted, as specified in § 50.4, and meet all the requirements of §§ 50.34(a) (1)–(9) and 50.34a (a) and (b), except that the preliminary safety analysis report shall be designated as a "design report" and any required information or analyses relating to site matters shall be predicated on postulated site parameters which must be specified in the application. The application must also include information pertaining to design features of the proposed reactor(s) that affect plans for coping with emergencies in the operation of the reactor(s).

* * * * *

25. In Appendix N, paragraph 2. is revised to read as follows:

Appendix N—Standardization of Nuclear Power Plant Designs: Licenses to Construct and Operate Nuclear Power Reactors of Duplicate Design at Multiple Sites

* * * * *

2. Applications for construction permits submitted pursuant to this Appendix must include the information required by §§ 50.33, 50.33a, 50.34(a) and 50.34a (a) and (b) and be submitted as specified in § 50.4. The applicant shall also submit the information required by § 51.50 of this chapter. * * *

* * * * *

26. In Appendix O, paragraph 2 is revised to read as follows:

Appendix O—Standardization of Design; Staff Review of Standard Designs

* * * * *

2. The submittal for review of the standard design must be made in the same manner and in the same number of copies as provided in §§ 50.4 and 50.30 for license applications.

* * * * *

27. In Appendix Q, paragraph 2 is revised to read as follows:

Appendix Q—Pre-Application Early Review of Site Suitability Issues

* * * * *

2. The submittal for early review of site suitability issue(s) must be made in the same manner and in the same number of copies as provided in §§ 50.4 and 50.30 for license applications. The submittal must include sufficient information concerning a range of postulated facility design and operation parameters to enable the Staff to perform the requested review of site suitability issues. The submittal must contain suggested conclusions on the issues of site suitability submitted for review and must be accompanied by a statement of the bases or the reasons for those conclusions. The submittal must also list, to the extent possible, any long-range objectives for ultimate development of the site, state whether any site selection process was used in preparing the submittal, describe any site selection process used, and explain what consideration, if any, was given to alternative sites.

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

28. The authority citation for Part 51 continues to read as follows:

Authority: Sec. 161, 68 Stat. 948, as amended (42 U.S.C. 2201); secs. 201, as amended, 202, 88 Stat. 1242, as amended, 1244 (42 U.S.C. 5841, 5842).

Subpart A also issued under National Environmental Policy Act of 1969, secs. 102, 104, 105, 83 Stat. 853–854, as amended (42 U.S.C. 4332, 4334, 4335); and Pub. L. 95–604, Title II, 92 Stat. 3303–3041. Section 51.22 also issued under sec. 274, 73 Stat. 688, as amended by 92 Stat. 3036–3038 (42 U.S.C. 2021).

29. Section 51.54 is revised to read as follows:

§ 51.54 Environmental report—manufacturing license.

Each applicant for a license to manufacture a nuclear power reactor or, for an amendment to a license to manufacture seeking approval of the final design of the nuclear power reactor, pursuant to Appendix M of Part 50 of this chapter, shall submit with its application, as specified in § 50.4, a separate document, entitled "Applicant's Environmental Report—Manufacturing License," or "Supplement to Applicant's Environmental Report—Manufacturing License." The environmental report shall address the environmental matters specified in Appendix M of Part 50 of this chapter, and shall contain the information specified in § 51.45, as appropriate.

30. Section 51.55 is revised to read as follows:

§ 51.55 Environmental report—number of copies; distribution.

(a) Each applicant for a license to construct and operate a production or utilization facility covered by paragraph (b)(1), (b)(2), (b)(3) or (b)(4) of § 51.20 or for a license amendment covered by paragraph (b)(5) of § 51.20 shall submit

to the Commission an environmental report, or any supplement to an environmental report in the manner specified in § 50.4. The applicant shall retain an additional 109 copies of the environmental report or any supplement to the environmental report for distribution to parties and Boards in the NRC proceeding, Federal, State, and local officials and any affected Indian tribes, in accordance with written instructions issued by the Director of Nuclear Reactor Regulation or the Director of Nuclear Material Safety and Safeguards, as appropriate.

(b) Each applicant for a license to manufacture a nuclear power reactor, or for an amendment to a license to manufacture seeking approval of the final design of the nuclear power reactor, pursuant to Appendix M of Part 50 of this chapter shall submit to the Commission an environmental report or any supplement to an environmental report in the manner specified in § 50.4. The applicant shall retain an additional 109 copies of the environmental report or any supplement to the environmental report for distribution to parties and Boards in the NRC proceeding, Federal, State, and local officials and any affected Indian tribes, in accordance with written instructions issued by the Director of Nuclear Reactor Regulation.

* * * * *

Dated at Bethesda, Maryland, this 31st day of October 1986.

For the Nuclear Regulatory Commission.

Victor Stello, Jr.,

Acting Executive Director for Operations.

[FR Doc. 86-25132 Filed 11-5-86; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket Number 86-ANE-42; Amdt. 39-5455]

Airworthiness Directives; Pratt & Whitney (PW) JT9D-7R4D, D1, E, and E1 Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) which requires the second stage high pressure turbine rotor (HPTR) four knife edge airseal to be replaced with or reworked to a HPTR three knife edge airseal on PW JT9D-7R4D, D1, E, and E1 turbofan engines. A modification to the turbine cooling air system which reduces the number of metering bolts in the first stage turbine rotor assembly and increases the airflow of the HPT cooling airduct is required. The AD is needed to prevent uncontained failure of the second stage HPTR airseal which could result in extensive engine and aircraft damage.

DATES: Effective December 8, 1986. Compliance Schedule—As prescribed in the body of the AD. Comments for inclusion in the docket must be received on or before January 5, 1987. Incorporation by Reference—Approved by the Director of the Federal Register as of December 8, 1986.

ADDRESSES: Comments on the amendment may be mailed in duplicate to: Federal Aviation Administration, New England Region, Office of the Regional Counsel, Attention: Rules Docket Number 86-ANE-42, 12 New England Executive Park, Burlington, Massachusetts 01803
or delivered in duplicate to Room 311 at the above address.

Comments delivered must be marked: "Docket Number 86-ANE-42".

Comments may be inspected at the New England Region, Office of the Regional Counsel, Room 311, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

The applicable Alert Service Bulletin (ASB) may be obtained from Pratt & Whitney, Commercial Products Division, 400 Main Street, East Hartford, Connecticut 06108. A copy of the ASB is contained in Rules Docket Number 86-ANE-42, in the Office of the Regional Counsel, Federal Aviation Administration, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803.

FOR FURTHER INFORMATION CONTACT: Diane Kirk, Engine Certification Branch, ANE-142, Engine Certification Office, Aircraft Certification Division, Federal Aviation Administration, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803, telephone (617) 273-7082.

SUPPLEMENTARY INFORMATION: The FAA has determined that fatigue cracks, attributed to high cycle fatigue (HCF), can originate on the tip of the fourth knife edge of the second stage HPTR airseal, and may propagate to fracture, which could result in an uncontained second stage HPTR airseal failure on JT9D-7R4D, D1, E, and E1 turbofan engines. A total of 11 fracture/crack events on airseal P/N 5001413-01 have occurred in a total population of 289 airseals. Four events have been in-service failures; two of these events were uncontained. Seven events, which had fourth knife edge HCF cracking in the airseal, were found by inspection in accordance with PW Service Bulletin (SB) JT9D-7R4-72-245. Although the mechanism of failure is not established, analysis indicates the most probable cause of the HPTR airseal rear knife edge HCF cracking is attributed to an aeroelastic instability.

Since this condition is likely to exist or develop on other engines of the same type design, an AD is being issued which requires replacement of second stage HPTR airseals, P/N 5001413-01 or 798916, with RPTR airseal, P/N 803673 or 803674 respectively, or rework of P/N 5001413-01 or 798916 in accordance with PW ASB JT9D-7R4-72-318, dated October 25, 1986, on JT9D-7R4D, D1, E, and E1 turbofan engines.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable.

Although this action is in the form of a final rule which involves requirements affecting flight safety and, thus, was not preceded by notice and public procedure, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above.

All communications received on or before the closing date for comments will be considered by the Director. This rule may be amended in light of comments received. Comments that provide a factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effectiveness of the AD and determining whether additional rulemaking is needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available for examination in the Rules Docket at the address given above by interested persons. A report summarizing each FAA-public contact, concerned with the substance of this AD, will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 86-ANE-42". The

postcard will be date/time stamped and returned to the commenter.

Conclusion

The FAA has determined that this regulation is an emergency regulation that is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, when filed, may be obtained by contacting the person identified under the caption "**FOR FURTHER INFORMATION CONTACT**".

List of Subjects in 14 CFR Part 39

Engines, Air transportation, Aircraft, Aviation safety, Incorporation by Reference.

Adoption of the Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration (FAA) amends Part 39 of the Federal Aviation Regulations (FAR) as follows:

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421, and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.89.

2. By adding to § 39.13 the following new airworthiness directive (AD):

Pratt & Whitney: Applies to Pratt & Whitney (PW) JT9D–7R4D, D1, E, and E1 turbofan engines.

Compliance is required as indicated, unless already accomplished.

To prevent failure of the second stage high pressure turbine rotor (HPTR) airseal that can cause an uncontained engine failure, accomplish the following:

(a) Remove from service, HPTR airseal Part Number (P/N) 5001413–01 or 798916 and replace with HPTR airseal P/N 803673 or 803674, respectively, or rework HPTR airseal P/N 5001413–01 or 798916 in accordance with PW Alert Service Bulletin (ASB) JT9D–7R4–72/318, dated October 25, 1986, or FAA approved equivalent, per the following schedule:

(1) JT9D–7R4d1 and JT9D–7R4E1 series engines:

(i) Within 400 cycles in service (CIS) after the effective date of this AD, for HPTR airseals with greater than 800 CIS since new on the effective date of this AD.

(ii) Within 400 CIS after the effective date of this AD, or 800 CIS since new, whichever occurs later, for HPTR airseals with 800 CIS since new or less on the effective date of this AD.

(2) JT9D–7R4D and JT9D–JT4E series engines:

(i) Within 900 CIS after the effective date of this AD, for HPTR airseals with greater than 1,600 CIS since new on the effective date of this AD.

(ii) Within 900 CIS after the effective date of this AD, or 1,600 CIS since new, whichever occurs later, for HPTR airseals with 1,600 CIS since new or less on the effective date of this AD.

(b) Remove first stage high pressure turbine cooling (HPTC) airduct assembly, P/N 796123, 796975, or 796746, and replace with HPTC airduct assembly, P/N 804146, 804145, or 804148, respectively, or rework HPTC airduct assembly, P/N 796123, 795975, or 796746, in accordance with PW ASB JT9D–7R4–72–318, dated October 25, 1986, or FAA approved equivalent, concurrent with accomplishing paragraph (a) above.

(c) Modify the first stage turbine rotor assembly, P/N 792041, 792931, 795121, or 801821, by removing two units each of bolt, P/N 746130; washer, P/N 151178; and nut, P/N 341859; and redistributing the remaining units in accordance with PW ASB JT9D–7R4–72–318, dated October 25, 1986, or FAA approved equivalent, concurrent with accomplishing paragraph (a) above.

Aircraft may be ferried in accordance with the provisions of FAR 21.197 and 21.199 to a base where the AD can be accomplished.

Upon request, an equivalent means of compliance with the requirements of this AD may be approved by the Manager, Engine Certification Office, Aircraft Certification Division, Federal Aviation Administration, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803.

Upon submission of substantiating data by an owner or operator through an FAA maintenance inspector, the Manager, Engine Certification Office, may adjust the compliance times specified in this AD.

Pratt & Whitney ASB JT9D–7R4–72–318, dated October 25, 1986, identified and described in this document, is incorporated herein and made a part thereof pursuant to 5 U.S.C. 552(a)(1). All persons affected by this directive who have not already received this document from the manufacturer may obtain copies upon request to Pratt & Whitney, Commercial Products Division, 400 Main Street, East Hartford, Connecticut 06108. This document also may be examined at the Office of the Regional Counsel, Federal Aviation Administration, 12 New England Executive Park, Burlington, Massachusetts 01803, Room 311, Rules Docket Number 86–ANE–42, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

This amendment becomes effective on December 8, 1986.

Issued in Burlington, Massachusetts, on October 24, 1986.

Jack A. Sain,

Acting Director, New England Region.

[FR Doc. 86–25045 Filed 11–5–86; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket Nos. 81N–204F and 76N–0175]

Milk, Lowfat Milk, and Skim Milk; Notice of Order and Partial Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Notice of order and partial confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Center for Food Safety and Applied Nutrition's motion for partial summary judgment on two of the four issues in the hearing concerning milk, lowfat milk, and skim milk is granted, and that the stays on those portions of the standards of identity for these products that concern the addition of vitamins and minerals and the use of stabilizers and emulsifiers are terminated. The agency is, therefore, confirming the effective date for compliance with those portions of the standards of identity as published in the Federal Register of October 10, 1973 (38 FR 27924).

DATE: Effective January 5, 1987 for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date.

FOR FURTHER INFORMATION CONTACT: Karen L. Carson, Center for Food Safety and Applied Nutrition (HFF–215), Food and Drug Administration, 200 C St. NW., Washington, DC 20204, 202–485–0110.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 6, 1983 (48 FR 45545), FDA published a notice of hearing on objections to the standards of identity for milk, lowfat milk, and skim milk. The hearing was granted on objections to (1) the portions of the standards of identity for milk, lowfat milk, and skim milk that limited the addition of vitamins and minerals to these products, (2) the portions of the standards of identity for lowfat milk and skim milk that restricted the use of stabilizers and emulsifiers in lowfat milk and skim milk, (3) the appropriateness

of the term "with added milk solids not fat" for lowfat and skim milks made to contain at least 10 percent milk-derived nonfat solids, and (4) the reasonableness of the decision to prohibit use of the terms "protein fortified" and "fortified with protein." The latter two issues, involving labeling of lowfat milk and skim milk made to contain not less than 10 percent milk-derived nonfat solids, have not been resolved and are, therefore, not included in this action.

Background

In the **Federal Register** of October 10, 1973 (38 FR 27924), FDA established standards of identity for milk, lowfat milk, and skim milk (21 CFR 131.110, 131.135, and 131.143; formerly 21 CFR 18.2, 18.10, and 18.20, respectively). These standards limited the vitamins that can be added to these products to vitamins A and D only and did not provide for the addition of minerals. The Milk Industry Foundation filed a timely objection and requested a hearing on the failure of the standards to provide for the addition of other vitamins and minerals.

The lowfat milk and skim milk standards promulgated in 1973 allowed the use of stabilizers and emulsifiers in these products only when milk-derived nonfat solids were added to the products and limited the quantity to not more than 2 percent by weight of the milk-derived nonfat solids added. The Celanese Corp. and the Detroit Milk Dealers, Inc., filed timely objections and requests for hearing on this restricted use of stabilizers and emulsifiers in lowfat milk and skim milk. (Other persons filed objections to the restriction but did not request a hearing.)

As a result of these objections and requests for a hearing, the effective dates of those portions of §§ 131.110(b), 131.135(b), and 131.143(b) that limit the addition of vitamins and minerals to these products to vitamins A and D and those portions of §§ 131.135(c)(3) and 131.143(c)(3) that limit the use of stabilizers and emulsifiers were stayed (39 FR 42351; December 5, 1974), pending the outcome of a hearing. In addition, stays of effective date were imposed on the following related provisions of the standards: (1) Provisions dealing with the use of carriers for vitamins A and D (§§ 131.110(c)(1), 131.135(c)(1), and 131.143(c)(1)); and (2) provisions dealing with labeling when vitamins are added to the foods (§§ 131.110(e)(1)(i), 131.135(e)(1)(ii), and 131.143(e)(1)(i)).

In the **Federal Register** of October 26, 1976 (41 FR 46873), FDA sought to resolve the stabilizer and emulsifier use issue with a proposal to permit the use of stabilizers and emulsifiers in lowfat milk and skim milk without the restrictions referred to above. FDA withdrew this proposal, however, because the agency decided that, based upon its review of the comments, this proposal was not appropriate.

A notice granting a hearing on these two issues, as well as on the labeling issues, was published in the **Federal Register** of October 6, 1983 (48 FR 45545). The specific issues, as stated in the notice of hearing, were:

1. Is a standard of identity for milk, lowfat milk, or skim milk that excludes the addition of vitamins and minerals other than vitamins A and D a reasonable standard of identity that will promote honesty and fair dealing in the interest of consumers?

2. Is a standard of identity for lowfat milk and skim milk that excludes the use of stabilizers and emulsifiers except when used in conjunction with added milk-derived nonfat solids such that the stabilizers and emulsifiers amount to no more than 2 percent by weight of the solids that are added a reasonable standard of identity that will promote honesty and fair dealing in the interest of consumers?

The Administrative Law Judge's Order

At the November 9, 1983, prehearing conference, the Milk Industry Foundation withdrew its objection to the failure of the standards to provide for addition of vitamins and minerals other than vitamins A and D. Also, neither of the parties who filed objections to the failure of the standards for lowfat milk and skim milk to provide for the unrestricted use of stabilizers and emulsifiers appeared. Therefore, the Center for Food Safety and Applied Nutrition moved for partial summary judgment. In accordance with 21 CFR 12.93, any other interested party had 10 days in which to oppose the motion. Because no oppositions to the motion were filed, the Administrative Law Judge issued an order, dated December 12, 1983, granted the motion for partial summary judgment. In that order he found that:

1. A standard of identity for milk, lowfat milk, and skim milk that excludes the addition of vitamins and minerals other than vitamins A and D is a reasonable standard of identity that will promote honesty and fair dealing in the interest of consumers; and

2. A standard of identity for lowfat milk and skim milk that excludes the use of stabilizers and emulsifiers except when used in conjunction with added milk-derived nonfat solids such that the stabilizers and emulsifiers amount to no more than 2 percent by weight of the solids that are added is a reasonable standard of identity that will promote honesty and fair dealing in the interest of consumers.

No exceptions were filed to this order by hearing participants. Therefore, under 21 CFR 12.120(e) and (f), which provide that the initial decision becomes the final decision of the Commissioner if no hearing participant files an exception, and that notice of this final decision must be published in the **Federal Register**, notice is hereby given that this order is the Commissioner's final decision regarding these two hearing issues.

List of Subjects in 21 CFR Part 131

Cream, Food standards, Milk, Yogurt.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10); *It is ordered* that the stays announced in the **Federal Register** of December 5, 1974 (39 FR 42351), on the portions of 21 CFR 131.110(b), 131.135(b), and 131.143(b), which preclude the addition of vitamins other than vitamins A and D to milk, lowfat milk, and skim milk, and the stays on 21 CFR 131.135(c)(3) and 131.143(c)(3), which limit the use of stabilizers and emulsifiers in lowfat milk and skim milk, are terminated. The Commissioner is also terminating the stays on related provisions in 21 CFR 131.110(c)(1), 131.135(c)(1), and 131.143(c)(1) providing for use of carriers for vitamins A and D, and in 21 CFR 131.110(e)(1)(i), 131.135(e)(1)(ii), and 131.143(e)(1)(i) requiring labeling when vitamins A or D are added to the foods. Notice is given that the amendments, as published in the **Federal Register** of October 10, 1973 (38 FR 27924), of §§ 131.110(b), 131.135(b), and 131.143(b) as they pertain to addition of vitamins A and D and §§ 131.135(c)(3) and 131.143(c)(3) as they pertain to use of stabilizers and emulsifiers in conjunction with addition of milk-derived nonfat solids and related provisions in §§ 131.110(c)(1) and (e)(1)(i), 131.135(c)(1) and (e)(1)(ii), and 131.143(c)(1) and (e)(1)(i) will become effective January 5, 1987.

Dated: October 31, 1986.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-25046 Filed 11-5-86; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD5-86-025]

Drawbridge Operations in North Carolina

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from Drawbridge Operation Regulations for Bridge Across Atlantic Intracoastal Waterway, at Fairfield, North Carolina.

SUMMARY: The Coast Guard has granted a temporary deviation from the regulations for the drawbridge across the Atlantic Intracoastal Waterway at mile 113.8 at Fairfield, North Carolina. The purpose of this deviation from the regulations is to allow the project contractor for the U.S. Army Corps of Engineers, the owner of the bridge, to repair the bridge. The repairs are expected to be completed by December 1, 1986.

DATES: This temporary deviation from the regulations becomes effective on October 27, 1986, and terminates on December 1, 1986, or earlier if bridge repairs are completed ahead of schedule.

FOR FURTHER INFORMATION CONTACT: Ann B. Deaton, Bridge Administrator, Commander (oan), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004, or telephone number (804) 398-6222.

SUPPLEMENTARY INFORMATION:

Drafting Information

The drafters of this notice are Ann B. Deaton, project officer, and CDR Robert J. Reining, project attorney.

List of Subjects in 33 CFR Part 117

Bridges.

PART 117—[AMENDED]

Temporary Deviation From Drawbridge Regulations

In consideration of the foregoing, the regulations in § 117.5 of Title 33, Code of Federal Regulations, do not apply to the bridge across the Atlantic Intracoastal Waterway, mile 113.8, at Fairfield, North Carolina.

From October 27, 1986, until December 1, 1986, or earlier if bridge repairs are completed ahead of schedule, the bridge may remain closed to vessel traffic from 8 a.m. to 5 p.m. daily, except that, the bridge shall open at 12 noon for all accumulated and approaching vessels. At all other times, the bridge shall open on signal.

(33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05-1(g), 117.35(d))

Dated: October 28, 1986.

B.F. Hollingsworth,

Rear Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

[FR Doc. 86-25094 Filed 11-5-86; 8:45 am]

BILLING CODE 4910-14-M

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 223

Sale and Disposal of Timber; Timber Export and Substitution

AGENCY: Forest Service, USDA.

ACTION: Final rule.

SUMMARY: This rule revises the reporting requirements at 36 CFR 223.48 related to the export of timber from National Forest System lands and the use of such timber to substitute for private timber exported by the purchaser. The rule changes the report from a biannual to an annual report of the timber exported, sold for export, exchanged or otherwise disposed of during the previous calendar year. The rule reduces the paperwork burden on purchasers of National Forest timber sales and on Forest Service employees while maintaining appropriate controls on log exports.

EFFECTIVE DATE: This rule is effective December 8, 1986.

FOR FURTHER INFORMATION CONTACT: Stephen J. Paulson, Timber Management Staff, Forest Service, USDA, P.O. Box 2417, Washington, DC 20013, (202) 475-3755.

SUPPLEMENTARY INFORMATION:

Background

In response to concerns about possible increases in third party substitution of National Forest timber for private timber which is exported, the Senate Subcommittee on Interior and Related Agencies Appropriations directed the Forest Service to report every 6 months on trends in log exports and substitution. In order to provide this information, the Forest Service required purchasers of National Forest timber to report every 6 months on the disposition of harvested timber (36 CFR 223.48).

On July 25, 1983, the Chairman of the Senate Committee on Appropriations and the Chairman of the Subcommittee on Interior and Related Agencies requested the United States General Accounting Office (GAO) to review the potential impacts of tightening Forest Service log export restrictions in the West. On January 28, 1985, GAO reported its findings and concluded that there was no significant amount of third party substitution occurring in the western United States and that tightened controls were unnecessary.

Concerned about burdening purchasers with the 6-month reporting requirements, the Forest Service subsequently requested that the Subcommittee change the reporting frequency to an annual report. In light of the GAO finding and Forest Service analysis of past years' reports, the Subcommittee agreed to the Forest Service request.

This final rule will not change the requirement that purchasers domestically process National Forest System timber or change the requirement for certification of domestic processing from other firms or individuals that receive unprocessed National Forest System timber. Under this rule, purchasers will be required to submit an annual certified report, for the previous calendar year, on the disposition of unprocessed timber from National Forests which is sold, exchanged, or otherwise disposed of to another party and report the sale of any timber from private lands owned or controlled by the purchaser which is exported or sold for export.

Analysis of Public Comments

The proposed rule was published in the **Federal Register** of May 16, 1986, at 51 FR 95. A total of 6 responses were received. A majority of the respondents were supportive of the attempt to reduce the paperwork burden on purchasers and urged the rule be implemented. One commenter expressed concern that the reporting forms should be no more complex than those currently in effect under the existing procedures. Some comments were received expressing concern that a change to an annual report would adversely effect allocation of non-manufacturer volumes for tracking the Small Business Set aside program. These concerns evolve from the fact that the current 6-month reporting frequency is utilized to approximate the distribution of these volumes to large or small businesses.

All suggestions and comments were reviewed and considered in preparation of this final rule. Responses are available for review in the office of the Timber Management Staff, Forest Service, USDA, Room 3224, South Agriculture Building, 12th and Independence Avenue, SW., Washington, DC.

The final rule will provide for submitting an annual report on the disposition of harvested volume. The

reporting forms associated with this report are being revised to reduce the number of forms to be submitted each year. Purchasers will be able to show the distribution of volumes for several sales on one form rather than completing a form for each individual sale. Steps are being taken to incorporate the information from the Automated Timber Statement Account into an automated reporting of timber harvested by the purchaser each year. These efforts should further reduce the amount of work in gathering and analyzing export and substitution data.

Tracking of the distribution of non-manufacturer harvest volumes will continue, although not through the biannual export and substitution reports prepared by purchasers. The Forest Service will use other available means to determine this distribution, namely tracking of scale station volumes, purchaser haul routes, or other appropriate procedures. The annual report established in this final rule will be utilized to refine the estimated distribution.

Regulatory Impact

This final rule has been reviewed under USDA procedures and Executive Order 12291. It has been determined that this regulation is not a major rule. The regulation will have little or no effect on the economy or on individuals since the regulation is essentially procedural. The changes will result in savings to the Forest Service and purchasers of National Forest timber sales by reducing the cost to prepare, submit, and review Timber Export and Substitution reports.

Based on past experience and an environmental analysis, it has been determined that this rule will have no significant effect on the human environment, individually or cumulatively. Therefore, it has been categorically excluded from documentation in an environmental analysis or an environmental impact statement. (40 CFR 1508.4)

Controlling Paperwork Burdens on the Public

Under this rule, individuals and firms who purchase National Forest timber sales would be required to submit reports annually rather than every 6 months. Therefore, the rule would reduce the information collection requirements as defined in Office of Management and Budget (OMB) regulations at 5 CFR 1320.7. The present semi-annual report has OMB approval under control number 0596–0021 for use through March 31, 1987.

List of Subjects in 36 CFR Part 223

Exports, Government contracts, National forests, Timber.

For the reasons set forth above, Part 223 of Chapter II, Title 36, of the Code of Federal Regulations is amended as follows:

1. The authority citation for Part 223 will continue to read:

Authority: 90 Stat. 2958, 16 U.S.C. 472a; 98 Stat. 2213, 16 U.S.C. 618, unless otherwise noted.

PART 223—[AMENDED]

§ 223.48 [Amended]

2. Revise paragraphs (a) and (b) of § 223.48 to read as follows:

§ 223.48 Reports on export or substitution of unprocessed timber.

* * * * *

(a) Submit annually, until all unprocessed timber is accounted for, a certified report on the disposition of any unprocessed timber harvested from the sale, including a description of unprocessed timber which is sold, exchanged, or otherwise disposed of to another person and a description of the relationship with the other person;

(b) Submit annually, until all unprocessed timber from the sale is accounted for, a certified report on the sale of any unprocessed timber from private lands in the tributary area which is exported or sold for export; and

* * * * *

3. Add a parenthetical note at the end of § 223.48 to read as follows:

(Approved by the Office of Management and Budget under control number 0596–0021)

§ 223.164 [Amended]

4. Remove the editorial note on Office of Management and Budget approval of report #0596–0021 that occurs at the end of § 223.164.

Dated: October 14, 1986.

Douglas W. MacCleery,

Deputy Assistant Secretary for Natural Resources and Environment.

[FR Doc. 86–25110 Filed 11–5–86; 8:45 am]

BILLING CODE 3410–11–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A–7–FRL–3106–1]

Approval and Promulgation of State Implementation Plans; Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rulemaking.

SUMMARY: This notice advises the public that EPA today takes final action to approve amendments to two regulations as part of the Missouri State Implementation Plan (SIP) for the attainment of the National Ambient Air Quality Standards (NAAQS). The amendments change the exemption level for requiring a bulk gasoline plant to be equipped with a vapor recovery system for controlling volatile organic compounds (VOC). The emission limits on major sources of VOC are required by the Clean Air Act.

EFFECTIVE DATE: This rule will become effective on December 8, 1986.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the Environmental Protection Agency, Region VII, Air Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101; Missouri Department of Natural Resources, 101 Jefferson Street, Jefferson City, Missouri 65101; Public Information Reference Unit, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460; and Office of the Federal Register, 1100 L Street NW., Room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Deann K. Hecht at (913) 236–2893 or FTS 757–2893.

SUPPLEMENTARY INFORMATION: On July 2, 1985, the state of Missouri submitted a request to approve a revision to the Missouri SIP. The revision is an amendment to state Rules 10 CSR 10–5.220 for the St. Louis Metropolitan Area, and 10 CSR 10–2.260 for the Kansas City Metropolitan Area, both entitled, "Control of Emissions from Petroleum Liquid Storage, Loading, and Transfer." On March 12, 1986, EPA published a notice in the **Federal Register** (51 FR 8517) proposing to approve the amendments to the state rules.

The amendments to the two regulations change the exemption level for requiring bulk gasoline plants to be equipped with a vapor recovery system for controlling VOC emissions, from 600,000 gallons average monthly throughput to 120,000 gallons. However, the control technique guideline (CTG) refers to an exemption of 4,000 gallons throughput per day for 286 working days in a year, or approximately 24 working days per month. This would mean an exemption level of 96,000 gallons average monthly throughput of gasoline. The state has demonstrated that the total VOC emissions from the bulk

plants are within 5 percent of the total VOC emissions obtained by applying the CTG exemption level. EPA can approve a state regulation if the emissions from a source category are higher than the CTG, but no more than 5 percent higher than the emissions would be if the CTG is followed exactly. Therefore, the state deviation from the CTG exemption level is acceptable. A more detailed description of EPA's review of the state's amendments can be found in the proposal. No public comments were received on the proposal.

Final Action

In today's notice, EPA takes final action to approve amendments to the Missouri state rules, changing the exemption level in both regulations from 600,000 gallons average monthly throughput of gasoline to 120,000 gallons.

This state submission constitutes revisions to the Missouri SIP. The Administrator's decision to approve or disapprove these revisions is based on a determination that the revisions meet the requirements of section 110 and 172 of the Clear Air Act; of 40 CFR Part 51, Requirements for Preparation, Adoption, and Submittal of State Implementation Plans; and of the 1982 SIP policy (46 FR 7184, January 22, 1981).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit within 60 days from today. This action may not be challenged later in proceedings to enforce its requirements.

Incorporation by reference of the State Implementation Plan for the state of Missouri was approved by the Director of the Federal Register on July 1, 1982.

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Hydrocarbons, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: October 23, 1986.

Lee M. Thomas,

Administrator.

PART 52—[AMENDED]

40 CFR Part 52 is amended as follows:

Subpart AA—Missouri

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401—7642.

2. Section 52.1320 is amended by adding paragraph (c)(57) to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

(57) On July 1, 1985, the Missouri Department of Natural Resources submitted amendments to Rules 10 CSR 10–5.220 for the St. Louis Metropolitan Area, and 10 CSR 10–2.260 for the Kansas City Metropolitan Area. The amendments require bulk gasoline plants to be equipped with a vapor recovery system if their monthly throughput is greater than the exemption level.

(i) Incorporation by reference.

(A) 10 CSR 10–5.220, and 10 CSR 10–2.260, Control of Emissions from Petroleum Liquid Storage, Loading, and Transfer, as published in the Missouri Register on May 1, 1985.

[FR Doc. 86–25105 Filed 11–5–86; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Part 52

[A-3-FRL-3105-6]

Approval and Promulgation of Implementation Plans; Revision of Allegheny County Portion; Commonwealth of Pennsylvania Implementation Plan

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Commonwealth of Pennsylvania has submitted a revision to its State Implementation Plan (SIP) to incorporate an amendment, Appendix 22, to the Allegheny County portion of the Pennsylvania SIP. The revision provides the Allegheny County Health Department (ACHD) with the authority to grant, on a case-by-case basis, extensions of the final air pollution compliance dates for surface coating and graphic arts sources in Allegheny County. For each case the extension would be granted only after being specifically approved by EPA.

Such extensions could extend the final compliance date until April 21, 1987. EPA has determined that approval of this revision will not interfere with the attainment and maintenance of the National Ambient Air Quality Standard (NAAQS) for ozone.

EFFECTIVE DATE: December 8, 1986.

ADDRESSES: Copies of this SIP revision and relevant support documents are available for public inspection during normal business hours at the following locations:

U.S. Environmental Protection Agency, Region III, Air Programs Branch, 841 Chestnut Building, Philadelphia, PA 19107, Attn: Denis M. Lohman

Commonwealth of Pennsylvania, Department of Environmental Resources, Bureau of Air Quality Control, 200 North Third Street, Harrisburg, PA 17120, Attn: Gary L. Triplett

Allegheny County Health Department, Bureau of Air Pollution Control, 301 Thirty-ninth Street, Pittsburgh, PA 15201, Attn: Roger C. Westman

Public Information Reference Unit, Room 2922, EPA Library, Environmental Protection Agency, 401 M Street SW. (Waterside Mall), Washington, DC 20460

Office of the Federal Register, 1100 L Street NW., Room 8401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Denis M. Lohman (3AM11) at the EPA address above, or telephone (215) 597–8375.

SUPPLEMENTARY INFORMATION: The change to the Pennsylvania SIP was submitted by the Allegheny County Health Department (ACHD) through the Pennsylvania Department of Environmental Resources (PADER). The change is an amendment to section 512.G of Article XX, Rules and Regulations of the Allegheny County Health Department. The amendment would provide the Bureau of Air Pollution Control (BAPC) with the authority to grant, on a case-by-case basis, extensions of the final compliance dates for surface coating and graphic arts sources in Allegheny County. These extensions would be granted through the issuance of a Delayed Compliance Order (DCO). The DCO must be approved by EPA in accordance with section 113(d) of the Clean Air Act. The final compliance date could be extended until April 21, 1987, or for up to three years after the original compliance date, whichever comes first.

The provisions of the amended section 512.G. specify that extended compliance dates, for surface coating and graphic arts sources, may only be granted if the source demonstrates one or more of the following:

a. That it is physically impossible for the source to comply with the applicable compliance schedule; or

b. That, by allowing an extension of the compliance schedule, innovative technology will be applied which will result in the achievement of emission

reductions which are significantly greater than those otherwise required; or

c. That additional time is necessary to allow for the development of low solvent systems when the only alternative is the application of add-on emission control equipment which would cause an undue economic burden.

Furthermore, the DCO must contain a commitment to install add-on emission control equipment if the low solvent development program is not successful.

There are four substantive changes to the current section 512.G. represented by the proposed amendment:

(1) A final compliance date of June 30, 1985, is replaced with the date of April 21, 1987;

(2) The conditions to be satisfied to qualify for a DCO are modified by deleting explicit reference to specific add-on emission control equipment and by deleting the participation in a state-wide control prioritization program;

(3) The subsection pertaining to Graphic Arts—Nonporous Substrates is deleted in entirety;

(4) The required commitment to install add-on control equipment if the low solvent development program fails, currently applicable to the nonporous substrate graphic arts sources, is extended to apply to all surface coating and graphic arts sources.

The rules and regulations of the Commonwealth of Pennsylvania, which pertain to the surface coating and graphic arts sources, are equivalent to the proposed rules for Allegheny County. The revision to section 512.G. was proposed by the ACHD in order to have equitable treatment of the same classes of sources in and adjacent to Allegheny County.

In accordance with 40 CFR 51.4, a public hearing was held and an opportunity for submitting written comments was announced. The public hearing was held on June 18, 1985. The amendment was approved and adopted by the Board of County Commissioners on June 27, 1985.

On March 12, 1986, (51 FR 8581) EPA published a proposed rule to approve the revision to the Allegheny County portion of the SIP. Public comment on the proposed revision was invited. Within the 30 day comment period only one comment was received. An attorney, representing a graphic arts source, stated that the proposed revision should be approved by EPA.

Final Action

EPA has reviewed the information submitted by the State and is approving the revision to the Allegheny County portion of the SIP. The revision will permit, with sufficient justification, the extension of final compliance dates for graphic arts sources in Allegheny County.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 5, 1987. This action may not be challenged later in proceedings to enforce its requirements (See 307(b)(2)).

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Hydrocarbons, Intergovernmental relations, Reporting and recordkeeping requirements, Incorporation by reference.

Note.—Incorporation by reference of the State Implementation Plan for the State of Pennsylvania was approved by the Director of the Federal Register on July 1, 1982.

Dated: October 17, 1986.

Lee M. Thomas,

Administrator.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Title 40, Part 52, Subpart NN of Code of Federal Regulations is amended as follows:

Subpart NN—Pennsylvania

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7642.

2. Section 52.2020 is amended by adding paragraph (c)(67) as follows:

§ 52.2020 Identification of plan.

* * * * *

(c) * * *

(67) Amendment to section 512.G. Extensions, of Article XX, Rules and Regulations of the Allegheny County Health Department providing authority to grant compliance date extensions for surface coating and graphic arts sources, submitted by DER Secretary Nicholas DeBenedictis on August 13, 1985.

(i) Incorporation by Reference.

(A) Letter of August 13, 1985 to EPA from the Pennsylvania Department of Environmental Resources, and Appendix 22, Amendment to section 512.G., Allegheny County portion of the Pennsylvania State Implementation Plan (extension of final air pollution compliance dates for surface coating and graphic arts) adopted by the Board of County Commissioners of June 27, 1985.

[FR Doc. 86–25103 Filed 11–5–86; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Parts 795 and 799

[OPTS–42065A; FRL–3080–4]

2-Ethylhexanoic Acid; Final Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final test rule.

SUMMARY: EPA is issuing a final test rule, under section 4 of the Toxic Substances Control Act (TSCA), requiring manufacturers and processors of 2-ethylhexanoic acid (EHA, CAS No. 149–57–5) to conduct 90-day subchronic toxicity, developmental toxicity, and pharmacokinetics (i.e., absorption, distribution, metabolism, and excretion) studies. This action follows EPA's proposed rule of May 17, 1985 (50 FR 20678).

DATE: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern daylight time on November 20, 1986. These regulations shall become effective on December 20, 1986. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Office of the Federal Register as of December 20, 1986.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS–799), Office of Toxic Substances, Rm. E–543, 401 M St., SW., Washington, DC 20460, (202–554–1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a final test rule under section 4(a) of TSCA to require health effects testing of EHA.

I. Introduction—Test Rule Development Under TSCA

This notice is part of the overall implementation of section 4 of TSCA (Pub. L. 94–469, 90 Stat. 2003 *et seq.*, 15 U.S.C. 2601 *et seq.*), which contains authority for EPA to require development of data relevant to assessing the risks to health and the environment posed by exposure to particular chemical substances or mixtures.

Under section 4(a)(1) of TSCA, EPA must require testing of a chemical substance to develop health or environmental data if the Administrator finds that:

(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

A more complete understanding of the statutory section 4 findings is provided in the Agency's first proposed test rule published in the **Federal Register** of July 18, 1980 (45 FR 48510).

II. Background

A. Profile

EHA is a colorless liquid with a mild odor. It has a vapor pressure of 0.03 torr at 20°C, boils at 226.9°C at 760 torr, and is 0.1 percent soluble in water at 20°C. EHA is used exclusively as a chemical intermediate or reactant in the production of 2-ethylhexanoate metal soaps, peroxy esters, or other derivatives (Refs. 1 and 2).

There are two domestic manufacturers and three importers of EHA (Ref. 3). Eastman Kodak Co. is the primary domestic manufacturer of EHA. Union Carbide Corp. is also a domestic manufacturer of EHA; American Hoechst Corp., BASF Wyandotte Corp., and Filo Chemical Inc. are importers of EHA. The annual U.S. supply (domestic production plus imports) of EHA is currently between 20 to 25 million pounds. The import level of EHA is about 1 to 2 million pounds annually (Ref. 4).

The total weight of evidence overwhelmingly suggests that EHA has strong developmental toxicity potential. Furthermore, the potential health hazards of EHA are expected to be high because of EHA's structural similarity to several chemicals that have been associated with oncogenicity, developmental toxicity, and subchronic toxicity, the metabolic interrelationships of these chemicals to EHA, and the suggestive evidence that chemicals that induce peroxisomal proliferation may have oncogenic potential.

EPA believes exposure to EHA is inherent from the widespread and variable conditions under which the 20 to 25 million pounds per year of EHA is encountered during manufacturing, processing, and use (i.e., transfers, drumming, undrumming, shipping, loading, unloading, maintenance, clean-up, and sampling). The various conditions under which the large volume of EHA is encountered include variations in industrial hygiene practices and engineering controls at 2 manufacturing and about 100 processing sites. These variations may affect exposure to about 400 workers. The physicochemical properties of EHA do not force workers to avoid contact with EHA. Dermal exposure is expected because protective equipment may not be used and may not be fully effective. Refer to the proposed rule (50 FR 20678) published in the **Federal Register** May 17, 1985 for a detailed discussion of the potential health hazards and exposure for EHA.

Based on current information, environmental release is considered negligible, and the physical and chemical properties of EHA suggest that, if released, it would not persist or bioaccumulate. If EHA were disposed of in a surface impoundment, however, it may potentially leach to contaminate ground water.

B. Regulatory History

The Interagency Testing Committee (ITC) designated EHA for priority consideration for health effects tests in its 14th Report, published in the **Federal Register** of May 29, 1984 (49 FR 22389). The ITC recommended that EHA be tested for chronic health effects including carcinogenicity. The ITC further identified, although it did not specifically recommend for testing, the following biological effects of concern to human health: Acute toxicity, teratogenicity/embryotoxicity, metabolism and pharmacokinetics, genotoxicity, and other effects (peroxisome induction).

EPA responded to the ITC's recommendations for EHA by publishing in the **Federal Register** of May 17, 1985 (50 FR 20678) a proposed test rule for EHA that would require developmental toxicity, subchronic toxicity, and pharmacokinetics (i.e., absorption, distribution, metabolism, and excretion) tests. EPA also made the findings for oncogenicity testing, but did not propose testing at that time because a bioassay was planned by the National Toxicology Program (NTP) for 2-ethylhexanol. The Agency planned to evaluate data from this bioassay along with other information to determine whether oncogenicity testing of EHA is necessary. Refer to the proposed rule for details of EPA's findings and the proposed test standards and reporting requirements. Subchronic oral toxicity testing proposed under 40 CFR 798.75 and pharmacokinetics testing proposed under 40 CFR 798.460 have been redesignated as 40 CFR 795.260 and 795.223, respectively, in this final rule, and the standard for 2-ethylhexanoic acid proposed under 40 CFR 799.2050 has been redesignated as 40 CFR 799.1650 in this final rule.

On October 8, 1985, EPA held a public meeting to hear and discuss comments presented on the proposed rule. The transcript of the public meeting is included in the docket for this rulemaking (Ref. 35), and substantive comments are addressed in Unit III. of this notice.

Following publication of the proposed rule, new information was received by the Agency which relates to the potential developmental toxicity of EHA and potential exposure to EHA. The new information consisted of a study and supplemental data by Ritter *et al.* (Refs. 6 and 7), which reported that a single dose of EHA administered during pregnancy resulted in fetal resorption and malformation in rats and a series of studies conducted by Nau (Refs. 8 and 9) and Nau and Loscher (Ref. 10), which provides additional suggestive evidence of EHA's potential developmental toxicity. The first two studies in the series by Nau (Refs. 8 and 9) describe the parental and fetal pharmacokinetics of valproic acid, a known human and animal developmental toxicant that is structurally related to EHA. The remaining study (Ref. 10) compares the developmental effects of valproic acid and a number of structurally similar compounds including other ethylhexyl-containing acids. The results suggest that as a class these compounds have potential developmentally toxic effects. In addition, industry conducted an industrial hygiene survey and a glove permeability study (Ref. 12). These studies were reviewed by the Agency and found not to support industry's contention that exposure is negligible and fully controlled.

III. Response To Public Comments

The Agency received comments, summarized below, from the Chemical

Manufacturers Association (CMA) Ethylhexanoic Acid Program Panel (the Panel) on the proposed test rule for EHA. The Panel members include Eastman Kodak Co., Union Carbide Corp., BASF Wyandotte Corp., American Hoechst Corp., and Filo Chemical Inc.

A. Exposure

1. *Review of the 1985 Survey of Safety Procedures for EHA.* The Panel contends that EHA has insufficient exposure potential to pose an unreasonable risk of injury, and, that without the potential for exposure, the Agency does not have the regulatory authority to require testing. In support of this claim, the results of a questionnaire survey regarding EHA safety procedures were submitted to the Agency (Ref. 12). The Panel claims that the survey results refute EPA's "speculation" that gloves and other protective equipment may not be used by all employees who could be exposed to EHA.

The Agency has reviewed the survey and has several concerns with regard to study design and execution. By its very nature, the questionnaire survey is a simplified form of an industrial hygiene audit. That is, an audit is a process used to determine the presence or absence of industrial hygiene program elements (Ref. 13). What is lacking from the audit process and from this survey are the necessary measures of program performance and effectiveness. The questionnaire survey succeeds only in providing mere indicators of activity, not compliance.

Moreover, the survey was designed and administered as a self-audit involving plant management and/or supervisory personnel. No indication is given that workers or their union representatives participated in the survey. This type of selection bias will predictably lead to diminished confidence in the objectivity of the responses.

Control of dermal exposures involves a combination of effective engineering controls, proper work practices, personal hygiene, and protective clothing. These are factors which can only be properly addressed through on-site industrial hygiene surveys, and not by questionnaire audits. Furthermore, there can be expected to exist considerable plant-to-plant variation in chemical control procedures (e.g., storage and loading facilities, physical plant conditions, waste disposal practices, etc.) and critical event planning (e.g., fire, explosion, chemical spill, etc.). These variables will impact significantly on the potential for worker exposure. Furthermore, according to the American Insurance Institute, the most important factors contributing to compensable losses in the chemical industry are equipment and operational failures (Ref. 14). Such failures may result in significant worker exposures to chemicals and are not reflected in the results of the questionnaire survey.

2. *Glove permeability test.* To demonstrate that glove materials used by industry are an effective barrier to EHA, the Panel submitted data from a glove permeation test. The test measured nitrile and neoprene glove materials using ASTM procedure F739–81 (Ref. 15). Although the data show no EHA breakthrough after 7 hours of continuous exposure, the data fail to establish the steady-state permeation rate for EHA as prescribed in the ASTM procedure. Data on the permeation rate are necessary in order to determine if EHA may eventually permeate the glove material and eventually, through persistent permeation, occur on the inside surface of the glove (Ref. 15). Permeation information would be significant for prolonged or repeated use of the gloves.

The survey of safety procedures (Ref. 12) indicated that glove materials other than nitrile and neoprene (e.g., rubber, polyvinyl chloride, latex, and cotton) are used by some workers potentially exposed to EHA. Since the selection of the type of glove material and use of gloves by specific industries is voluntary, the potential for dermal exposure is likely to be variable among the companies that manufacture and use EHA.

EHA will be processed in mineral spirits, but the data fails to show the breakthrough or permeation rate of EHA in mineral spirits. Data on the migration of the pure component of a mixture may vary drastically with data for a mixture (Ref. 16). Because the materials tested do not necessarily represent materials used by industry, because the ASTM procedure was not completed to show the permeation rate for the material tested, and because actual exposure will likely be with EHA in mineral spirits and not with pure EHA, EPA believes the glove permeation data do not provide conclusive evidence that worker exposure to EHA will be precluded by industries' use of gloves.

3. *Dermal contact determination for EHA.* The Panel believes that EPA's estimate of "worst-case" dermal exposure to hands (500 mg/kg/contact) in the proposed rule is excessive.

EPA agrees and, based on a model for incidental hand exposure which the Panel and EPA believes more accurately describes exposure for EHA, the "worst case" exposure to EHA is revised to 60 mg/kg/contact.

Both Eastman Kodak Co. (Ref. 17) and Union Carbide Corp. (Ref. 18) report that EHA is a mild to moderate dermal irritant, and it is labeled as a mild acid. EPA believes that the acute effects from EHA and the current label do not preclude dermal exposure to EHA, but suggest a greater potential for lax industrial hygiene practices and a greater potential for dermal exposure than if the compound was labeled as a more severe hazard or was more acutely toxic.

B. Health Effects

1. *Developmental toxicity test.* The Panel made several comments on the adequacy of the study conducted by Ritter *et al.* (Ref. 6). The Ritter study was a single high dose (12.5 mmol/kg, approximately 1.8 g/kg) and a second lower dose (6.25 mmol/kg approximately 0.9 g/kg) administered on day 12 of gestation to pregnant Wistar rats via the oral route. In the control group, the incidence of total fetal toxicity was 4.4 percent as compared to 71.1 percent in the high dose EHA-treated group. In addition, the low dose EHA-treated group had an incidence of 7.1 percent for total embryo toxicity. The data from the Ritter study are consistent with the hypothesis that EHA causes developmental toxicity. Although submitted after the proposed EHA rule was published, the Ritter study was shared with industry in time to be included with other industry comments. Industry stated that the study was not reported in sufficient detail to allow adequate evaluation of the study design and results, and that the study was not state-of-the-art. The Panel also commented that a single high dose as reported in this study is inappropriate, that the authors did not report on maternal toxicity, and that there was no indication that a negative control was included in the study. EPA agrees the study is not of state-of-the-art design and would be inappropriate for assessing human risk. The Agency believes, however, that this study and other available data raise sufficient concern about the potential for developmental toxicity of EHA to support the hazard component of the "may present an unreasonable risk" finding. If these studies were of sufficient quality to fully assess the potential for developmental toxicity of EHA, further testing would be unnecessary.

The Panel believes that human exposure cannot be equated in magnitude with the single high dose

exposure used in the Ritter study (Ref. 6). The Panel cited evidence from Johnson (Ref. 23) that states that short duration high dose level studies have little value in establishing human safety guidelines. EPA generally agrees with this finding, but EPA disagrees that this supposition should modify the decision to test. The report by Johnson suggests that any effects of one-day exposures would also be discovered in longer duration segment II studies. The type of developmental effect produced would, of course, be dependent on the gestational stage(s) insulted and more severe effects would be elicited at lower doses since treatment is prolonged. Until an adequate state-of-the-art is performed, the no-observed-effect level for the developmental effects of EHA will remain undetermined.

The Panel believes tests conducted by Hazelton Laboratories (Ref. 19) were severely compromised, since all compounds at the dose tested produced overt signs of maternal toxicity. In addition, the Panel does not consider [[[3,5-bis(1,1-dimethylethyl)-4-hydroxyphenly]methyl]thio] acetic acid, 2-ethylhexyl ester, which was tested by CIBA–GEIGY (Ref. 20), an adequate analogue for EHA. EPA believes these studies viewed by themselves would be of little assistance in the evaluation of EHA; but, when considered along with other evidence of the potential developmental toxicity of EHA, they add to the weight of evidence supporting the potential developmental toxicity of EHA and thus the need for more definitive testing.

The Panel suggests the comparison between EHA and valproic acid is not justified based largely on the Panel's belief that the study of Brown and Coakley (Ref. 21) "does not provide any evidence to warrant a comparison of EHA to valproic acid." The comparison, however, is based on both structural similarities and the evidence of Brown and Coakley. Both EHA and valproic acid are isomeric acids which differ only in the placement of a –COOH group on an octane backbone. Thus, EHA corresponds to 3-carboxyoctane, and valproic acid corresponds to 4-carboxyoctane. There is a great deal of evidence as stated in the review by Gram and Bentsen (Ref. 22) that valpoic acid is both an animal and human developmental toxicant. The structural similarity alone between these two acids would support making the "may present" finding. The major significance of the Brown and Coakley study is that it describes the similarity in biologic effects between EHA and valprioc acid, which is supported by the previously discussed structural similarity.

The Agency believes that the total weight of evidence presented in the proposed test rule for EHA is adequate to support the Agency's finding that EHA may present an unreasonable risk for developmental effects. Since the proposed test rule, EPA has obtained additional information that further supports the Agency's hazard finding. In addition to the study by Ritter discussed above, in a series of studies in mice conducted by Nau (Refs. 8 and 9) and Nau and Loscher (Ref. 10), several short-chain acids were examined for fetal effects at doses of 600 mg/kg given on day 8 of gestation. Neural tube defects were observed in offspring of groups treated with valproic acid, 2-propyl-hexanoic acid, 2-butylhexanoic acid, and 2-ethylpentanoic acid. Furthermore, the Agency has evaluated results from a preliminary study (Ref. 11) reporting that decreases in pup weight on days 1 and 3 after parturition were observed in groups of mice exposed by gavage to EHA at 1,000 mg/kg on days 7 through 13 of gestation. Although these studies are not of adequate design to allow full assessment of the effects of EHA on fetal development, the studies do add further support to the need for testing.

2. *Subchronic toxicity testing.* The Panel does not believe that sufficient justification exists for the Agency to require subchronic toxicity testing. The Panel believes: (1) The study by Moody and Reddy (Ref. 24) used by EPA is inadequate justification; (2) data from related compounds suggest a low order of subchronic toxicity; and (3) the NTP subchronic study on 2-ethylhexanol should provide adequate data to evaluate EHA.

The objective of this test is to characterize fully the subchronic toxicity of EHA, and since the Agency may use a bioassay to be conducted on 2-ethylhexanol to evaluate whether oncogenicity testing of EHA will be required, the subchronic test is necessary to compare 2-ethylhexanol and EHA. At this time, it is not clear whether NTP will conduct the subchronic toxicity study of 2-ethylhexanol.

In the study by Moody and Reddy (Ref. 24), EHA exposure resulted in a greater than 50 percent increase in liver weight and substantial changes in certain measured biochemical parameters. These effects, observed in a study of only 3 weeks duration, are of a magnitude which EPA believes would indicate that a toxic process was involved rather than a simple adaptation. These data are sufficient to raise concern for the potential chronic toxicity of EHA.

Valproic acid, a close structural analogue of EHA, has been shown to be toxic to the liver in both humans and animals (Refs. 36 through 39), and this increases concern for potential liver effects from EHA.

In its comments on the relative subchronic toxicity of EHA, the Panel suggets EHA is less toxic compared with other chemicals tested because, on a molar basis, up to 3 times more EHA is required to produce similar effects. The Agency believes that in comparing the toxicity of EHA with other chemical substances, the comparison should be made on the relative molar levels of the 2-ethylhexyl moiety since it is this moiety that is hypothesized to be the active agent. Using this assumption, the differences in molar dose are no greater than approximately 50 percent.

3. *Oncogenicity.* The Panel considers the available data insufficient for the Agency to make a finding that EHA may present an unreasonable risk for an oncogenic effect. The Agency based its finding on the structural similarity of EHA with four compounds, which also contain the ethylhexyl moiety [di(2-ethylhexyl) phthalate, sodium 2-ethylhexyl sulfate, di(2-ethylhexyl) adipate, and tris(2-ethylhexyl) phosphate] and have been demonstrated to produce neoplasias in laboratory animals in bioassays conducted by NTP. In addition, EHA has been shown to cause peroxisomal proliferation, an effect produced by many carcinogenic compounds (Ref. 24). Despite possible flaws, the Agency considers that taken together this evidence constitutes sufficient justification for concern that EHA "may present an unreasonable risk" for oncogenicity.

4. *Pharmacokinetic test standard.* The Panel raised several comments regarding the proposed pharmacokinetic test standard, and the Panel submitted an alternative pharmacokinetic test standard. Principal concerns raised by the Panel were: (1) The need to include two experimental animal species, (2) the need to measure placental transfer of EHA, and (3) the need for a repeated dose study. In addition, questions were raised regarding proposed test methods involving: (1) The use of oral versus dermal absorption kinetics to assess bioavailability, (2) isolation of sufficient amounts of urinary metabolites to permit structure elucidation, and (3) the long time interval between blood sampling points.

In response to questions raised by the Panel about the proposed methods, the

Agency has modified the test standard as follows:

1. Intravenous administration has been included in the bioavailability test to provide a base line that is certain to produce 100 percent bioavailability;
2. Up to 10 percent unidentified labeled material is allowed;
3. Shorter blood collection intervals are required during the first hour of the study;
4. The Fischer 344 rat only will be used for the study; and
5. The placental transfer requirement is deleted.

The Panel contends that there are no data to suggest that EPA presents a chronic hazard; thus there is no need for a repeated dose study. Given the postulated exposure scenario for EHA, involving intermittent low-level dermal contact in the workplace the Agency believes data are needed on both repeated dose exposure and single dose exposure. An important pharmacokinetic consideration in toxicology is dose-dependent disposition, involving both dose-dependent availability and concentration-dependent elimination. Since the biotransformation of xenobiotics is controlled by enzymatic processes, metabolism is usually directly proportional to the substrate concentration provided the metabolizing enzymes do not become saturated. Enzyme saturation typically occurs with compounds that are rapidly absorbed and have a large volume of distribution, and is a function of the size and/or number of doses. The consequences of dose-dependent disposition can be a change in the urinary excretion profile for the unchanged parent compound and its metabolites, or large increases in toxic effects with increasing dose beginning at the dose level where saturation occurs. To evaluate the likelihood for dose-dependent disposition to occur, studies should be conducted that compare pharmacokinetics at high and low single doses of the same compound, or single and repeated administration of the substance at a constant dose. In a repeated dose study, however, it is not likely that dose-dependent disposition would be evident unless the dosing interval was less than the elimination half-life. Estimation of the elimination half-life would require the conduct of a preliminary single-dose study.

The rationale for performing a repeated dose pharmacokinetic study for EHA should be viewed in light of current knowledge regarding the metabolism of xenobiotic carboxylic acids. Many carboxylic acids, particularly those with low pK_a values, will be eliminated in the urine without any metabolic alteration (Ref. 26). An important route of carboxylic acid biotransformation is conjugation with glucuronic acid. β-Oxidation and other oxidative pathways to acidic metabolites are also important. Such metabolites are frequently excreted as glucuronides. Therefore, one may expect to find unchanged EHA and/or EHA glucuronide plus other acids and/or their glucuronides in the urine of EHA-dosed rats. The proportions of these metabolites can be expected to vary as pathways become saturated. For valproic acid, the formation of a relatively minor metabolite (2-*n*-propyl-4-pentenoic acid) is critical for the expression of toxicity to the liver (Ref. 36). A similar situation may hold for EHA toxicity.

IV. Final Test Rule for EHA

A. Findings

EPA is basing the final health testing requirements for EHA on the authority of section 4(a)(1)(A) of TSCA.

EPA finds that EHA may present an unreasonable risk of oncogenicity, developmental toxicity, and subchronic toxicity. These findings are based on the strongly suggestive evidence of toxicity discussed in Unit II. of this preamble and in Unit II. of the proposed rule and the potential for dermal exposure of workers engaged in manufacturing, transfer, storage, and processing of EHA. Because EPA believes EHA has a high hazard potential, EPA believes the exposure potential need not be very high to justify the 4(a)(1)(A) finding. Furthermore, although current exposure may appear to be low, future exposure from the same or different uses may change.

Inadequate data exist to characterize oncogenicity, developmental toxicity, subchronic toxicity, and pharmacokinetics of EHA. In addition, the dermal exposure of an estimated 400 workers during the manufacture, transfer, storage, and processng of EHA has not been sufficiently characterized to conclude that there is no unreasonable risk from this exposure to EHA. Furthermore, the potential health hazard of EHA is significant because of: (1) Its structural similarity to several chemicals that have been associated with such health effects; (2) the metabolic interrelationships of certain of these chemicals to EHA; and (3) the suggestive evidence that chemicals such as EHA that induce peroxisomal proliferation may have oncogenic potential. The available data on the health effects of concern are inadequate to reasonably predict or determine the health risks posed by present exposure to EHA. At this time, the Agency does not find that oncogenicity "testing is necessary to develop such data" for EHA. The Agency is currently negotiating with industry to obtain a bioassay for 2-ethylhexanol (EH), the immediate precursor of EHA, under the recently published consent agreement process but will propose such testing if a consent agreement cannot be achieved. The Agency will evaluate data from the EH bioassay along with other information to determine if oncogenicity testing of EHA will be necessary.

Data are not available to characterize the pharmacokinetics, subchronic toxicity, and developmental toxicity of EHA. The Agency is unaware of any ongoing or planned testing in these areas of concern. Therefore, the Agency finds that the testing specified below is necessary to characterize these risks.

B. Required Testing

On the basis of these findings, the Agency is requiring developmental toxicity, 90-day subchronic, and pharmacokinetic testing as a basis for determining the health risks of EHA.

The Agency is requiring that the following health effects test guidelines be the test standards for the purpose of testing EHA.

The Agency believes that the pharmacokinetic test standard developed by the Office of Toxic Substances (OTS) for this final rule is appropriate for determining and comparing the absorption, distribution, metabolism, and excretion of EHA for both the oral and dermal routes of administration. Data from these studies are necessary to aid in the evaluation of test results from other toxicology studies and to determine the comparability of oral and dermal dosing.

The Agency requires that 7- to 9-week-old Fischer 344 rats be used for the pharmacokinetics studies. Furthermore, Fischer 344 rats are required for subchronic testing or EHA and have been used extensively by NTP for testing ethylhexyl-containing chemicals. They have also been used extensively in percutaneous absorption studies. Two doses shall be required in the pharmacokinetics studies, a "low" dose and a "high" dose. When administered orally, the "high" dose level should ideally induce some overt toxicity such as weight loss. The "low" dose level should correspond to a no-effect level. The same "high" and "low" dose shall be administered orally and dermally. The required studies evaluate blood levels, urinary and fecal excretion, and biotransformation of

EHA when administered dermally and orally. In addition, the extent to which washing removes dermally-applied EHA is also evaluated.

In response to comments from industry, the final test standards have been modified to include an intravenous administration in the bioavailability test, allow up to 10 percent unidentified labeled material in the urine, and require shorter collection intervals during the first hour of the study.

The Agency believes that this modified pharmacokinetics test methodology represents the state-of-the-art and forms the basis for a valid and scientifically acceptable test standard. This test standard was proposed under 40 CFR 798.460 published in the Federal Register of May 17, 1985 (50 FR 20689), and is published in the final rule below under 40 CFR 795.223.

The Agency believes that the subchronic exposure oral toxicity test standard developed by OTS for this final rule is appropriate in determining the subchronic toxicity of EHA. This test permits the determination of the no-observed-effect level, the characterization of toxic effects associated with continuous or repeated exposure for a period of 90 days, and provides information on target organs.

The subchronic test is conducted by administering a chemical substance such as EHA orally for 90 days in graduated daily doses to several groups of experimental animals, one dose level per group. During the period of administration the animals are observed daily to detect signs of toxicity. Animals which die during the period of administration are necropsied, and at the conclusion of the test all surviving animals are sacrificed and histopathological examinations conducted on the tissues. Given the test results of Moody and Reddy (Refs. 24 and 31), the subchronic toxicity evaluation should pay particular attention to hepatotoxicity and serum lipid alterations.

The Agency believes that this subchronic toxicity test methodology represents the state-of-the-art and forms the basis for a valid and scientifically acceptable test standard. This test standard was proposed under 40 CFR 798.75, published in the Federal Register of May 17, 1985 (50 FR 20687), and is published in the final rule below under § 795.260.

To determine the developmental hazard of EHA, EPA proposed that testing be conducted by either the OTS guideline, which on May 17, 1985 was entitled "Developmental Toxicity (HG-Organ/Tissue-Developmental Toxicity-Oral, OTS Health Effects Test Guidelines)", or the OECD test guideline entitled "Teratogenicity", No. 414, adopted May 12, 1981. No comments were received on either test standard. However, since publication of the proposed rule for EHA, the Agency published the test guideline entitled "Developmental Toxicity Study" under 40 CFR 798.4900 (50 FR 39433; September 27, 1985). The Agency proposed modifications to this guideline in the Federal Register of January 14, 1986 (51 FR 1523). These modifications provide more explicit guidance on the necessary minimum elements for this testing. In addition, these revisions avoid repetitive chemical-by-chemical changes to the guidelines in its adoption as a test standard. The OTS guideline proposed for EHA, therefore, will be subject to change. EPA believes, nonetheless, that the OECD test guideline as proposed for EHA represents a state-of-the-art method and forms the basis for a valid and scientifically acceptable test standard.

The developmental toxicity test is conducted by administering a chemical substance such as EHA orally in graduated doses, for at least that part of the pregnancy covering the period of organogenesis, to several groups of pregnant experimental animals, one dose level being used per group. Shortly before the expected date of delivery, the pregnant females are sacrificed, the uteri removed, and the contents examined for structural malformations, *in utero* death, and growth retardation.

Rats and a nonrodent mammalian species should be utilized. EPA recommends rabbits as the nonrodent species. The Agency believes that multispecies testing is a more sensitive means of detecting developmental hazards than single species testing (Refs. 32, 33, and 34). Testing EHA in the rat and a nonrodent mammalian species will provide the Agency with the data needed to reasonably determine or predict whether EHA poses a risk of developmental toxicity to humans.

The Agency believes that the OECD oral developmental toxicity test guideline represents a state-of-the-art methodology and forms the basis for a valid and scientifically acceptable test standard for evaluating the developmental toxicity of a chemical substance such as EHA. The guideline has been reviewed to ensure that it reflects the most current scientific approach to developmental toxicity testing.

C. Test Substance

EPA is requiring that EHA of at least 99 percent purity be used as the test substance. EHA of this purity is commercially available at nominal cost. EPA has specified a relatively pure substance for testing because the Agency is interested in evaluating the effects attributable to EHA itself. Radiolabeled ^{14}C-EHA will be needed for the pharmacokinetics testing.

D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which the Administrator makes section 4(a) findings (manufacture, processing, distribution, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures giving rise to the potential risk occur during use, distribution, or disposal.

Because EPA has found that existing data are inadequate to assests the health risks from the manufacture, transfer, storage and processing of EHA, EPA is requiring that persons who manufacture or process, or intend to manufacture or process, EHA at any time from the effective date of the final test rule to the end of the reimbursement period are subject to the pharmacokinetic, subchronic toxicity, and developmental toxicity testing requirements contained in the final rule. The end of the reimbursement period will be 5 years after the last final report is submitted for EHA or an amount of time equal to that which was required to develop data if more than 5 years after the submission of the last final report required under the test rule.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

Manufacturers (including importers) subject to this rule are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the final test rule. The required procedures for submitting such

letters and applications are described in 40 CFR Part 790.

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing, unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, the Agency will publish a separate notice in the Federal Register to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing for EHA. As noted in Unit IV.C. above, EPA is interested in evaluating the effects attributable to EHA and has specified a relatively pure substance for testing.

Manufacturers and processors who are subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790 for single-phase rulemaking.

E. Reporting Requirements

EPA is requiring that all data developed under this rule be reported in accordance with its final TSCA Good Laboratory Practice (GLP) standards, which appear in 40 CFR Part 792.

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans within 45 days before initiation of each study.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. Specific reporting requirements for each of the proposed test standards follow:

The pharmacokinetic test shall be completed, and the final results submitted to the Agency within 1 year of the effective date of the final test rule. An interim progress report shall be provided 6 months from the effective date of this rule.

The subchronic toxicity tests shall be completed, and the final results submitted to the Agency within 15 months of the effective date of the final test rule. Interim progress reports shall be provided 6 months and 12 months from the effective date of this rule.

The developmental toxicity tests shall be completed, and the final results submitted to the Agency within 18 months of the effective date of the final test rule. Interim progress reports shall be provided 6 months and 12 months from the effective date of this rule.

NTP's experience with testing other ethylhexyl moiety substances and the Agency's experience with Negotiated Testing Agreements with industry suggest that this testing can be completed within the specified time. The 18-month extension for pharmacokinetics testing requested by industry is therefore denied at this time. If technical problems arise during this testing, the sponsors may request that the Agency modify this rule requirement.

TSCA section 14(b) governs Agency disclosure of all test data submitted to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the Federal Register as required by section 4(d).

Persons who export a chemical substance or mixture which is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) are in 40 CFR Part 707 (45 FR 82844). In brief, as of the effective date of this test rule, an exporter of EHA must report to EPA the first annual export or intended export of EHA to any one country. EPA will notify the foreign country concerning the test rule for the chemical.

F. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records; (2) submit reports, notices, or other information; or (3) permit access to or copying of records required by the Act or any regulation or rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce." The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection.

Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with the final rule for EHA. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers that fail to submit a letter of intent or an exemption request and that continue manufacturing after the deadlines for such submissions.

This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.48(b)). Intentional violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

V. Economic Analysis of Final Rule

To assess the potential economic impact of this rule, EPA has prepared an economic analysis (Ref. 4) that evaluates the potential for significant economic impacts on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these test costs by examining four market characteristics of EHA: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. If there is no indication of adverse effect, no further economic analysis is performed. However, if the first level of analysis indicates a potential for significant economic impact, a more comprehensive and detailed analysis is conducted which more precisely predicts the magnitude and distribution of the expected impact.

Total testing costs for this final rule are estimated to range from $216,210 to $275,620. In order to predict the financial decision-making practices of manufacturing firms, these costs have been annualized. Annualized costs are compared with annual revenue as an indication of potential impact. The annualized costs represent equivalent constant costs which would have to be recouped each year of the payback period in order to finance the testing expenditure in the first year.

The annualized test costs (using a cost of capital of 25 percent over a period of 15 years) range from $56,000 to $71,400. Based on an estimated minimum production volume for EHA of 12 million pounds, the unit test costs will be about 0.6 cents per pound. In relation to the selling price of 57 cents per pound for EHA, these costs are equivalent to one percent of price.

Based on these costs and the uses of EHA, the economic analysis indicates that the potential for significant adverse economic impact as a result of this testing rule is low. This conclusion is based on the following observations:

1. EHA is an intermediate whose demand is dispersed over several markets;

2. The dosage requirements of EHA derivatives, notably metal octoates, are very small in relation to their end products;

3. The estimated unit test costs are low, one percent of current price in the upper-bound case; and

4. The unit costs, when dispersed over the production costs of EHA derivatives and their end products, will be significantly reduced due to both the intermediate nature of EHA and the small percent composition requirements of its derivatives.

Refer to the economic analysis for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

VI. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules and test programs negotiated with industry in place of rulemaking. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing (PB 82-140773)", can be obtained through the National Technical Information Service (NTIS).

On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing in this rule.

VII. Rulemaking Record

EPA has established a record for this rulemaking (OPTS-42065A). This record includes basic information considered by the Agency in developing this rule and appropriate **Federal Register** notices.

The record includes the following information:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this decision consisting of:

(a) Notice containing the ITC designation of EHA to the Priority List (49 FR 22389; May 29, 1984).

(b) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (48 FR 53922; November 29, 1983).

(c) Notice of final rule on two-phase test rule development and exemption procedures (49 FR 39774; October 10, 1984).

(d) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20678; May 17, 1985).

(e) Notice of final rule on data reimbursement policy and procedures (48 FR 31786; July 11, 1983).

(f) Notices requiring TSCA section 8 (a) and (d) reporting requirements for EHA (49 FR 22284, 22286; May 29, 1984).

(g) Notice of EHA proposed test rule (50 FR 20678; May 17, 1985).

(h) Toxic Substance Control Act Test Guidelines Final Rule, 40 CFR Parts 796, 797, and 798, September 27, 1985.

(i) Notice of final rule amending TSCA section 8(d) reporting requirements for EHA (51 FR 32720; September 15, 1986).

(2) Support documents: consisting of:

(a) Study of availability of test facilities and personnel.

(b) EHA economic analysis.

(3) Records of minutes of informal meetings.

(4) Communications before proposal consisting of:

(a) Written public and intra- or interagency memoranda and comments.

(b) Summaries of telephone conversations.

(c) Reports—published and unpublished factual materials.

(5) Test guidelines proposed as standards.

B. References

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(2) Eastman Kodak Co. Letter from R.G. Gerwe to F. Benenati on the use of 2-Ethylhexanoic Acid in Mining Applications. (February 11, 1985)

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(13) Corn, M. and Lees, P.S.J. "The industrial hygiene audit: Purposes and implementation." *American Industrial Hygiene Association Journal.* 44(2):135–141. (1983)

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(17) Eastman Kodak Co. Material Safety Data Sheet: Kodaflex TEG–EH Triethylene Glycol Di-2-ethylhexanoate. (June 1983)

(18) Union Carbide Corp. Cover letter from G.P. Bigelow, Union Carbide to R. Borghi, Dynamac Corp. (October 14, 1983) Enclosures:

(a) Product Literature on Organic Acids.

(b) Material Safety Data Sheet for 2-Ethylhexanoic Acid.

(19) Hazleton Laboratories America, Inc. Screening of priority chemicals for potential reproductive hazard. Final report. NIOSH Contract No. 200–82–2542. Hazleton Study Nos. 6125–101 through 6125–110. Atlanta, GA: Centers for Disease Control, NIOSH. (1983)

(20) CIBA–GEIGY Corp. TSCA Section 8(e) Notice on [[[3,5-bis(1,1,-dimethyl-ethyl)-4-hydroxyphenyl]methyl]thio]acetic acid, 2-ethylhexyl ester. Submitted by Anthony Di Battista to Document Control Officer, Office of Toxic Substances, U.S. Environmental Protection Agency. (January 31, 1985) [EPA document control number 8EHQ–0285–0544, 88–0500724.]

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Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Room. NE–G004, 401 M Street, SW., Washington, DC from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

VIII. Other Regulatory Requirements

A. Classification of Rule

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order; i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprise to compete with foreign enterprises.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96–354, September 19, 1980), EPA is certifying that this test rule, if promulgated, will not have a significant impact on a substantial number of small businesses because: (1) They will not perform testing themselves, or will not participate in the organization of the testing effort; (2) they will experience only very minor costs in securing exemption from testing requirements; and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned them OMB number 2070–0033.

List of Subjects in 40 CFR Parts 795 and 799

Testing, Environmental protection, Hazardous substances, Chemicals, Reporting and recordkeeping requirements, Incorporation by reference.

Dated: October 27, 1986.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:

1. By adding new Part 795, consisting at this time of §§ 795.223 and 795.260, to read as follows:

PART 795—PROVISIONAL TEST GUIDELINES

Subpart A—[Reserved]

Subpart B—[Reserved]

Subpart C—[Reserved]

Subpart D—Provisional Health Effects Guidelines

Sec.

795.223 Pharmacokinetic test.

795.260 Subchronic oral toxicity test.

Authority: 15 U.S.C. 2603, 2625.

Subparts A–C—[Reserved]

Subpart D—Provisional Health Effects Guidelines

§ 795.223 Pharmacokinetic test.

(a) *Purpose.* The purpose of these tests is to determine:

(1) The bioavailability of a test substance after dermal administration.

(2) Whether or not the biotransformation of the test substance is qualitatively and quantitatively the same after dermal and oral administration.

(3) Whether or not the biotransformation of the test substance is changed qualitatively or quantitatively by repeated dosing.

(b) *Definitions*—(1) Bioavailability refers to the rate and extent to which the administered compound is absorbed, i.e., reaches the systemic circulation.

(2) Relative percent of percutaneous absorption is defined as 100 times the ratio between total urinary excretion of compound following topical administration and total urinary excretion of compound following intravenous injection.

(c) *Test procedures*—(1) *Animal selection*—

(i) *Species.* The species utilized for investigating the test substance shall be the rat, a species for which historical data on the toxicity and carcinogenicity of several compounds are available and which is used extensively in percutaneous absorption studies.

(ii) *Animals.* Adult female Fischer 344 rats shall be used. The rats shall be 7 to 9 weeks old and weigh 125 to 175 grams. Prior to testing the animals shall be selected at random for each group. Animals showing signs of ill health shall not be used.

(iii) *Animal care.* (A) The animals should be housed in environmentally controlled rooms with 10 to 15 air changes per hour. The rooms should be maintained at a temperature of 25±2° C and humidity of 50±10 percent with a 12-hour light/dark cycle per day. The rats should be kept in a quarantine facility for at least 7 days prior to use.

(B) During the acclimatization period, the rats should be housed in cages on hardwood chip bedding. All animals shall be provided with conventional laboratory diets and water *ad libitum.*

(2) *Administration of test substance*—(i) *Test compound.* Test studies require the use of both nonradioactive test substance and ^{14}C-labeled test substance. Both preparations are needed to investigate under paragraph (a)(2) of this section. The use ^{14}C-test substance is required to investigate under paragraphs (a)(1), (2), and (3) of this section because it will facilitate the work, improve the reliability of quantitative determinations, and increase the probability of observing the presence of previously unidentified metabolities.

(ii) *Dosage and treatment.* (A) Two doses shall be used in the study, a "low" dose and a "high" dose. When administered orally, the "high" dose level should ideally induce some overt toxicity such as weight loss. The "low" dose level should correspond to a no-effect level.

(B) The same "high" and "low" doses shall be administered orally and dermally.

(C) Oral dosing shall be performed by gavage or by administering encapsulated test substance. Whichever method is selected for this study shall be the same as used for the 90-day oral subchronic toxicity testing conducted for comparison purposes.

(D) For dermal treatment, the doses shall be applied at a volume adequate to deliver the prescribed doses. The backs of the rats should be lightly shaved with an electric clipper shortly before treatment. The dose shall be applied with a micropipette on 2 cm^2 of the freshly shaven skin. The dosed areas shall be occluded with an aluminum foil patch which is secured in place with adhesive tape.

(iii) *Bioavailability study in rats.* At least eight rats shall receive a single intravenous (low) dose of ^{14}C-test substance and serial samples of blood removed from four animals at 15 minutes, 30 minutes, 1 hour, 8 hours, 24 hours, 48 hours, and 96 hours. All animals shall be housed in metabolism cages and urine and feces collected at 8, 24, 48, 72, and 96 hours. The procedure shall be repeated with eight rats in which ^{14}C-test substance is maintained in contact with the skin for the duration of the study (96 hours). If dermal adsorption cannot be demonstrated, the study should be repeated using a higher dose. Total radioactivity shall be measured in the blood, urine, and feces samples collected from all animals. The results shall be used to construct a blood concentration-time curve and to calculate bioavailability by the ratio of the total 96-hour urinary excretion of radioactivity after dermal and intravenous administration. Bioavailability is expressed as (percent dose dermal/percent dose intravenous)×100=percent dermal absorption. Urine shall be saved for metabolite identification, if it becomes necessary.

(iv) *Biotransformation in rats after oral and dermal administration.* Eight rats shall be dosed orally, and eight rats shall be dosed dermally (96-hour contact) with the high dose of ^{14}C-test substance. The results of the bioavailability study (see paragraph (c)(2)(iii) of this section shall be evaluated first to ensure that the dermal dose applied will result in the appearance of radioactivity in the urine. All animals shall be housed in metabolism cages allowing for separate collection of urine and feces at 8, 24, 48, 72, and 96 hours. The parent compound and any metabolite that comprises greater than 10 percent of the dose shall be identified in the urine. These results shall be qualitatively compared to the urinary excretion data obtained in the low dose bioavailability study (see paragraph (c)(2)(iii) of this section); metabolites in the low dose urine shall also be identified if a different pattern of metabolism is evident.

(v) *Repeated dosing study.* Four rats shall receive a series of single daily oral doses of nonradioactive test substance over a period of at least 14 days, followed at 24 hours after the last dose by a single oral dose of ^{14}C-test substance. Each dose shall be at the low-dose level. If the pattern of urinary metabolite excretion is qualitatively different from that obtained with the orally dosed animals in the single-dose biotransformation study at 24 and 48 hours (see paragraph (c)(2)(iv) of this section), metabolites shall be identified in accordance with the procedure given in paragraph (c)(2)(iii) of this section.

(vi) *Skin washing study.* If greater than 10 percent of test substance is absorbed through the skin (see paragraphs (c)(2) (ii) and (iii) of this section) then a washing efficacy

experiment shall be performed to assess the extent of removal of the applied test substance by washing with soap and water. Four rats should be lightly anesthetized and treated with a dermal dose of test compound previously shown to result in measurable percutaneous absorption greater than 10 percent. Soon after application (5 to 10 minutes) the treated animals shall be washed with soap and water, then housed in individual metabolism cages for excreta collection. Measurements of total radioactivity in urine and feces shall be made in the same manner as described in paragraph (c)(2)(iii) of this section.

(d) *Data and Reporting*—(1) *Treatment of results.* Data shall be summarized in tabular form.

(2) *Evaluation of results.* All observed results, quantitative or incidental, shall be evaluated by an appropriate statistical method.

(3) *Test report.* In addition to the reporting requirements as specified in the TSCA Good Laboratory Practice Standards, 40 CFR Part 792, Subpart J, the following specific information shall be reported:

(i) Species, strain, and supplier of laboratory animals.

(ii) Information on the degree (i.e., specific activity for a radiolabel) and site(s) of labeling of the test substances.

(iii) A full description of the sensitivity and precision of all procedures used to produce the data.

(iv) Relative percent absorption by the dermal route for rats administered low and high doses of ^{14}C-test substance, compared with 100 percent of the intravenous dose.

(v) Quantity of isotope, together with percent recovery of the administered dose, in feces, urine, and blood.

(vi) Biotransformation pathways and quantities of the test substance and metabolites in urine collected after administering single high and low oral and dermal doses.

(vii) Biotransformation pathways and quantities of test substance and metabolites in urine collected after administering repeated low doses of test substance to rats.

§ 795.260 Subchronic oral toxicity test.

(a) *Purpose.* In the assessment and evaluation of the toxic characteristics of a test substance, the determination of subchronic oral toxicity may be carried out after initial information on toxicity has been obtained by acute testing. The subchronic oral study has been designed to permit the determination of the no-observed-effect level and toxic effects associated with continuous or repeated exposure to a test substance for a period of 90 days. The test is not capable of determining those effects that have a long latency period for development (e.g., carcinogenicity and life shortening). It provides information on health hazards likely to arise from repeated exposure by the oral route over a limited period of time. It will provide information on target organs, the possibilities of accumulation, and can be of use in selecting dose levels for chronic studies and for establishing safety criteria for human exposure.

(b) *Definitions.* (1) Subchronic oral toxicity is the adverse effects occurring as a result of the repeated daily exposure of experimental animals to a chemical for a part (approximately 10 percent for rats) of a life span.

(2) Dose is the amount of test substance administered. Dose is expressed as weight of test substance (g, mg) per unit weight of test animal (e.g., mg/kg), or as weight of test substance per unit weight of food or drinking water.

(3) No-effect level/No-toxic-effect level/No-adverse-effect level/No-observed-effect level is the maximum dose used in a test which produces no observed adverse effects. A no-observed-effect level is expressed in terms of the weight of a substance given daily per unit weight of test animal (mg/kg). When administered to animals in food or drinking water, the no-observed-effect level is expressed as mg/kg of food of mg/ml of water.

(4) Cumulative toxicity is the adverse effects of repeated doses occurring as a result of prolonged action on, or increased concentration of, the administered substance or its metabolites in susceptible tissue.

(c) *Principle of the test method.* The test substance is administered orally in graduated daily doses to several groups of experimental animals, one dose level per group, for a period of 90 days. During the period of administration the animals are observed daily to detect signs of toxicity. Animals which die during the period of administration are necropsied. At the conclusion of the test all animals are necropsied and histopathological examinations carried out.

(d) *Test procedures*—(1) *Animal selection*—

(i) *Species.* Rats and mice shall be used.

(ii) *Age.* (A) Young adult animals shall be employed. At the commencement of the study the weight variation of animals used shall not exceed ± 20 percent of the mean weight for each sex.

(B) Dosing shall begin as soon as possible after weaning, ideally before the animals are 6 weeks old, and in any case not more than 8 weeks old.

(iii) *Sex.* (A) Equal numbers of animals of each sex should be used at each dose level.

(B) The females should be nulliparous and non-pregnant.

(iv) *Numbers.* (A) At least 20 rats and 20 mice (10 females and 10 males of each species) shall be used at each dose level.

(B) If interim sacrifices are required, the number shall be increased by the number of animals scheduled to be sacrificed before the completion of the study.

(2) *Control groups.* A concurrent control group is required. This group shall be an untreated or sham-treated control group or, if a vehicle is used in administering the test substance, a vehicle control group. If the toxic properties of the vehicle are not known or cannot be made available, both untreated and vehicle control groups are required.

(3) *Satellite group.* A satellite group of 20 rats and 20 mice (10 females and 10 males of each species) shall be treated with the high dose level for 90 days and observed for reversibility, persistence, or delayed occurrence of toxic effects for a post-treatment period of not less than 28 days.

(4) *Dose levels and dose selection.* (i) In subchronic toxicity tests, it is desirable to have a dose response relationship as well as no-observed-toxic-effect level. Therefore, at least three dose levels with a control and, where appropriate, a vehicle control (corresponding to the concentration of vehicle at the highest exposure level) shall be used. Doses should be spaced appropriately to produce test groups with a range of toxic effects. The data shall be sufficient to produce a dose-response curve.

(ii) The highest dose level shall result in toxic effects but not produce an incidence of fatalities which would prevent a meaningful evaluation.

(iii) The lowest dose level shall not produce any evidence of toxicity. Where there is a usable estimation of human exposure the lowest dose level shall exceed this.

(iv) Ideally, the intermediate dose level(s) should produce minimal observable toxic effects. If more than one intermediate dose is used, the dose levels should be spaced to produce a gradation of toxic effects.

(v) The incidence of fatalities in low and intermediate dose groups and in the controls should be low to permit a meaningful evaluation of the results.

(5) *Exposure conditions.* Ideally the animals should be dosed with the test substance on a 7-day per week basis

over a period of 90 days. However, based primarily on practical considerations, dosing by gavage or capsule studies on a 5-day per week basis shall be acceptable.

(6) *Observation period.* (i) Duration of observation shall be for at least 90 days.

(ii) Animals in the satellite group scheduled for followup observations shall be kept for not less than 28 days without treatment to detect recovery from, or persistence of, toxic effects.

(7) *Administration of the test substance.* (i) The test substance shall be administered in the diet or in capsules. Alternatively, it may be administered by gavage or in the drinking water.

(ii) All animals shall be dosed by the same method during the entire experimental period.

(iii) Where necessary, the test substance is dissolved or suspended in a suitable vehicle. If a vehicle or diluent is needed, ideally it should not elicit important toxic effects itself nor substantially alter the chemical or toxicological properties of the test substance. It is recommended that wherever possible the usage of an aqueous solution be considered first, followed by consideration of a solution of oil, and then by possible solution in other vehicles.

(iv) For substances of low toxicity, it is important to ensure that when administered in the diet the quantities of the test substance involved do not interfere with normal nutrition. When the test substance is administered in the diet, either a constant dietary concentration (ppm) or a constant dose level in terms of the animals' body weight shall be used; the alternative used shall be specified.

(v) For a substance administered by gavage or capsule, the dose shall be given at similar times each day, and adjusted at intervals (weekly or biweekly) to maintain a constant dose level in terms of animal body weight.

(8) *Observation of animals.* (i) Each animal shall be handled and its physical condition appraised at least once each day.

(ii) Additional observation shall be made daily with appropriate actions taken to minimize loss of animals to the study (e.g., necropsy or refrigeration of those animals found dead and isolation or sacrifice of weak or moribund animals).

(iii) Signs of toxicity shall be recorded as they are observed including the time of onset, degree, and duration.

(iv) Cage-side observations shall include, but not be limited to, changes in skin and fur, eyes and mucous membranes, respiratory, circulatory, autonomic and central nervous systems, somatomotor activity, and behavior pattern.

(v) Measurements shall be made weekly of food consumption or water consumption when the test substance is administered in the food or drinking water, respectively.

(vi) Animals shall be weighed weekly.

(vii) At the end of the 90-day period all survivors in the nonsatellite treatment group shall be sacrificed. Moribund animals shall be removed and sacrificed when noticed.

(9) *Clinical examinations.* (i) The following examinations shall be made on at least five animals of each sex in each group of rats.

(A) Certain hematology determinations shall be carried out just prior to terminal sacrifice at the end of the test period. The following hematology determinations shall be carried out: Hematocrit, hemoglobin concentration, erythrocyte count, total and differential leucocyte count, and a measure of clotting potential such as clotting time, prothrombin time, thromboplastin time, or platelet count.

(B) Certain clinical biochemistry determinations shall be carried out just prior to terminal sacrifice at the end of the test period. The following clinical biochemical test areas shall be carried out: Electrolyte balance, carbohydrate metabolism, and liver and kidney function. The selection of additional tests shall be influenced by observations on the mode of action of the substance. Suggested additional determinations include: calcium, phosphorus, chloride, sodium, potassium, fasting glucose (with period of fasting appropriate to the species/breed), serum glutamic-pyruvic transaminase (now known as serum alanine aminotransferase), serum glutamic oxaloacetic transaminase (now known as serum aspartate aminotransferase), ornithine decarboxylase, gamma glutamyl transpeptidase, urea nitrogen, albumen, blood creatinine, total bilirubin, and total serum protein measurements. Other determinations which may be necessary for an adequate toxicological evaluation include analyses of lipids, hormones, acid/base balance, methemoglobin, and cholinesterase activity. Additional clinical biochemistry may be employed where necessary to extend the investigation observed effects.

(ii) The following examinations shall be made on at least five animals of each sex in each group.

(A) Ophthalmological examination, using an ophthalmoscope or equivalent suitable equipment, shall be made prior to the administration of the test substance and at the termination of the study. If changes in the eyes are detected, all animals shall be examined.

(B) Urinalysis is required only when there is an indication based on expected or observed toxicity.

(10) *Gross necropsy.* (i) All animals shall be subjected to a full gross necropsy which includes examination of the external surface of the body, all orifices, and the cranial, thoracic and abdominal cavities and their contents.

(ii) At least the liver, kidneys, adrenals, gonads, and brain shall be weighed wet, as soon as possible after dissection to avoid drying.

(iii) The following organs and tissues, or representative samples thereof, shall be preserved in a suitable medium for possible future histopathological examination: All gross lesions; brain—including sections of medulla/pons, cerebellar cortex and cerebral cortex; pituitary; thyroid/parathyroid; thymus; lungs; trachea; heart; sternum with bone marrow; salivary glands; liver; spleen; kidneys/adrenals; pancreas; gonads; uterus; accessary genital organs (epididymis, prostrate, and, if present, seminal vesicles); aorta; (skin), (non-rodent gall bladder); esophagus; stomach; duodenum; jejunum; ileum; cecum; colon; rectum; urinary bladder; representative lymph node; (mammary gland), (thigh musculature), peripheral nerve; (eyes), (femur including articular surface), (spinal cord at three levels—cervical, midthoracic and lumbar); and, (rodent-exorbital lachrymal glands).

(11) *Histopathology.* (i) Full histopathology shall be performed on the organs and tissues, listed under paragraph (d)(10) (ii) and (iii) of this section of all animals in the control and high-dose groups, and all animals that died or were killed during the study.

(ii) Histopathology shall be performed on all gross lesions in all animals.

(iii) Histopathology shall be performed on target organs in all animals.

(iv) Histopathology shall be performed on the tissues mentioned in brackets under paragraph (d)(10)(iii) of this section if indicated by signs of toxicity or target organ involvement.

(v) Histopathology shall be performed on lungs, liver, and kidneys of all animals. Special attention to examination of the lungs should be made for evidence of infection since this provides a convenient assessment of the state of health of the animals.

(vi) For the satellite group, histopathology shall be performed on tissues and organs identified as showing effects in the treated groups.

(e) *Data and reporting*—(1) *Treatment of results.*

(i) Data shall be summarized in tabular form, showing for each test group the number of animals at the start of the test, the number of animals showing lesions, the type of lesions, and the percentage of animals displaying each type of lesion.

(ii) All observed results, quantitative and incidental, shall be evaluated by an appropriate statistical method. Any generally acceptable statistical methods may be used; the statistical methods should be selected during the design of the study.

(2) *Evaluation of the study results.* (i) The findings of a subchronic oral toxicity study should be evaluated in conjunction with the findings of preceding studies and considered in terms of the toxic effects and the necropsy and histopathological findings. The evaluation shall include the relationship between the dose of the test substance and the presence or absence, the incidence and severity, of abnormalities, including behavioral and clinical abnormalities, gross lesions, identified target organs, body weight changes, effects on mortality and any other general or specific toxic effects. The test shall provide a satisfactory estimation of a no-effect level.

(ii) In any study which demonstrates an absence of toxic effects, further investigation to establish absorption and bioavailability of the test substance shall be considered.

(3) *Test report.* In addition to the reporting requirements as specified in the TSCA Good Laboratory Practice Standards, Subpart J of Part 792 of this chapter, the following specific information shall be reported:

(i) *Group animal data.* Tabulation of toxic response data by species, strain, sex, and exposure level for:

(A) Number of animals dying.

(B) Number of animals showing signs of toxicity.

(C) Number of animals exposed.

(ii) *Individual animal data.* (A) Time of death during the study or whether animals survived to termination.

(B) Time of observation of each abnormal sign and its subsequent course.

(C) Body weight data.

(D) Food consumption data when collected.

(E) Hematological tests employed and all results.

(F) Clinical biochemistry tests employed and all results.

(G) Necropsy findings.

(H) Detailed description of all histopathological findings.

(I) Statistical treatment of results where appropriate.

PART 799—[AMENDED]

2. In Part 799:

a. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

b. By adding § 799.1650, to read as follows:

§ 799.1650 2-Ethylhexanoic acid.

(a) *Identification of test substance.* (1) 2-Ethylhexanoic acid (CAS No. 149–57–5) (hereinafter "EHA") shall be tested in accordance with this section.

(2) EHA of at least 99-percent purity shall be used as the test substance.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture or process EHA other than as an impurity from the effective date of this section, December 20, 1986, to the end of the reimbursement period shall submit an exemption application, or shall submit a letter of intent to conduct testing, study plans, conduct tests, and submit data as specified in this section, Subpart A of this Part, and Parts 790 and 792 of this chapter. The end of the reimbursement period shall be 5 years after the submission of the last final report required under this test rule.

(c) *Health effects testing*—(1) *Pharmacokinetics*—

(i) *Required testing.* Metabolism studies of the oral and dermal routes of exposure shall be conducted with EHA using Fischer 344 rats in accordance with the test standard specified in § 795.223 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 45 days prior to initiating testing.

(B) An interim progress report shall be provided to the Agency 6 months after the effective date of the final test rule.

(C) The final report of results shall be submitted to the Agency no later than 1 year from the effective date of the final test rule.

(2) *Subchronic toxicity*—(1) *Required testing.* Subchronic toxicity tests shall be conducted with EHA using Fischer 344 rats and B6C3F1 mice in accordance with the test standard specified in § 795.260 of this chapter.

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 45 days prior to initiating testing.

(B) Interim progress reports shall be provided to the Agency 6 months and 12 months after the effective date of the final test rule.

(C) The final report of results shall be submitted to the Agency no later than 15 months from the effective date of the final test rule.

(3) *Administration of test substance.* Oral dosing for testing required under paragraph (c) (1) and (2) of this section shall be by the same method for both tests, as specified in § 795.223(c)(2)(ii)(C) of this chapter.

(4) *Development toxicity*—(i) *Required testing.* Developmental toxicity tests shall be conducted with EHA using one rodent and one nonrodent mammalian species in accordance with the OECD guideline entitled "Teratogenicity", No. 414, adopted May 12, 1981. The OECD guideline is available in OECD Publication No. ISBN 92–64–12221–4 and is sold by the OECD Publication and Information Center, Room Number 1207, 1750 Pennsylvania Avenue, NW., Washington, DC. Copies of this document may be inspected at the Office of the Federal Register, 1100 L Street, NW., Room 8401, Washington, DC, or the OPTS Reading Room (docket No. OPTS–42065), Room N.E.–G004, Environmental Protection Agency, 401 M Street, SW., Washington, DC. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. These materials are incorporated as they exist on the effective date of this rule; a notice of any change will be published in the **Federal Register.**

(ii) *Reporting requirements.* (A) Study plans shall be provided to the Agency at least 45 days prior to initiating testing.

(B) Interim progress reports shall be provided to the Agency 6 months and 12 months after the effective date of the final test rule.

(C) The final report of results shall be submitted to the Agency no later than 18 months from the effective date of the final test rule.

(Information collection requirements are approved by the Office of Management and Budget under control number 2070–0033.)

[FR Doc. 86–24992 Filed 11–5–86; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA–6728]

Changes in Flood Elevation Determinations; Illinois; Correction

AGENCY: Federal Emergency Management Agency.

ACTION: Interim rule; correction.

SUMMARY: This document corrects a Notice of Changes in Flood Elevation Determinations previously published at 51 FR 31635 on September 4, 1986. This correction notice provides a more accurate representation of the dates the newspaper notice was published for the Village of Lincolnshire, Lake County, Illinois.

FOR FURTHER INFORMATION CONTACT: Mr. John Matticks, Acting Chief, Risk Studies Division, Federal Insurance Administration, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2767.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency gives notice of the correction to the Notice of Changes in Flood Elevation Determinations for selected locations in the Village of Lincolnshire previously published at 51 FR 31635 on September 4, 1986, in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 44 CFR Part 65.

On page 31635, in the September 4, 1986 issue of the **Federal Register**, entry under "Illinois: Lake, Village of Lincolnshire", is corrected to read as follows:

State and county	Location	Date and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Illinois: Lake	Village of Lincolnshire	August 28, 1986, September 4, 1986, The Deerfield Review.	The Honorable Evelyn Cooper, Mayor, Village of Lincolnshire, 175 Olde Half Day Road, Lincolnshire, Illinois 60069.	July 24, 1986	170378

Issued: October 30, 1986.

Harold T. Duryee,

Administrator, Federal Insurance Administration.

[FR Doc. 86-25080 Filed 11-5-86; 8:45 am]

BILLING CODE 6718-03-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Administration

48 CFR Parts 2413 and 2433

[Docket No. R-86-1263; FR-2098]

Implementation of the Competition in Contracting Act of 1984 Into the HUD Acquisition Regulation

AGENCY: Office of the Assistant Secretary for Administration, HUD.

ACTION: Final rule.

SUMMARY: This final rule adopts the interim rule for the implementation of the Competition in Contracting Act of 1984 (CICA) into the HUD Acquisition Regulation (HUDAR), which was published in the **Federal Register** of November 8, 1985 (50 FR 46572). In addition, it revises the interim rule to reflect the broadened authority of the General Accounting Office (GAO) under CICA to decide bid protests and GAO's recent decision in *Matter of CoMont, Inc.* that GAO has jurisdiction to decide protests of National Housing Act procurements. This rule also revises the interim rule to reflect current procedures for the Department's treatment of bid protests and to delegate to the Senior Procurement Executive the authority to establish further procedures for the use of imprest funds in accordance with Treasury requirements.

DATE: *Effective Date:* Upon expiration of the first period of 30 calendar days of continuous session of Congress after publication, but not before further notice of the effective date is published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Edward L. Girovasi, Jr., Director, Policy and Evaluation Division, Office of Procurement and Contracts, telephone (202) 755-5294. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

The uniform regulation for the procurement of supplies and services by Federal departments and agencies, the Federal Acquisition Regulation (FAR), was promulgated on September 19, 1983 (48 FR 42102). The FAR is codified in Title 48, Chapter 1 of the Code of Federal Regulations. The FAR has been signficantly revised to implement the Competition in Contracting Act of 1984 (CICA) (41 U.S.C. 253, 41 U.S.C. 403, and 31 U.S.C. 3551-3556).

HUD promulgated its regulations to implement the FAR on March 1, 1984 (49 FR 7696). The HUD Acquisition Regulation (HUDAR) was revised in an interim rule published in the **Federal Register** of November 8, 1985 (50 FR 46572) to implement CICA. This interim rule was later amended by technical corrections published in the **Federal Register** of March 7, 1986 (51 FR 7947). (For a description of the pertinent regulatory provisions of the FAR, the HUDAR, and the CICA, see 50 FR 46572-46574, November 8, 1985.)

II. Interim Rule for the Implementation of CICA

The interim HUDAR rule of November 8, 1985 supplemented the FAR procedures for the implementation of CICA. In particular, the interim rule supplemented the FAR in the following topic areas: (1) The designation of certain managers and staff in HUD to carry out various competition in contracting requirements, (2) the designation of "competition advocates" to implement certain responsibilities under CICA, and (3) the establishment of bid protest procedures implementing various functions under CICA. Because of the possibility of public interest in portions of the rule, the Department published these HUDAR changes as interim rulemaking and provided for a public comment period of 60 days. No public comments were received. However, HUD has determined that several revisions to the interim rule are necessary to accord with the Department's current procurement procedures.

III. Revisions to the Interim Rule

A. Authority of GAO for the Resolution of Bid Protests

Section 2741 of CICA (31 U.S.C. 3551-3556) modified Federal procurement law affecting procedures for bid protests. In particular, section 2741 of CICA specifically authorizes the Comptroller General of the General Accounting Office (GAO) to decide bid protests concerning procurement decisions of Federal agencies. FAR Subpart 33.1 (Protests) and Subpart 33.2 (Disputes and Appeals) implement those procedures, with certain exemption. HUDAR Part 2433 of the interim rule implemented CICA section 2741 and established procedures for the consideration of bid protests.

In *Matter of CoMont, Inc.* B-219730 (November 15, 1985), the Comptroller General has determined that bid protests of procurement contracts awarded under the National Housing Act (NHA), 12 U.S.C. 1702, are subject to

GAO's statutory authority under CICA to decide protests of procurements by Federal agencies. Prior to the enactment of CICA, the Comptroller General has held that GAO lacked jurisdiction to decide protests of National Housing Act procurements.

Because GAO may now consider NHA bid protests, the Department is revising the bid protest provisions of the HUDAR to cover protests of departmental procurements awarded under the authority of the NHA. Accordingly, this rule deletes the exemption in HUDAR Part 2433.000 for procurements under the Acquired Property Program. (In addition, the Department has promulgated a final rule (which was published in the **Federal Register** of August 7, 1986, 51 FR 28364) rescinding the authority of the HUD Board of Contract Appeals to decide bid protests of NHA contracts.) As a result of today's rule, interested parties protesting future departmental procurements under the NHA will file their protests with the Contracting Officer or GAO.

This rule also revises HUDAR 2433.104(f) which involves situations where HUD decides not to comply with a GAO recommendation on a bid protest. Under current HUDAR 2433.104(f), the Head of the Contracting Activity (HCA) must report to GAO if HUD has decided not to comply with a GAO recommendation concerning a bid protest against a HUD procurement decision. Under this revision to the HUDAR, the HCA must obtain the concurrence of the Senior Procurement Executive (the Assistant Secretary for Administration) and the Office of General Counsel if he or she decides not to comply with a GAO recommendation. The purpose for this revision is to ensure that this decision by the HCA will be approved by the HUD official who has been delegated authority to set HUD procurement policy and by counsel.

In addition, HUDAR 2433.104–70 is added, to provide for notice procedures to GAO on protests filed for procurements under the Department's Acquired Property Program. This section provides for HUD Headquarters' review of proposals not to implement a GAO recommendation by requiring the HCA to notify the Reconditioning and Contracting Branch, Office of Multifamily Housing of its proposal within 30 days of receiving GAO's recommendation. The Chief of the Reconditioning and Contracting Branch shall then notify GAO a HUD's decision not to comply with GAO's recommendation.

B. Authority of the GSBCA for the Resolution of ADP Bid Protests

Section 2713 of CICA provides that a protest against a Federal agency's awarding of an automated data processing (ADP) procurement may now be filed with the General Services Board of Contract Appeals (GSBCA). The GSBCA has the authority to make a final determination concerning such protests, and pending its decision and at the request of an interested party, the GSBCA may suspend the agency's procurement authority to acquire further goods or services under the protested contract. The GSBCA will suspend the procurement authority unless the agency establishes that urgent and compelling circumstances significantly affecting the interests of the United States will not permit waiting for the decision of the Board. GSBCA's procedures require that the urgent and compelling circumstances must be established by a Determination and Finding (D&F) executed by the agency head or designee. FAR 33.105 states procedures for filing and resolution of these protests.

Under the current HUDAR 2433.105(d)(2), the HCA has the authority to execute the Determination and Finding (D&F) that establishes the circumstances for GSBCA's not suspending the Department's authority to award an ADP procurement. This revision to HUDAR 2433.105(d)(2) requires that the Assistant Secretary for Administration execute the D&F. The purpose of this revision is to ensure that the individual responsible for both ADP and procurement policy executes the D&F.

C. Imprest Fund Limitations

The addition of HUDAR 2413.404(a) delegates to the Senior Procurement Executive the authority to establish additional procedures for the use of imprest funds in accordance with Treasury requirements.

IV. Miscellaneous

A. Executive Order 12291

This rule does not constitute a "major rule" as that term is defined in section 1(b) of Executive Order 12291. The rule does not: (1) Have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local agencies or geographic regions; or (3) have significant adverse effect on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. This rule involves modifications of various departmental procedures for HUD procurement activities. These modifications will not affect specific HUD contractors or prospective contractors, but rather revise the procedures for HUD procurement decisions. In addition, the revisions to HUDAR Part 2433 merely implement certain precedents set by the Comptroller General.

B. Regulatory Flexibility Act

Consistent with the provisions of section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601), the Undersigned certifies that this rule does not have a significant economic impact on a substantial number of small entities because to the extent changes are made to current regulations, they are designed to foster and promote participation of small entities in the Department's procurement program.

C. Paperwork Reduction Act

HUDAR 2401.105 of this interim rule states that under the Paperwork Reduction Act of 1980 (44 U.S.C. 3520), information collection requests covered by the Act have been approved by OMB. This final rule refers to departmental procedures for HUD procurement activities and does not involve additional information collection burdens to those in the May 1984 HUDAR.

The following OMB control number applies for information collection requests under this final rule: OMB Approval Number 2535–0091. The expiration date is March 31, 1987. This OMB approval refers to the following information collection activities: (1) Organizational conflict of interest disclosure or representation (2409.504(a)); (2) organizational conflict of interest clause (2409.504(b)); (3) determination of award fee earned clause (2416.405(e)(1)); and (4) certification of status as a Minority Business Enterprise (MBE) (2421.103).

D. National Environmental Policy Act

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR Part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the General Counsel, Rules Docket Clerk, Room 10276, 451 Seventh Street, SW., Washington, DC 20410.

E. Administrative Procedure Act

With the exception of revisions to HUDAR Parts 2413 and 2433, the text of this rule is identical to the interim rule published on November 8, 1985 as amended by a March 7, 1986 final rule making minor technical corrections. The Department traditionally has provided for prior notice and comment even when not required by the Administrative Procedure Act (*see* 24 CFR 10.1). Although this is the general policy of the Department, we have determined, with respect to the largely procedural revisions to HUDAR 2413 and 2433 contained in this rule, that it is unnecessary to delay promulgation. The revisions to the interim rule implement the *CoMont* decision of the Comptroller General and provide other revisions to include the Department's Senior Procurement Executive in certain HUD procurement decisions.

F. Department's Semiannual Agenda of Regulations

This final rule is listed as item 948 in the Department's Semiannual Agenda of Regulations published on October 27, 1986 (51 FR 38424, 38465) under Executive Order 12291 and the Regulatory Flexibility Act.

List of Subjects in 48 CFR Parts 2413 and 2433

Government procurement.

Accordingly, the interim rule published on June 6, 1984 (50 FR 46572) as amended by a March 7, 1986 final rule (51 FR 7947) making technical revisions is adopted as final without further change, except as indicated below.

PART 2413—SMALL PURCHASE AND OTHER SIMPLIFIED PURCHASE PROCEDURES

1. The authority citation for 48 CFR Part 2413 is revised to read as follows:

Authority: Section 205(c) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 486(c)); sec. 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

2. The Table of Contents for Part 2413 is revised to read as follows:

Subpart 2413.4—Imprest Fund

Sec.
2413.403 Agency responsibilities.
2413.404 Conditions for use.

3. A new 2413.404 is added, to read as follows:

§ 2413.404 Conditions for use.

(a) The transaction does not exceed $500 or such other limits as have been approved by the Senior Procurement Executive;

PART 2433—PROTESTS, DISPUTES, AND APPEALS

4. The authority citation for 48 CFR Part 2433 continues to read as follows:

Authority: Competition in Contracting Act of 1984 (31 U.S.C. 3551–3556); sec. 205(c) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 486(c)); sec. 7(d) of the Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

5. The Table of Contents for Part 2433 is revised to read as follows:

Sec.
2433.000 Scope of part.

Subpart 2433.1—Protests

2433.101–70 Definitions.
2433.102 General.
2433.102–70 Responsibility.
2433.103 Protests to the agency.
2433.103–70 Times for filing
2433.103–71 Agency decision.
2433.104 Protests to GAO.
2433.104–70 Notice to GAO on protests filed under the Acquired Property Program.
2433.105 Protests to GSBCA.

6. HUDAR 2433.000 is revised to read as follows:

2433.000 Scope of part.

This part identifies the responsible agents and sets forth procedural requirements for handling protests.

7. HUDAR 2433.104, paragraph (f) is revised to read as follows:

2433.104 Protests to GAO.

* * * * *

(f) *Notice to GAO.* If the HCA proposes not to comply with a GAO recommendation concerning the resolution of a protest of a procurement award, prior to reporting to the Comptroller General concerning that decision, the HCA shall obtain the concurrence of the Office of General Counsel and the Senior Procurement Executive.

8. HUDAR 2433.104–70 is added, to read as follows:

2433.104–70 Notice to GAO on protests filed under the Acquired Property Program.

With respect to protests filed under the Office of Housing's Acquired Property Program, the HCA shall notify the Reconditioning and Contracting Branch, Office of Multifamily Housing Management in the event that he or she proposes not to comply with a GAO recommendation concerning the resolution of a protest. The notification shall be in writing, shall include supporting documentation and a rationale, and shall be submitted to the Reconditioning and Contracting Branch within 30 days from the date of the Department's receipt of GAO's decision. The Reconditioning and Contracting Branch shall obtain the concurrence of the Office of General Counsel and the Senior Procurement Executive. The Chief, Reconditioning and Contracting Branch shall then notify the Comptroller General of the Department's decision not to comply with GAO's recommendation.

9. HUDAR 2433.105 is revised to read as follows:

2433.105 Protests to GSBCA.

(d)(2) The Determination and Findings (D&F) establishing the circumstances for not suspending the Department's procurement authority shall be executed by the Assistant Secretary for Administration.

Dated: October 22, 1986.

Judith L. Tardy,

Assistant Secretary for Administration.

[FR Doc. 86–25089 Filed 11–5–86; 8:45 am]

BILLING CODE 4210–01–M

Proposed Rules

Federal Register
Vol. 51, No. 215
Thursday, November 6, 1986

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

Production and Utilization Facilities; Request for Comments on Development of Policy for Nuclear Power Plant License Renewal

AGENCY: Nuclear Regulatory Commission.

ACTION: Policy statement: Request for comments.

SUMMARY: In light of the industry and government initiatives which are already underway, the U.S. Nuclear Regulatory Commission (the Commission) is considering the development of a regulatory policy on extending nuclear power plant licenses beyond 40 years. In order to solicit early comments from the public, industry and other government agencies on various issues that will require timely resolution, responses to questions bearing on the issues that the Commission has identified to date are being solicited via this notice of a Request for Comments on Development of Policy for Nuclear Power Plant License Renewal.

DATE: The comment period expires January 5, 1987.

ADDRESSES: Send written comments or suggestions to the Secretary of the Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of comments received by the Commission may be examined at the NRC Public Document Room, 1717 H Street NW., Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Jerry E. Jackson, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555 Telephone (301) 492–8544.

SUPPLEMENTARY INFORMATION: In the early part of the twenty-first century, a significant number of the licenses for the existing operating nuclear power plants are due to expire. Without renewal of these licenses, these plants will be shut down and their generating capacity will be lost. If this potential loss of generating capacity is combined with potential losses of electric generating capacity from other existing non-nuclear sources, the electric power which would have to be supplied from new generating capacity is substantial. In response to their recognition of this situation and the necessity to address life extension issues early, the utilities, industry and the Department of Energy (DOE) are sponsoring programs to study plant life extension for both nuclear and non-nuclear generating plants.

The Commission recognizes the long term nature of the issues and believes that it may be desirable to develop an agency policy at this time to help assure that issues which could affect public health and safety are identified and resolved in a timely manner. And, further, it would be a help in planning for the nation's long term stable supply of commercial nuclear energy. In addition, although not all issues can be resolved at this time, it may be useful at this time to develop a unified approach to the extension of operating licenses beyond 40 years. The Commission also believes that the operating performance of nuclear power plants, especially in the 10 to 20 years prior to the end of a plant's operating license term will be a significant factor in its determination of any license extension. Therefore, it is the Commission's intention that any license extension and the conditions for extending a license will take into account the operating performance history of the power plant.

Applicable Statutory Requirements

The current regulatory requirements for extending a plant's operating license are quite general. Chapter 10, section 103(c) of the Atomic Energy Act of 1954, as amended, states:

> Each license shall be issued for a specified period, as determined by the Commission, depending on the type of activity to be licensed, but not exceeding forty years, and may be renewed upon the expiration of such period.

10 CFR 50.51 reflects this requirement and states:

> Each license will be issued for a fixed period of time to be specified in the license but in no case to exceed 40 years from the date of issuance . . . . Licenses may be renewed by the Commission upon the expiration of the period.

Another important provision is stated in Title 5 of the U.S. Code, Chapter 5, Subchapter II, section 558(c):

> . . . When the licensee has made timely and sufficient application for a renewal or a new license in accordance with agency rules, a license with reference to an activity of a continuing nature does not expire until the application has been fully determined by the agency.

10 CFR 2.109 implements this provision by providing that:

> If, at least thirty (30) days prior to the expiration of an existing license authorizing any activity of a continuing nature, a licensee files an application for a renewal or for a new license for the activity so authorized, the existing license will not be deemed to have expired until the application has been finally determined.

Current NRC Initiatives

In its 1986 Policy and Planning Guidance, the Commission has stated:

> Requests for an operating license renewal are to be anticipated and will require advanced planning and analysis. The Commission intends to continue development of the policies and criteria to define requirements for operating license extensions to help assure that industry's efforts in this area are focused on the primary regulatory concerns.

The following guidance is provided to the staff to implement this policy:

> In view of industry initiatives to address operating license renewals, the staff should propose policy guidance and develop licensing criteria to define requirements for operating license extensions. The staff should work with industry to ensure that key regulatory issues are identified.

The NRC staff has approved limited research on nuclear power plant "aging" issues for several years. In recognition of the importance of aging issues to plant life extensions and to be responsive to the industry interests in extension of nuclear plant life extension, these efforts have been directed to consider the life extension issue. The NRC staff is in the process of developing its "Plan to Accomplish Technical Integration for Plant Aging/Life Extension." One of the primary purposes of this plan is to integrate current NRC activities in aging so that any overlaps or deficiencies in agency programs may be identified and state-of-the-art information on aging is coordinated and disseminated within the NRC and among its contractors. A key element of

this plan is the establishment of a Technical Integration Review Group for Aging and Life Extension (TIRGALEX) which will involve all interested NRC offices in the formulation and implementation of the plan.

Questions for Public Comment

To aid the NRC in developing this policy, and in its planning for timely responses to any requests for nuclear power plant operating license extensions beyond a forty-year period and to help assure that the staff and industry resources are allocated appropriately, and the relevant programs are coordinated effectively, the Commission is soliciting the public, government and industry views on the following issue questions that will require timely resolution.

1. Timeliness of Policy

(a) To what extent should the NRC proceed at this time in defining the regulatory policy which would be applicable to requests by utilities to extend the operational life of commercial light-water power reactors beyond the current forty-year operating license period?

(b) Is an effort by the Commission to formulate such policy well in advance of the expiration of operating licenses appropriate?

(c) When must such a policy be in place? What is the basis for this time?

(d) To what extent are the individual reactor licensees or industry groups acting on behalf of licensees actively planning at this time to request NRC permission for extended operation beyond the expiration of power reactor licenses?

2. Timing and Length of License Extension Requests

(a) What criteria should be applied to judge that a request for license extension is both timely and sufficient?

(b) Current regulations do not define a time limit beyond the initial 40 year term for which plants could operate while being considered for license extension. Should there be a limitation? If so, what should the limiting period beyond the 40 year term be during which a plant could continue operation while undergoing license extension review?

3. Acceptable Level of Plant Safety

(a) In additon to NRC's current requirements, how should the NRC incorporate performance based information coupled with insights derived from probabilistic risk assessment into the decision making process?

(b) Should plants applying for life extension be required to demonstrate conformance to regulations in effect on the date of the extension application? On what basis should a licensee not have to demonstrate continued conformance with applicable rules and regulations?

(c) Should the intent to operate in excess of a forty-year operating period be factored into current and future benefit-cost analyses and safety findings for backfitting considerations? If not, why not?

4. Scope of Plant Life Extension Applications

(a) Should a life extension application be for a specific period of time? If so, for what length should it be? Should the Commission specify varying requirements based on the period requested for life extension?

(b) Which, if any, of NRC's licensing criteria are not appropriate for the purpose of reviewing plant life extension requests?

(c) How and to what extent should the prior operating history of the plant be factored into considerations for license extensions?

5. Technical Considerations for Plant Life Extension

(a) Which components and structures will require residual lifetime evaluations in consideration for license extensions? What are the criteria for the selection of these components and structures?

(b) What are the major technical parameters and criteria which should be considered in NRC reviews to permit power reactor operation beyond the expiration of licenses?

(c) What additional monitoring and maintenance programs will be needed to assure safety during extended life?

(d) Which of these technical factors, including degradation processes and methods for detecting such degradation, are major "leadtime" items requiring data accumulation over the years prior to expiration of power reactor licenses?

(e) How should codes and standards be revised to support license extension?

(f) What investigations and research have been or are going on that address nuclear plant life extension? What mechanisms should be established to assure timely information exchange with the NRC to encourage communication, early consideration and avoid duplication?

6. Schedule for Resolution of Issues

(a) What overall schedule is appropriate to achieve major milestones and for resolution of the issues relative to nuclear plant license extension?

7. Procedural Considerations

(a) Should there be any procedural changes regarding future operating license extensions and current treatment of initial operating license applications? If so, what changes should be made?

(b) Please be as specific as possible, e.g., identify the specific procedural requirement and describe how it should be changed; identify whether such change can be accomplished under the current provisions of applicable statutes or whether it would involve a statutory change.

Dated at Washington, DC, this 3rd day of November 1986.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 86-25112 Filed 11-5-86; 8:45 am]

BILLING CODE 7590-01-M

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10 CFR Part 50

[Docket No. PRM-50-45]

Petition for Rulemaking, Kenneth G. Sexton; Extension of Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; extension of comment period.

SUMMARY: On October 6, 1986 (51 FR 35518), the NRC published a notice of a petiton for rulemaking filed by Kenneth G. Sexton. The petition requested that the Commission amend its regulations to require that current methodolgies and analytical techniques be used to reevaluate the established Emergency Planning Zone (EPZ) for nuclear power plants. The notice of receipt requested public comment on the petition and established a comment closing date of December 5, 1986.

In response to requests from the Nuclear Information and Resource Service and the Committee to Bridge the Gap, the NRC is extending the comment period on PRM-50-45 for 90 days from the original comment closing date.

DATES: The comment period for PRM-50-45 has been extended from December 5, 1986 to March 9, 1987.

ADDRESSES: A copy of the petition for rulemaking is available for public inspection in the Commission's Public Room, 1717 H Street, NW., Washington, DC. A copy of the petition may be obtained by writing to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

All persons desire to submit written comments concerning the petition for

rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Acting Branch Chief, Rules and Procedures Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301–492–7758 or Toll Free: 800–368–5642.

Dated at Washington, DC, this 3d day of November 1986.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 86–25111 Filed 11–5–86; 8:45am]

BILLING CODE 7590–01–M

FEDERAL TRADE COMMISSION

16 CFR Part 13

[File No. 852 3262]

International Masters Publishers Inc.; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would require, among other things, a Los Angeles mail-order seller of recipe cards to honor cancellation and return requests in a timely manner and would prohibit respondent from misrepresenting its return and cancellation policies.

DATE: Comments will be received until January 5, 1987.

ADDRESS: Comments should be addressed to: FTC/Office of the Secretary, Room 136, 6th St. and Pa. Ave. NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Janet Grady, Director, San Francisco Regional Office, Federal Trade Commission, 450 Golden Gate Ave., San Francisco, CA 94102. (415) 556–1270.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(14) of the Commission's Rules of Practice (16 CFR 4.9(b)(14)).

List of Subjects in 16 CFR Part 13

Mail-order, Recipe cards, Trade practices.

Before Federal Trade Commission

[File No. 852–3262]

Agreement Containing Consent Order to Cease and Desist

In the Matter of International Masters Publishers Inc. a corporation.

The Federal Trade Commission having initiated an investigation of certain acts and practices of International Masters Publishers Inc., a corporation, (hereinafter sometimes referred to as proposed respondent), and it now appearing that proposed respondent is willing to enter into an agreement containing an order to cease and desist from the acts and practices being investigated,

It is hereby agreed by and between International Masters Publishers Inc., and its attorney, and counsel for the Federal Trade Commission that:

1. Proposed respondent International Masters Publishers Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of California, with its offices and principal place of business located at 4929 Wilshire Blvd., Los Angeles, California 90010.

2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint here attached.

3. Proposed respondent waives:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and

d. All claims under the Equal Access to Justice Act.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by the proposed respondent that the law has been violated as alleged in the draft of complaint there attached.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to-order to proposed respondent's address as stated in this agreement shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the proposed complaint and order contemplated hereby. It understands that once the order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the order. Proposed respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order

For purposes of this Order, the following definitions shall apply:

A. "Continuity sales plan" means a sales plan requiring the consumer to receive periodic installments of merchandise or services on approval.

B. "Billing cycle" means that period of time between the sending of one scheduled invoice or billing document (whether accompanying a shipment of goods or not) and the sending of the following scheduled invoice or billing document.

C. "Return" means any item returned under the provisions of a continuity sales plan, as defined above.

D. "Received by respondent" or "receipt by respondent" includes material received at any mail drop respondent has established.

I

It is Ordered that respondent International Masters Publishers Inc. ("IMP"), its successors and assigns, and their officers, agents, representatives, and employees, directly or through any corporation, subsidiary division, or other device, in connection with the advertising, offering for sale, sale or distribution of recipe cards or any other product or service by means of a continuity sales plan in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, as amended, do forthwith cease and desist from:

A. Misrepresenting in any manner, directly or by implication, any term or condition for cancellation of enrollment or return of merchandise, or misrepresenting, in any manner, directly or by implication, any right granted to, or any duty or obligation imposed on, any consumer.

B. Failing, by the end of the first billing cycle following the billing cycle in which a consumer's request for cancellation of enrollment is received by respondent, to cancel that consumer's enrollment, and, if thereafter the consumer is contacted in connection with any obligation arising out of the enrollment, to notify that consumer in writing that the enrollment has been cancelled.

C. Sending a consumer more than one additional installment of merchandise following receipt by respondent of an enrollment cancellation request.

D. Failing, by the end of the first billing cycle following the billing cycle in which a consumer's return of merchandise or goods is received by respondent, to credit that consumer's account for the return, and, if thereafter the consumer is contacted in connection with any obligation arising out of the enrollment, to notify the consumer in writing that the account has been credited for the return; provided, however, that such written notification may be made in a scheduled billing document or in a separately mailed document.

E. Failing to include in the first communication from respondent to each consumer following enrollment in any of respondent's continuity sales programs the statement attached hereto as Attachment A, or a statement similar thereto, explaining return and cancellation policies; provided, however, that should respondent represent to consumers that cancellations of enrollment, credits for returns of merchandise, or the sending of written confirmations thereof will be accomplished in a shorter time than required under Paragraphs I B or I D of this Order, respondent, its successors and assigns, shall amend attachment A to conform with such representation.

II

It is Further Ordered that respondent International Masters Publishers Inc., its successors and assigns, and their officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, offering for sale, sale or distribution of any recipe card or other product or service in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, that any consumer's credit rating will or may be adversely affected, or representing, in any manner, directly or by implication, that there will or may be any adverse consequence to failing to pay any amount claimed to be delinquent, unless there is a reasonable likelihood such rating will be so affected or such consequence will occur.

III

It is Further Ordered that for five (5) years after the date of service of this Order respondent, its successors and assigns shall maintain, and upon written request make available to the Federal Trade Commission for inspection and copying the following records:

A. For a period of two (2) years from the date of receipt, all documents containing, reflecting, or referring to each consumer complaint relating to cancellation of enrollment in a continuity sales plans, return of merchandise, alleged billing error, or collection effort, as well as such documents or records as will disclose any response thereto.

B. For a period of one year from the date of receipt, copies of each written request for cancellation of enrollment received during the week starting with the third Monday of each month.

C. For a period of one year from the date of preparation, records sufficient to show the date on which each return of merchandise and request for cancellation was made effective.

D. For a period of two years from the date of their last use, specimen copies of all form communications, promotional materials, and advertisements as well as documents sufficient to show the period of time when such documents or materials were in use.

IV

It is Further Ordered that respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the respondent, such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation that may affect compliance obligations arising out of the Order.

V

It is Further Ordered that respondent shall, within sixty (60) days after service upon it of this Order, submit to the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this Order.

Attachment A—Important Information: Please Retain for Your Records

Returning Merchandise

To return merchandise to us at no cost to you, simply place the goods in the original package, reseal it, and deposit it in a mailbox. Please allow up to two billing cycles [number of days in two billing cycles] for us to process the return. If you receive an invoice or other request for payment for the merchandise returned, you do not need to pay it.

Cancellation Information

You may cancel your enrollment in our program by calling [number], or by writing to us at [address]. Please allow up to two billing cycles [number of days in two billing cycles] for us to process the cancellation.

In some circumstances, because of unforseen delays, you may receive one additional shipment from us. If so, merely return the merchandise and any enclosed invoice to us. You will not be charged for that shipment.

Before Federal Trade Commission

[File No. 852-3262]

Analysis of Proposed Consent Order to Aid Public Comment

In the Matter of International Masters Publishers Inc., a corporation.

The Federal Trade Commission has provisionally accepted an agreement containing a consent order to cease and desist from International Masters Publishers Inc ("IMP"). The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action, or make final the proposed order contained in the agreement.

This matter concerns representations and other actions by IMP in connection with its sale of recipe cards through a "continuity program"—*i.e.*, a sales plan requiring consumers enrolling in the program to receive periodic installments of merchandise on approval. The Commission's complaint in this matter charges that IMP represented to consumers that it would honor their enrollment cancellation requests and returns of merchandise within a reasonable period of time. In fact, the complaint alleges, in a substantial number of cases, IMP did not honor enrollment cancellation requests or returns of merchandise in a reasonable period of time. Instead, according to the complaint, a substantial number of consumers were billed and dunned by IMP and collection agencies for returned merchandise or merchandise received after they had attempted to cancel their enrollments.

The complaint also alleges that, in its attempts to collect alleged debts, IMP falsely represented to consumers that referral of their names to a designated credit reporting agency might adversely affect their ability to obtain credit for typical consumer transactions.

The consent order is designed to remedy the practices alleged, as well as to prevent IMP from engaging in similar acts and practices in the future.

Part I of the consent order addresses the issues of enrollment cancellations and returns of merchandise in connection with IMP's continuity sales programs. First, it generally prohibits IMP from misrepresenting the enrollee's rights, duties, and obligations. Second, it specifically requires IMP to honor all requests for enrollment cancellations and merchandise returns by the end of the billing cycle following the billing cycle in which the request or return is received by IMP. It also requires IMP to provide information to consumers on how to cancel enrollments and how to return merchandise.

Part II of the consent order addresses IMP's alleged debt collection misrepresentations by prohibiting IMP from representing that a consumer's credit may be adversely affected if payment is not made unless there is a reasonable likelihood that such a consequence will actually result.

The order also contains provisions requiring IMP to retain records documenting enrollment cancellations, merchandise returns, and consumer complaints.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Emily H. Rock,

Secretary.

[FR Doc. 86-25053 Filed 11-5-86; 8:45 am]

BILLING CODE 6750-01-M

TENNESSEE VALLEY AUTHORITY

18 CFR Part 1307

Enforcement of Nondiscrimination on the Basis of Handicap in Tennessee Valley Authority Programs

AGENCY: Tennessee Valley Authority.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed regulation would amend the regulation issued by Tennessee Valley Authority for enforcement of section 504 of the Rehabilitation Act of 1973, as amended, in federally assisted programs or activities to include a cross-reference to the Uniform Accessibility Standards.

DATE: To be assured of consideration, comments must be in writing and must be received on or before January 5, 1987.

ADDRESSES: Comments should be sent to: William L. Osteen, Jr., Associate General Counsel, Office of the General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, Knoxville, Tennessee 37902.

Comments received will be available for public inspection in the TVA Technical Library, 400 West Summit Hill Drive, Knoxville, Tennessee 37902. Copies of this notice are available on tape for persons with impaired vision. They may be obtained at the above address.

FOR FURTHER INFORMATION CONTACT: William L. Osteen, Jr., Associate General Counsel, Office of the General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, Knoxville, Tennessee 37902, Phone: 856-4142, Commercial (615) 632-4142.

SUPPLEMENTARY INFORMATION: Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), provides that:

> No otherwise qualified handicapped individual in the United States . . . shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. . . .

The existing Tennessee Valley Authority (TVA) section 504 regulation for federally assisted programs requires that new construction be designed and built to be accessible and that alterations of facilities be made in an accessible manner. It requires new construction or alteration to be accomplished in accordance with standards specified by TVA in the contract for the program. The standards used by TVA were ANSI Standard A117.1, "Specifications for Making Buildings and Facilities Accessible to, and Usable by, Physically Handicapped People." The proposed revision states that new construction or alteration accomplished in accordance with the Uniform Federal Accessibility Standards (UFAS) meets the requirements of section 504.

On August 7, 1984, UFAS was issued by the four agencies establishing standards under the Architectural Barriers Act (49 FR 31528) (see discussion *infra*). The Department of Justice, as the agency responsible under Executive Order 12250 for coordinating the enforcement of section 504, has recommended that agencies amend their section 504 regulations for federally assisted programs or activities to establish that, with respect to new construction and alterations, compliance with UFAS shall be deemed to be in compliance with section 504. Because facilities subject to new construction or alteration requirements under section 504 are also subject to the Architectural Barriers Act, Government-wide reference to UFAS would diminish potential conflict between standards enforced by the responsible funding agencies under the two statutes. In addition, compliance with UFAS by Federal agencies and States will reduce potential conflicts when a building is subject to the section 504 regulations of more than one Federal agency and also

when it is subject to State or local accessibility requirements as well.

Background of Assessibility Standards

The Architectural Barriers Act of 1968, 42 U.S.C. 4151–4157 (1982), requires certain Federal and federally funded buildings to be designed, constructed, and altered in accordance with accessibility standards. It also designates four agencies (the General Services Administration, the Departments of Defense and of Housing and Urban Development, and the U.S. Postal Service) to prescribe the accessibility standards. Section 502 of the Rehabilitation Act of 1973 established the Architectural and Transportation Barriers Compliance Board (ATBCB). In 1978 the Rehabilitation Act was amended to require the ATBCB, inter alia, to issue minimum guidelines and requirements for the standards to be issued by the four standard-setting agencies. The minimum guidelines were published on August 4, 1982 (45 FR 33862), and are codified at 36 CFR Part 1190.[1]

On August 7, 1984, the four standard-setting agencies issued the Uniform Federal Accessibility Standards as an effort to minimize the differences among the four agencies' Barriers Act standards, and among those standards and accessibility standards used by the private sector. The General Services Administration (GSA) and Department of Housing and Urban Development (HUD) have incorporated UFAS into their Barriers Act regulations (*see* 49 FR 31625 (1984) (to be codified at 41 CFR Parts 101–19) (GSA) and 49 FR 31620 (1984) (to be codified at 24 CFR Part 40) (HUD)). In order to ensure uniformity, UFAS was designed to be consistent with the scoping and technical provisions of the ATBCB's minimum guidelines and requirements, as well as with the technical provisions of ANSI A117.1–1980, published by the American National Standards Institute (ANSI). (The 1980 ANSI standard contains few scoping provisions.) ANSI is a private, national organization that publishes recommended standards on a wide variety of subjects. ANSI's original accessibility standard, ANSI A117.1, "Specifications for Making Buildings and Facilities Accessible to, and Usable by, Physically Handicapped People," was published in 1961 and reaffirmed in 1971. The current edition, issued in 1980, is ANSI A117.1–1980. The 1961 and 1980 ANSI standards are frequently used in private practice and by State and local governments.

This proposed amendment would amend the current regulation implementing section 504 in federally assisted programs or activities receiving Federal financial assistance from TVA to refer to UFAS.

The agency has determined that it will not require the use of UFAS, or any other standard, as the sole means by which recipients can achieve compliance with the requirement that new construction and alterations be accessible. To do so would unnecessarily restrict recipients' ability to design for particular circumstances. In addition, it would create conflicts with State or local accessibility requirements that may also apply to recipients' buildings and that are intended to achieve ready access and use. It is expected that in some instances recipients will be able to satisfy the section 504 new construction and alteration requirements by following applicable State or local codes, and vice versa.

Effect of Amendment

The amendment would not affect the current section 504 requirement that new facilities be designed and constructed to be readily accessible and that alterations be accessible to the maximum extent feasible. It would merely provide that compliance with UFAS with respect to buildings shall be deemed compliance with these requirements with respect to those buildings. Thus, for example, an alteration is accessible "to the maximum extent feasible" if it is done in accordance with UFAS. It should be noted that UFAS contains special requirements for alterations where meeting the general standards would be impracticable or infeasible (*see, e.g.*, UFAS 4.1.6(1)(b), 4.1.6(3), 4.1.6(4), and 4.1.7).

The amendment also includes language providing that departures form particular UFAS technical and scoping requirements are permitted so long as the alternative methods used will provide substantially equivalent or greater access to and utlization of the building. Allowing these departures from UFAS will provide recipients with necessary flexibility to design for special circumstances and will facilitate the application of new technologies that are not specified in UFAS. As explained under "Background of Accessibility Standards," we anticipate that compliance with some provisions of applicable State and local accessibility requirements will provide "substantially equivalent" access. In some circumstances, recipients may choose to use methods specified in model building codes or other State or local codes that are not necessarily applicable to their buildings but that achieve substantially equivalent access.

The amendment requires that the alternative methods provide "substantially" equivalent or greater access, in order to clarify that the alternative access need not be precisely equivalent to that afforded by UFAS. Application of the "substantially equivalent access" language will depend on the nature, location, and intended use of a particular building. Generally, alternative methods will staisfy the requirement if in material respects the access is substantially equivalent to that which would be provided by UFAS in such respects as safety, convenience, and independence of movement. For example, it would be permissible to depart from the technical requirement of UFAS 4.10.9 that the inside dimensions of an elevator car be at least 68 inches or 80 inches (depending on the location of the door) on the door opening side, by 54 inches, if the clear floor area and the configuration of the car permits wheelchair users to enter the car, make a 360° turn, maneuver within reach of controls, and exit from the car. This departure is permissible because it results in access that is safe, convenient, and independent, and therefore substantially equivalent to that provided by UFAS.

With respect to UFAS scoping requirements, it would be permissible in some circumstances to depart from the UFAS new construction requirement of once accessible principal entrance at each grade floor level of a building (*see* UFAS 4.1.2(8)), if safe, convenient, and independent access is provided to each level of the new facility by a wheelchair user from an accessible principal entrance. This departure would not be permissible if it required a handicapped person to travel an extremely long distance to reach the spaces served by the inaccessible entrances or otherwise provided access that was substantially less convenient than that which would be provided by UFAS.

It would not be permissible for a recipient to depart from UFAS's requirement that, in new construction of a long-term care facility, at least 50 percent of all patient *bedrooms* be accessible (see section 4.1.4(9)(b)), by using large accessible wards that make it possible for 50 percent of all *beds* in

[1] The ATBCB Office of Technical Services is available to provide technical assistance to recipients upon request relating to the elimination of architectural barriers. Its address is: U.S. ATBCB, Office of Technical Services, 330 C Street, SW., Washington, DC 20201. The telephone number is (202) 472–2700 [voice/TDD]. This is not a toll free number.

the facility to be accessible to handicapped persons. The result is that the population of handicapped persons in the facility will be concentrated in large wards, while able-bodied persons will be concentrated in smaller, more private rooms. Because convenience for handicapped persons is therefore compromised to such a great extent, the degree of accessibility provided to handicapped persons is not substantially equivalent to that intended to be afforded by UFAS.

It should be noted that the amendment does not require that existing buildings leased by recipients meet the standards for new construction and alterations. Rather, it continues the current Federal practice under Section 504 of treating newly leased buildings as subject to the program accessibility standard for existing facilities.

The proposed revision includes language modifying the effect of UFAS 4.1.6(1)(g), which provides an exception to UFAS 4.1.6, *Accessible buildings: alterations.* Section 4.1.6(1)(g) of UFAS states that "mechanical rooms and other spaces which normally are not frequented by the public or employees of the building or facility or which by nature of their use are not required by the Architectural Barriers Act to be accessible are excepted from the requirements of 4.1.6." Particularly after the development of specific UFAS provisions for housing alterations and additions, UFAS 4.1.6(1)(g) could be read to exempt alterations to privately owned residential housing, which is not covered by the Architectural Barriers Act unless leased by the Federal Government for subsidized housing programs. This exception, however, is not appropriate under section 504, which protects beneficiaries of housing provided as part of a federally assisted program. Consequently, the proposed amendment provides that, for purposes of this section, section 4.1.6(1)(g) of UFAS shall be interpreted to exempt from the requirements of UFAS only spaces that, because of their intended use, will not require accessibility to the public or handicapped residents or employees.

The proposed revision also provides that whether or not the recipient opts to follow UFAS in satisfaction of the ready access requirement, the recipient is not required to make building alterations that have little likelihood of being accomplished without removing or altering a load-bearing structural member. This provision does not relieve recipients of their obligation under the current regulation to ensure program accessibility.

This document has been reviewed by the Department of Justice. It is an adaptation of a prototype prepared by the Department of Justice under Executive Order 12250 (45 FR 72995, 3 CFR, 1980 Comp., at 298).

The Architectural and Transportation Barriers Compliance Board has also been consulted in the development of this document in accordance with 28 CFR 41.7.

This regulation is not a major rule within the meaning of Executive Order 12291 (46 FR 13193, 3 CFR, 1981 Comp. at 127) because it imposes no new requirements. Therefore, a regulatory impact analysis has not been prepared.

It does not have an impact on small entities and, therefore, is not subject to the Regulatory Flexibility Act (5 U.S.C. 601–612).

List of Subjects in 18 CFR Part 1307

Blind, Civil rights, Deaf, Disabled, Discrimination against handicapped, Federal buildings and facilities, Handicapped, Nondiscrimination, Physically handicapped.

For the reasons stated in the preamble, Part 1307 of Title 18 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1307—[AMENDED]

1. The authority citation for Part 1307 continues to read as follows:

Authority: TVA Act, 48 Stat. 58 (1933) as amended, 16 U.S.C. 831—831dd (1976) and sec. 504 of the Rehabilitation Act of 1973, Pub. L. 93–112, as amended, 29 U.S.C. 794 (1976; Supp. II 1978).

2. In 1307.6, paragraph (d) is revised to read as follows:

§ 1307.6 Program availability.

* * * * *

(d) *New construction.* (1) New facilities required under a program subject to this part shall be designed and constructed to be readily accessible to and usable by handicapped persons. For the purposes of this part, a new facility is one on which actual construction began after May 2, 1978.

(2) Effective as of (the effective date of this amendment), design, construction, or alteration of buildings in conformance with sections 3–8 of the Uniform Federal Accessibility Standards (UFAS) (41 CFR 101–19.6 app. A) shall be deemed to comply with the requirements of this section with respect to those buildings. Departures from particular technical and scoping requirements of UFAS by the use of other methods are permitted where substantially equivalent or greater access to and usability of the building is provided.

(3) For purposes of this section, 4.1.6(1)(g) of UFAS shall be interpreted to exempt from the requirements of UFAS only mechanical rooms and other spaces that, because of their intended use, will not require accessibility to the public or beneficiaries or result in the employment or residence therein of physically handicapped persons.

(4) This section does not require recipients to make building alterations that have little likelihood of being accomplished without removing or altering a load-bearing structural member.

W.F. Willis,

General Manager.

October 29, 1986.

[FR Doc. 86–25062 Filed 11–5–86; 8:45 am]

BILLING CODE 8120–01–M

DEPARTMENT OF THE TREASURY

31 CFR Part 10

Tax Practitioners; Solicitation for Extended Comments

AGENCY: Department of the Treasury.

ACTION: Proposed rule; solicitation for extended comments; extension of time for comments.

SUMMARY: This notice solicits public comments on the issue of the standard of practice with respect to tax return preparation and advice. A notice of proposed rulemaking was published in the **Federal Register** on August 14, 1986 (51 FR 29113) and solicited comments from the public. The overall area on which comments are invited is broadened by this notice, and the time for comments is being extended to February 13, 1987.

DATE: Comments must be mailed or delivered by February 13, 1987.

ADDRESS: Director of Practice, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224, Attn: PM:HRMS:DP.

FOR FURTHER INFORMATION CONTACT: Mr. Leslie S. Shapiro, Director of Practice, Internal Revenue Service, Washington, DC 20224. Telephone 202–535–6787 (Not a toll-free number).

SUPPLEMENTARY INFORMATION: By notice of proposed rulemaking published in the **Federal Register** on August 14, 1986 (51 FR 29113), the Treasury Department proposed certain additions to 31 CFR

Part 10 (Treasury Department Circular No. 230), which contains regulations governing practice before the Internal Revenue Service. On August 27, 1986, the Treasury Department published (51 FR 30510) a notice extending the deadline for public comments to November 13, 1986.

The proposed rule would amend Circular 230 to require that, in a situation where the provisions of section 6661 of the Internal Revenue Code may apply, a practitioner must exercise due diligence with respect to tax return preparation and the advice provided on tax return positions. The proposal arose from the concern that, in the absence of an express standard of practice with respect to return preparation and advice, some practitioners are advising taxpayers to take very aggressive tax return positions that have little or no chance of being sustained if challenged by the IRS. Such a practice, by exploiting the so-called audit lottery, substantially undermines the integrity of the voluntary self-assessment system.

Despite this continuing concern, the Treasury Department is still considering whether it is appropriate to link a uniform standard of practice for return advice and preparation to the application of the section 6661 penalty. There is concern that such a linkage may inhibit the IRS from asserting the section 6661 penalty, because successful assertion could result in disbarment of a practitioner or return preparer. Moreover, comments received to date have pointed out certain inconsistencies and mechanical problems that may result from implementing the proposed rule in its current form.

Accordingly, the Treasury Department requests that interested persons comment, not only on the specific language of the proposed rule, but also on the broader issue of the standard of practice that should apply with respect to tax return preparation and advice. Because of the expansion of comments contemplated in this notice and pursuant to requests from the practitioner community, the time for comments on the proposed rulemaking is being extended to February 13, 1987.

The effective date of the rule to be adopted will be prospective in nature and will be published in a future notice.

Dated: November 3, 1986.

Leslie S. Shapiro,

Director of Practice.

[FR Doc. 86-25090 Filed 11-5-86; 8:45 am]

BILLING CODE 4810-25-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05-86-01]

Special Local Regulations for Marine Events; Norfolk/Portsmouth Harbor, Elizabeth River, VA

AGENCY: Coast Guard, DOT.

ACTION: Supplemental notice of proposed rule making.

SUMMARY: The Coast Guard is considering a proposal that would establish special local regulations for the Elizabeth River in the vicinity of the "Waterside" area of downtown Norfolk, Virginia, and the "Portside" area of downtown Portsmouth, Virginia. This area is the site of several large marine events each year, including Norfolk's Harborfest, Portsmouth's Seawall Festival, Independence Day Celebration power boat races, and boat parades. These regulations would govern vessel activities during those events. Notices of the precise dates and times that regulations are effective will be published in the Local Notices to Mariners and Federal Register. These special local regulations are considered necessary to control vessel traffic and provide for the safety of life and property on the navigable waters within the immediate vicinity of the event.

DATES: Comments must be received on or before December 22, 1986.

ADDRESSES: Comments should be hand delivered, or mailed to Commander (bb), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004. The comments will also be available for inspection and copying at Room 209 of this address. Normal office hours are between 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Billy J. Stephenson, Chief, Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004, telephone number: (804) 398-6204.

SUPPLEMENTARY INFORMATION: On March 3, 1986 the Coast Guard published a notice of proposed rule making in the **Federal Register** relating to the annual Norfolk Harborfest (51 FR 7286). Interested persons were requested to submit comments. No comments were received.

This supplemental proposal reduces the size of the regulated area and extends its effective dates to cover all events held in the area.

Interested persons are invited to participate in this rulemaking by submitting written views, data, or arguments. Persons submitting comments should include their names and addresses, identify this notice (CGD 05-86-01) and the specific section of the proposal to which their comments apply, and given reasons for each comment. Receipt of comments will be acknowledged if a stamped, self-addressed postcard or envelope is enclosed. The rules may be changed in light of comments received. All comments received before the expiration of the comment period will be considered before final action is taken on this proposal.

No public hearing is planned, but one may be held if written requests for a hearing are received and it is determined that the opportunity to make oral presentations will aid the rulemaking process.

Drafting Information

The drafters of this notice are Billy J. Stephenson, project officer, Chief, Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, and CDR Robert J. Reining, project attorney, Fifth Coast Guard District Legal Office.

Discussion of Proposed Regulations

This proposal supplements the notice of proposed rulemaking that would have established special local regulations for the City of Norfolk Harborfest. It would apply the same regulations to most marine events held in Norfolk harbor. These regulations are necessary due to the confined nature of the waterway and the expected congestion at the time of the various events. The area subject to the special local regulations is smaller than the area which has been subject to the regulations for previous Norfolk Harborfests. The special regulations are substantially the same as those established in the past. Norfolk Harborfest and Portsmouth Seawall Festivals are annual weekend events, designed to promote and enhance the City of Norfolk and Portsmouth's nautical heritage. The events held are a combination of land and water activities centered about the downtown portion of Norfolk and Portsmouth. They typically include speedboat races, air-sea rescue demonstrations of military vessels and riverine warfare craft, and fireworks displays. Other events that have been regulated in the past include a parade of sailing ships into the Waterside area and subsequent open house periods for public viewing of the ships; fireworks displays; power boat races; and parades of lighted boats. The events have drawn

large numbers of boats to the Town Point Reach area creating congestion.

Economic Assessment and Certification

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979). Its economic impact is expected to be minimal since, as in the past, closure of the waterway for any extended period is not anticipated and commercial traffic should not be severely disrupted at any given time.

Comments received concerning past events indicate that commercial interests normally using the waterways can adapt to the minor restrictions they may encounter.

Since the impact of these regulations is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water).

Proposed Regulations

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations is amended as follows:

PART 100—[AMENDED]

1. The authority citation for Part 100 continues to read as follows:

Authority: (33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35).

2. Section 100.501 is added to read as follows:

§ 100.501 Norfolk Harbor, Elizabeth River, Norfolk and Portsmouth, Virginia.

(a) *Definitions*—(1) *Regulated Area.* The waters of the Elizabeth River and its branches from shore to shore, bounded to the northwest by a line drawn across the Port Norfolk Reach section of the Elizabeth River between the northern corner of the landing at Hospital Point, Portsmouth, Virginia, at latitude 36°50'51" North, longitude 076°18'09" West, and the north corner of the City of Norfolk Mooring Pier at the foot of Brooke Avenue located at latitude 36°51'00" North, longitude 076°17'52" West; bounded on the southwest by a line drawn from the southern corner of the landing at Hospital Point, Portsmouth, Virginia, at latitude 36°50'50" North, longitude 076°18'10" West, to the northern end of the eastern most pier at the Tidewater Yacht Agency Marina, located at 36°50'29" North, longitude 076°17'52" West; bounded to the south by a line drawn across the Lower Reach of the Southern Branch of the Elizabeth River, between the Portsmouth Lightship Museum located at the foot of London Boulevard, in Portsmouth, Virginia at latitude 36°50'10" North, longitude 076°17'47" West, and the northwest corner of the Norfolk Shipbuilding & Drydock, Berkley Plant, Pier No. 1, located at latitude 36°50'08" North, longitude 076°17'39" West; and to the southeast by the Berkley Bridge which crosses the Eastern Branch of the Elizabeth River between Berkley at latitude 36°50'21.5" North, longitude 076°17'14.5" West, and Norfolk at latitude 36°50'35.0" North, longitude 076°17'10.0" West.

(2) *Coast Guard Patrol Commander.* (a) The Coast Guard Patrol Commander is a commissioned or petty officer of the Coast Guard, who has been designated by Commander, Coast Guard Group Hampton Roads.

(b) *Special Local Regulations.* (1) Except for participants registered with the event sponsor and vessels that are moored to a pier, dock, or shore, no vessel underway or at anchor may enter or remain in the regulated area without the permission of the Coast Guard Patrol Commander.

(2) The operator of any vessel in the regulated areas shall—

(a) Stop his vessel immediately when directed to do so by any Coast Guard officer or petty officer on board a vessel displaying a Coast Guard ensign; or

(b) Proceed as directed by any Coast Guard officer or petty officer.

(3) Spectator vessels may anchor outside of the regulated area specfied in paragraph (1) of these regulations but may not block a navigable channel.

(4) The Coast Guard Patrol Commander may stop the event to assist the transit of marine traffic through the regulated area.

(5) *Effective Dates.* These regulations are effective on those dates and times published in notices in the Local Notice to Mariners and **Federal Register.**

Dated: October 24, 1986.

B.F. Hollingsworth,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 86-25097 Filed 11-5-86; 8:45 am]

BILLING CODE 4910-14-M

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33 CFR Part 117

[CGD8-86-09]

Drawbridge Operation Regulations; Bayou Teche, LA

AGENCY: Coast Guard, DOT.

ACTION: Proposed rule.

SUMMARY: At the request of the Louisiana State University (LSU) Agricultural Experiment Center, the Coast Guard is considering a change to the regulation governing the operation of the swing span bridge across Bayou Teche, mile 46.5, near Jeanerette, Iberia Parish, Louisiana. This proposed change would require the draw of the bridge to open on at least four hours advance notice from 7 a.m. to 5 p.m., Monday through Friday, to be consistent with the existing opening requirement for the bridge immediately upstream at mile 43.5 and the bridge downstream at mile 48.7. The bridge at mile 46.5 is maintained in the open position at all other times.

This proposal is being made because of infrequent requests to open the draw. This action should relieve the bridge owner of the burden of having a person constantly available at the bridge from 7 a.m. to 5 p.m., while still providing for the reasonable needs of navigation.

DATE: Comments must be received on or before December 22, 1986.

ADDRESS: Comments should be mailed to Commander (obr), Eighth Coast Guard District, 500 Camp Street, New Orleans, Louisiana 70130. The comments and other materials referenced in this notice will be available for inspection and copying in Room 1115 at this address. Normal office hours are between 8:00 a.m. and 3:30 p.m., Monday through Friday, except holidays. Comments may also be hand-delivered to this address.

FOR FURTHER INFORMATION CONTACT: Perry Haynes, Chief, Bridge Administration Branch, at the address given above, telephone (504) 589-2965.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this proposed rulemaking by submitting written views, comments, data or arguments. Persons submitting comments should include their names and addresses, identify the bridge, and give reasons for concurrence with or any recommended change in the proposal. Persons desiring acknowledgment that their comments have been received should enclose a stamped, self-addressed postcard or envelope.

The Commander, Eighth Coast Guard District, will evaluate all communications received and determine a course of final action on this proposed. This proposal regulation may be changed in the light of comments received.

Drafting Information

The drafters of this notice are Perry Haynes, project officer, and Lieutenant Commander James Vallone, project attorney.

Discussion of Proposed Regulation

The LSU Agricultural Experiment Center bridge over Bayou Teche at mile 46.5 has a closed position vertical clearance of 5 feet above high water. Waterway traffic consists of an occasional commercial vessel (mainly fishing/shrimping boats) and recreational craft. Data submitted by the Louisiana Department of Transportation and Development show that traffic is infrequent. Bridge opening statistics were reviewed and showed the bridge averages well under one opening per day during the prescribed advance notice period.

Considering the few openings involved for the bridge, the Coast Guard feels that four hours notice can be adopted with only minimal economic impact This arrangement will allow for relief to the bridge owner, while still providing for the reasonable needs of navigation.

The advance notice of opening the draw would be given by placing a collect call to the LSU Agricultural Experiment Center between the hours of 7:30 a.m. and 4:30 p.m., telephone (318) 276–5527; at all other times call (318) 276–9422 or 6337. From afloat, this contact may be made by radiotelephone through a public coast station. A call is required for passage from 7 a.m. to 5 p.m., Monday through Friday only. The bridge is maintained in the open to navigation position at all other times.

The LSU Agricultural Experiment Center recognizes that there may be an unusual occasion when there may be a need to open the bridge on less than four hours notice for a bona fide emergency, or to operate the bridge on demand for an isolated but temporary surge in waterway traffic, and has committed to doing so if such and event should occur.

Economic Assessment and Certification

This proposed regulation is considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under the Department of Transportation regulatory policies and procedures (44 FR 11034, February 26, 1979).

The economic impact of this proposal is expected to be so minimal that a full regulatory evaluation is unnecessary. The basis for this conclusion is that few vessels pass through the bridge as evidenced by the 1984 bridge opening statistics. These vessels can reasonably give four hours notice for a bridge opening by placing a collect call to the bridge owner at any time from ashore or afloat. Mariners requiring the bridge openings are mainly repeat users of the waterway and scheduling their arrival at the bridge at the appointed time during the proposed advance notice period should involve little or no additional expense to them. Since the economic impact of this proposal is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 33 CFR Part 117

Bridges.

Proposed Regulation

In consideration of the foregoing, the Coast Guard proposes to amend Part 117 of Title 33, Code of Federal Regulations, as follows:

PART 117—DRAWBRIGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g).

2. Section 117.501 is revised by redesignating existing paragraphs (b)(8) through (b)(18) as (b)(9) through (b)(19), and by adding a new paragraph (b)(8) to read as follows:

§ 117.501 Teche Bayou.

* * * * *

(b) * * *

(8) LSU Agri bridge, mile 46.5 near Jeanerette (notice required for opening from 7 a.m. to 5 p.m., Monday through Friday except holidays).

* * * * *

Dated: October 23, 1986.

Peter J. Rots,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 86–25095 Filed 11–5–86; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW-FRL-3106-6]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Extension of Comment Period

AGENCY: Environmental Protection Agency.

ACTION: Extension of public comment period for two previously proposed exclusions for delisting petitions.

SUMMARY: Today's notice announces the extension of the public comment periods for two previously proposed Agency decisions regarding the grant of exclusions for delisting petitions. Today's extension responds to a request received from the Environmental Defense Fund (EDF) on October 31, 1986. The proposed grant of these exclusions responds to delisting petitions submitted to the Agency under 40 CFR 260.20, which allows any person to petition the Administrator to modify or revoke any provision of Parts 260 through 265, 124, 270, and 271 of Title 40 of the code of regulations, and specifically provides generators the opportunity to petition the Administrator to exclude a waste on a "generator-specific" basis from the hazardous waste list. The effect of the proposed action, if made final, would be to exclude certain wastes generated at four particular facilities from listing as hazardous waste under 40 CFR Part 260. The proposed exclusions previously published were for three facilities of Tricil Environmental Services, Inc. (see 51 FR 36974, October 16, 1986) and one facility of Lederle Laboratories, a Division of the American Cyanamid Company (see 51 FR 37760, October 24, 1986). The comment periods for these decisions were originally to end on October 31, 1986 for the proposed decisions on Tricil Environmental Services, Inc. and November 3, 1986 for the proposed decision on Lederle Laboratories. Today's notice extends both of these comment periods.

DATES: EPA will accept public comments on the previously proposed decisions until November 7, 1986 for Tricil Environmental Services, Inc., and November 24, 1986 for Lederle Laboratories. These dates reflect an extension of the original comment periods as cited in the proposed rules. Comments postmarked after the close of the extended comment periods will be stamped "late".

ADDRESSES: Send three copies of your comments to EPA. Two copies should be sent to the Docket Clerk, Office of Solid Waste (WH–562), 401 M Street, SW., Washington, DC 20460. A third copy should be sent to Jim Kent, Variance Section, Assistance Branch, PSPD/OSW (WH–563), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. All comments must be identified at the top with the appropriate docket number. Comments addressing the proposed decisions for Tricil Environmental Services, Inc.

should be identified using docket number "F–86–TRPE–FFFFF". Comments addressing the proposed decision for Lederle Laboratories should be identified using docket number "F–86–LPE–FFFFF".

The public docket where the information can be viewed for both of the proposed rules is located at the U.S. Environmental Protection Agency, 401 M Street, SW. (sub-basement), Washington, DC 20460. The docket is open from 9:30 a.m. to 3:30 p.m., Monday through Friday, excluding Federal holidays. Call Mia Zmud at (202) 475–9327 or Kate Blow at (202) 382–4675 for appointments. The public may copy a maximum of 50 pages of material from any one regulatory docket at no cost. Additional copies cost $0.20 per page.

FOR FURTHER INFORMATION CONTACT: RCRA Hotline, toll free at (800) 424–9346, or at (202) 382–3000. For technical information, contact Ms. Lori DeRose, Office of Solid Waste (WH–562B), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 382–5096.

SUPPLEMENTARY INFORMATION: The Agency proposed to exclude the wastes generated at four facilities from hazardous waste control in response to delisting petitions submitted under 40 CFR 260.20 and 260.22. These facilities included: (1) Tricil Environmental Services, Inc., located in Hilliard, Ohio (see 51 FR 36976, October 16, 1986); (2) Tricil Environmental Services, Inc., located in Nashville, Tennessee (see 51 FR 36979, October 16, 1986); (3) Tricil Environmental Services, Inc., located in Muskegon, Michigan (see 51 FR 36983, October 16, 1986); and (4) Lederle Laboratories a Division of American Cyanamid Co., located in Pearl River, New York (see 51 FR 37762, October 24, 1986). The public comment periods for these proposed rules were originally scheduled to end on October 31, 1986, for the proposed decisions regarding the three Tricil facilities (see 51 FR 36974, October 16, 1986) and November 3, 1986, for the proposed decision regarding Lederle Laboratories (see 51 FR 37760, October, 24, 1986).

During the original public comment period for the proposed rules, the Agency received a request from the Environmental Defense Fund to extend the public comment period for the proposed rules to allow additional time for submission of comments regarding the Agency's decisions. The Agency has agreed to extend the comment period for these two proposed rules and will now accept public comments until November 7, 1986, for the proposed Tricil decisions and until November 24, 1986, for the proposed Lederle Laboratories decision.

Dated: October 31, 1986.

Jeffery D. Denit,

Acting Director, Office of Solid Waste.

[FR Doc. 86–25100 Filed 11–5–86; 8:45 am]

BILLING CODE 6560–50–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 533

[Docket No. FE–86–02; Notice 2]

Light Truck Average Fuel Economy Standards; Request for Comments; Extension of Period for Public Comment

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for comments; extension of period for public comment.

SUMMARY: On September 16, 1986, NHTSA published in the **Federal Register** (51 FR 32802), a notice requesting comments to assist the agency in carrying out its rulemaking responsibilities concerning average fuel economy standards for light trucks. In response to a request from General Motors, the comment period closing date is changed from November 17, 1986, to December 19, 1986.

DATE: Comments on the September 16, 1986 notice must be received on or before December 19, 1986.

ADDRESSES: Comments on the September 16, 1986 notice must refer to the docket and notice numbers set forth in that notice and be sumitted (preferably in 10 copies) to the Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street SW., Washington, DC 20590. Submissions containing information for which confidential treatment is requested should be submitted (three copies) to Chief Counsel, National Highway Traffic Safety Administration, Room 5219, 400 Seventh Street SW., Washington, DC 20590, and seven additional copies from which the purportedly confidential information has been deleted should be sent to the Docket Section.

FOR FURTHER INFORMATION CONTACT: Mr. Orron Kee, Acting Chief, Motor Vehicle Requirements Division, Office of Market Incentives, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590 (202) 366–4936.

SUPPLEMENTARY INFORMATION: Section 502(b) of the Motor Vehicle Information and Cost Savings Act requires NHTSA to issue light truck average fuel economy standards at least 18 months before the beginning of each model year The agency is now in the process of beginning a rulemaking analysis to determine the level of light truck average fuel economy standards for model years after 1989. On September 16, 1986, NHTSA published in the **Federal Register** (51 FR 32802) a notice requesting comments, to assist the agency in developing that analysis. Comments were to be provided by November 17, 1986.

In a letter dated October 10, 1986, General Motors (GM) requested that the comment period be extended to December 19, 1986. That company indicated that its plans for model years 1990–91 are being significantly revised, and that its new product plan is scheduled for completion and for management approval in December. GM indicated that an extension of the comment period would enable it to provide more up-to-date information that would reflect its latest forecasts of fuel prices, competitive actions, and market trends.

NHTSA has determined that there is merit in the arguments presented by GM. The comment closing date is therefore changed from November 17, 1986, to December 19, 1986. All comments received before the close of business on the comment closing date will be considered, and will be available for examination in the docket at the above address. To the extent possible, comments filed after the closing date will also be considered. NHTSA will continue to file relevant material in the docket as it becomes available after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

List of Subjects in 49 CFR Part 533

Energy conservation, Gasoline, Imports, Motor vehicles.

Authority: 15 U.S.C. 2002, delegations of authority at 49 CFR 1.50 and 49 CFR 501.8.

Issued on October 31, 1986.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 86–25086 Filed 11–5–86; 8:45 am]

BILLING CODE 4910–59–M

Notices

Federal Register
Vol. 51, No. 215
Thursday, November 6, 1986

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

Animal and Plant Health Inspection Service

[Docket No. 86-411]

National Animal Damage Control Advisory Committee; Criteria for Membership Selection

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: This document specifies the criteria that will be used for the selection of members to the National Animal Damage Control Advisory Committee. The National Animal Damage Control Advisory Committee is being formed to advise the Secretary of Agriculture on policies, program issues, and research needed to conduct the Animal Damage Control Program of USDA.

DATE: Comments concerning the criteria must be received on or before December 8, 1986.

ADDRESS: Views and comments of interested persons may be submitted to Bert W. Hawkins, Administrator, Animal and Plant Health Inspection Service (APHIS), USDA, Room 312-E, Administration Building, 14th and Independence Avenue, SW., Washington, DC 20250. Please state that your comments are in response to Docket No. 86-411. You may inspect written comments received in Room 312-E of the Administration Building between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: James O. Lee, Jr., Deputy Administrator for Animal Damage Control, APHIS, USDA, Room 1624 South Building, 14th and Independence Avenue, SW., Washington, DC 20250; telephone Area Code (202) 447-2054.

SUPPLEMENTARY INFORMATION: On June 30, 1986, the Office of the Secretary of Agriculture published a notice announcing the formation of the National Animal Damage Control Advisory Committee (NADCAC). The NADCAC is being formed to provide advice to the Secretary of Agriculture on policies, programs, issues, and research needed to conduct the Animal Damage Control (ADC) Program of USDA. The NADCAC is also intended to serve as a public forum which will enable those affected to have a voice in the ADC Program's policies.

Notice is hereby given that the Secretary of Agriculture proposes to use the following criteria for selection of members to the NADCAC.

Members of the committee will be chosen from a list of interested persons representing a variety of organizations. The proposed criteria to be used in selecting organizations for representation on the committee will include the following:

1. National in scope.
2. Non-Federal (except for congressionally directed).
3. Experience in cooperative working relationships.
4. Tradition of national public interest and service.
5. Record of achievement in national public interest goals.
6. Subject matter knowledge and experience.
7. Represents clients fairly and comprehensively.
8. Continuing interest in ADC.

This notice is given in compliance with the Federal Advisory Committee Act (Pub. L. 92-468).

Done in Washington, DC, this 3rd day of November, 1968.

Bert W. Hawkins,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 86-25187 Filed 11-5-86; 8:45 am]

BILLING CODE 3410-34-M

Cooperative State Research Service

Committee of Nine; Meeting

In accordance with the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776), the Cooperative State Research Service announces the following meeting:

Name: Committee of Nine.
Date: December 3, 1986.
Time: 8:00 a.m.-5:00 p.m.
Place: Breckenridge King's Inn, 9600 Natural Bridge Road, St. Louis, Missouri.

Type of meeting: Open to the public. Persons may participate in the meeting as time and space permit.

Comments: The public may file written comments before or after the meeting with the contact person listed below.

Purpose: To evaluate and recommend proposals for cooperative research on problems that concern agriculture in two or more States, and to make recommendations for allocation of regional research funds appropriated by Congress under the Hatch Act for research at the State agricultural experiment stations.

Contact person for agenda and more information: Dr. Edward M. Wilson, Executive Secretary, U.S. Department of Agriculture, Cooperative State Research Service, Room 206 Justin Smith Morrill Bldg., Washington, DC 20251; Telephone: (202) 447-6040.

Done at Washington, DC this 26th day of October 1986.

John Patrick Jordan,

Administrator, Cooperative State Research Service.

[FR Doc. 86-25079 Filed 11-5-86; 8:45 am]

BILLING CODE 3410-22-M

Forest Service

Public Meeting Schedule for the Review of the Draft Environmental Impact Statement and Proposed Land and Resource Management Plan for the Inyo National Forest Involving Portions of Mono, Inyo, Tulare, Madera, Fresno Counties, CA, and Esmeralda, Mineral Counties, NE

AGENCY: Forest Service, USDA.

ACTION: Notice of public meetings for review of the Draft Environmental Impact Statement and Proposed Land and Resource Management Plan.

SUMMARY: Meetings to assist the public in understanding the content of the Draft Environmental Impact Statement and Proposed Plan will be held at 2 to 5 PM and again at 7 to 10 PM at the following locations and dates:

June Lake, California, November 18, 1986
Mammoth Lakes, California, November 25, 1986
Bishop, California, December 4, 1986
Lone Pine, California, December 9, 1986

Additional public meetings will be held at 2 to 5 PM and again at 7 to 9 PM at the following locations and dates:

Glendale, California, January 6, 1987
Santa Ana, California, January 7, 1987
Ridgecrest, California, January 8, 1987

A public hearing at which formal comment may be presented will be held at 1 to 4 PM and again at 7 to 9 PM in Bishop, California, January 26, 1987.

Special information about those meetings has already been made available through direct mailing to the project mailing list; media releases will be made in the near future.

FOR FURTHER INFORMATION CONTACT: Oliver Sapousek at Inyo National Forest, 873 North Main Street, Bishop, California, 93514, or by calling (619) 873–5841.

Dated: October 30, 1986.

Dennis W. Martin,

Forest Supervisor.

[FR Doc. 86–25128 Filed 11–5–86; 8:45 am]

BILLING CODE 3410-11-M

Soil Conservation Service

Cull Creek Watershed, California; Environmental Impact Statement

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of a finding of no significant impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for Cull Creek Watershed, Alameda and Contra Costa Counties, California.

FOR FURTHER INFORMATION CONTACT: Eugene E. Andreuccetti, State Conservationist, Soil Conservation Service, 2121–C Second Street, Davis, California, 95616, telephone (916) 449–2848.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Eugene E. Andreuccetti, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The project concerns a plan for flood control and watershed protection. The planned works of improvement include clearing and snagging, post wire revetment and tree planting in Cull Creek, rangeland management and gully stabilization for land treatment and accelerated technical assistance for land treatment.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various Federal, State, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Eugene E. Andreuccetti.

No administrative action on implementation of the proposal will be taken until December 8, 1986.

(This activity is listed in the Catalog of Federal Domestic Assistance under no. 10.904—Watershed Protection and Flood Prevention—and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials.)

Eugene E. Andreuccetti,

State Conservationist.

October 29, 1986.

[FR Doc. 86–25119 Filed 11–5–86; 8:45 am]

BILLING CODE 3410-16-M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–122–016]

Choline Chloride From Canada; Preliminary Results of Antidumping Duty; Administrative Review

AGENCY: International Trade Administration, Import Administration, Commerce.

ACTION: Notice of preliminary results of antidumping duty administrative review.

SUMMARY: In response to a request by Chinook Chemicals Co., Ltd., the Department of Commerce has conducted an administrative review of the antidumping duty order on choline chloride from Canada. The review covers Chinook Chemicals Co., Ltd. and the period April 30, 1984 through October 31, 1985. The review indicates the existence of *de minimis* dumping margins during the period.

As a result of the review, the Department has preliminarily determined to assess antidumping duties equal to the calculated differences between United States price and foreign market value.

Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: November 6, 1986.

FOR FURTHER INFORMATION CONTACT: Edward Haley or Robert J. Marenick, Office of Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377–5289/5255.

SUPPLEMENTARY INFORMATION:

Background

On November 16, 1984, the Department of Commerce ("the Department") published in the **Federal Register** (49 FR 45469) the antidumping duty order on choline chloride from Canada. Chinook Chemicals Co., Ltd. requested in accordance with § 353.53a(a) of the Commerce Regulations that we conduct an administrative review. The Department published a notice of initiation of an antidumping duty administrative review on December 13, 1985 (50 FR 50933). As required by section 751 of the Tariff Act of 1930 ("the Tariff Act") the Department has now conducted that administrative review.

Scope of the Review

Imports covered by the review are shipments of choline chloride, currently classifiable under item 439.5055 of the Tariff Schedules of the United States Annotated. Choline chloride is marketed in several forms including, but not limited to, a solution of 70 percent choline chloride in water (aqueous choline chloride) or in potencies of 50 to 60 dried on a cereal carrier.

The review covers Chinook Chemicals Co., Ltd, and the period April 30, 1984 through October 31, 1985.

United States Price

The calculating United States price the Department used purchase price or exporter's sales price ("ESP "), both as defined in section 772 of the Tariff Act, as appropriate. Purchase price and exporter's sales price were based on the packed or unpacked, duty-paid, delivered price to unrelated purchasers in the United States. Where applicable, we made adjustments for U.S. and foreign inland freight, import duties, brokerage and handling charges, commissions to unrelated parties, and indirect selling expenses. We also included in the calculated of purchase price for aqueous choline chloride part of a free shipment to one customer. No other adjustments where claimed or allowed.

Foreign Market Value

In calculating foreign market value the Department used home market price, as defined in section 773 of the Tariff Act, since sufficient quantities of such or similar merchandise were sold in the home market to provide a basis for comparison. Home market price was based on the packed or unpacked, ex-factory or delivered price to unrelated purchasers in Canada. We make adjustments, where applicable, for inland freight, credit, and other selling expenses when a commission was paid in one market and not the other. In accordance with § 353.14(a) of the Commerce Regulations, we did not include sales of small quantities of aqueous choline chloride in drums in calculating home market price. These sales amounted to less than two percent of Chinook's Canadian sales of aqueous choline chloride. No other adjustments were claimed or allowed.

Preliminary Results of the Review

As a result of our comparison of United States price of foreign market value we preliminarily determine that a margin of 0.17 percent exists during the period April 30, 1984 through October 31, 1985.

Interested parties may submit written comments on these preliminary results within 21 days of the date of publication of this notice and may request disclosure and/or a hearing within 5 days of the date of publication. Any hearing, if requested, will be held 21 days after the date of publication or the first workday thereafter. Any request for an administrative protective order must be made no later than 5 days after the date of publication. The Department will publish the final results of the administrative review including the results of its analysis of any such comments or hearing.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between United States price and foreign market value may vary from the percentage stated above. The Department will issue appraisement instructions directly to the Customs Service.

Further, as provided for by section 751(a)(1) of the Tariff Act, a cash deposit of estimated antidumping duties shall be required. Since the margin for Chinook is less than 0.5 percent and therefore *de minimis* for cash deposit purposes, the Department waives the deposit requirement for that firm. For any future entries of this merchandise from a new exporter, whose first shipments occurred after October 31, 1985 and who is unrelated to Chinook Chemicals Co., Ltd., the Department waives the cash deposit requirement. This waiver is effective for all shipments of choline chloride entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and § 353.53a of the Commerce Regulations (19 CFR 353.53a).

Dated: October 30, 1986.

Gilbert B. Kaplan,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 85-25123 Filed 11-5-86; 8:45 am]

BILLING CODE 3510-DS-M

[A-588-606]

Certain Forged Steel Crankshafts From Japan; Initiation of Antidumping Duty Investigation

AGENCY: International Trade Administration, Import Administration, Commerce.

ACTION: Notice.

SUMMARY: On the basis of a petition filed in proper form with the United States Department of Commerce, we are initiating an antidumping duty investigation to determine whether certain forged steel crankshafts from Japan are being, or are likely to be, sold in the United States at less than fair value. We are notifying the United States International Trade Commission (ITC) of this action so that it may determine whether imports of this product are causing material injury, or threaten material injury to, a United States industry. If this investigation proceeds normally, the ITC will make its preliminary determination on or before November 23, 1986, and we will make ours on or before March 18, 1987.

EFFECTIVE DATE: November 6, 1986.

FOR FURTHER INFORMATION CONTACT: Charles Wilson or James Riggs, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 377-5288 or (202) 377-4929.

SUPPLEMENTARY INFORMATION:

The Petition

On October 9, 1986, we received a petition in proper form filed by Wyman-Gordon Company. In compliance with the filing requirements of 353.36 of the Commerce Regulations (19 CFR 353.36), the petition alleged that imports of the subject merchandise from Japan are being, or are likely to be, sold in the United states at less than fair value within the meaning of section 731 of the Tariff Act of 1930, as amended (the Act), and that these imports are causing material injury, or threaten material injury to, a United States industry.

Initiation of Investigation

Under section 732(c) of the Act, we must determine, within 20 days after a petition is filed, whether it sets forth the allegations necessary for the initiation of an antidumping duty investigation and, further, whether it contains information reasonably available to the petitioner supporting the allegations.

We examined the petition on certain forged steel crankshafts from Japan and have found that it meets the requirements of section 732(b) of the Act. Therefore, in accordance with section 732 of the Act, we are initiating an antidumping duty investigation to determine whether certain forged steel crankshafts from Japan are being, or are likely to be, sold in the United States at less than fair value.

Scope of Investigation

The products covered by this investigation are forged carbon or alloy steel crankshafts with a shipping weight between 40 and 750 pounds, whether machined or unmachined. These products are currently classified under items 660.6713, 660.6727, 660.6747, 660.7113, 660.7127 and 660.7147 of the *Tariff Schedules of the United States Annotated (TSUSA)*. Neither cast crankshafts nor forged crankshafts with shipping weights of less than 40 pounds or greater than 750 pounds are subject to this investigation.

United States Price and Foreign Market Value

Petitioner based United States price on sales or offers, C.I.F., delivered, duty paid, by a Japanese manufacturer. Deductions were made for foreign inland freight and insurance, ocean freight and marine insurance, U.S. customs duties, U.S. brokerage and handling charges, U.S. inland freight and insurance, commissions and other selling expenses incurred in the United States, and the cost of a U.S. seller inventory to arrive at an ex-factory packed price.

Petitioner based foreign market value on the home market prices of a Japanese manufacturer. Deductions were made for foreign inland freight and credit costs to arrive at an ex-factory packed price.

Based on this method of comparison, petitioner alleges a dumping margin of 29.22 percent.

Notification of ITC

Section 732(d) of the Act requires us to notify the ITC of this action and to provide it with the information we used to arrive at this determination. We will notify the ITC and make available to it by nonprivileged and nonproprietary information. We will also allow the ITC access to all privileged and confidential information in our files, provided it confirms that it will not disclose such information either publicly or under an administrative protective order without the consent of the Deputy Assistant Secretary for Import Administration.

Preliminary Determination by ITC

The ITC will determine by November 23, 1986, whether there is a reasonable indication that imports of certain forged steel crankshafts from Japan are causing material injury, or threaten material injury to, a United States industry. If its determination is negative, the investigation will terminate; otherwise, it will proceed according to the statutory procedures.

Gilbert B. Kaplan,

Deputy Assistant Secretary for Import Administration.

October 29, 1986.

[FR Doc. 86-25122 Filed 11-5-86; 8:45 am]

BILLING CODE 3510-DS-M

[A-412-602]

Certain Forged Steel Crankshafts From the United Kingdom; Initiation of Antidumping Duty Investigation

AGENCY: International Trade Administration, Import Administration, Commerce.

ACTION: Notice.

SUMMARY: On the basis of a petition filed in proper form with the United States Department of Commerce, we are intitiating an antidumping duty investigation to determine whether certain forged steel crankshafts from the United Kingdom (U.K.) are being, or are likely to be, sold in the United States at less than fair value. We are notifying the United States International Trade Commission (ITC) of this action so that it may determine whether imports of this product are causing material injury, or threaten material injury, to a United States industry. If this investigation proceeds normally, the ITC will make its preliminary determination on or before November 24, 1986, and we will make ours on or before March 18, 1987.

EFFECTIVE DATE: November 6, 1986.

FOR FURTHER INFORMATION CONTACT: Charles Wilson or James Riggs, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 377-5288 or (202) 377-4929.

SUPPLEMENTARY INFORMATION:

The Petition

On October 9, 1986, we received a petition in proper form filed by Wyman-Gordon Company. In compliance with the filing requirements of § 353.36 of the Commerce Regulations (19 CFR 353.36), the petition alleged that imports of the subject merchandise from the U.K. are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Tariff Act of 1930, as amended (the Act), and that these imports are causing material injury, or threaten material injury, to a United States industry.

Initiation of Investigation

Under section 732(c) of the Act, we must determine, within 20 days after a petition is filed, whether it sets forth the allegations necessary for the initiation of an antidumping duty investigation and, further, whether it contains information reasonably available to the petitioner supporting the allegations.

We examined the petition on certain forged steel crankshafts from the U.K. and have found that it meets the requirements of section 732(b) of the Act. Therefore, in accordance with section 732 of the Act, we are initiating an antidumping duty investigation to determine whether certain forged steel crankshafts from the U.K. are being, or are likely to be, sold in the United States at less than fair value.

Scope of Investigation

The products covered by this investigation are forged carbon or alloy steel crankshafts with a shipping weight between 40 and 750 pounds, whether machined or unmachined. These products are currently classified under items 660.6713, 660.6727, 660.6747, 660.7113, 660.7127 and 660.7147 of the *Tariff Schedules of the United States Annotated (TSUS).* Neither cast crankshafts nor forged crankshafts with shipping weights of less than 40 pounds or greater than 750 pounds are subject to this investigation.

United States Price and Foreign Market Value

Petitioner based United States price on sales or offers, C.I.F., delivered, duty paid, by a British manufacturer. Deductions were made for foreign inland freight and insurance, ocean freight and marine insurance, U.S. customs duties, U.S. brokerage and handling charges, U.S. inland freight and insurance, and other selling expenses incurred in the United States, and the cost of a U.S. seller's inventory to arrive at an ex-factory packed price.

Because petitioner was unable to provide information on home market or third country market selling prices in the U.K., petitioner based foreign market value on constructed value. British material, labor, and power costs were provided. Depreciation, maintenance and other factory overhead were calculated using ratios based on petitioner's experience. To the sum of materials and fabrication costs, petitioner added the statutory minimums of ten and eight percent for general expenses and profit, respectively.

Based on this method of comparison, petitioner alleges an average dumping margin of 18.10 percent.

Notification of ITC

Section 732(d) of the Act requires us to notify the ITC of this action and to provide it with the information we used to arrive at this determination. We will notify the ITC and make available to it all nonprivileged and nonproprietory information. We will also allow the ITC access to all privileged and proprietary information in our files, provided it confirms that it will not disclose such information either publicly or under an administrative protective order without the consent of the Deputy Assistant Secretary for Import Administration.

Preliminary Determination by ITC

The ITC will determine by November 24, 1986, whether there is a reasonable indication that imports of certain forged steel crankshafts from the U.K. are causing material injury, or threaten material injury to, a United States industry. If its determination is negative, the investigation will terminate; otherwise, it will proceed according to statutory procedures.

Gilbert B. Kaplan,

Deputy Assistant Secretary for Import Administration.

October 29, 1986.

[FR Doc. 86-25120 Filed 11-5-86; 8:45 am]

BILLING CODE 3510-DS-M

[A-428-604]

Certain Forged Steel Crankshafts From the Federal Republic of Germany; Initiation of Antidumping Duty Investigation

AGENCY: International Trade Administration, Import Administration, Commerce.

ACTION: Notice.

SUMMARY: On the basis of a petition filed in proper form with the United States Department of Commerce, we are initiating an antidumping duty investigation to determine whether certain forged steel crankshafts from the Federal Republic of Germany (FRG) are being, or are likely to be, sold in the United States at less than fair value. We are notifying the United States International Trade Commission (ITC) of this action so that it may determine whether imports of this product are causing material injury, or threaten material injury to, a United States industry. If this investigation proceeds normally, the ITC will make its preliminary determination on or before November 24, 1986, and we will make ours on or before March 18, 1987.

EFFECTIVE DATE: November 6, 1986.

FOR FURTHER INFORMATION CONTACT: Charles Wilson or James Riggs, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 377-5288 or (202) 377-4929.

SUPPLEMENTARY INFORMATION:

The Petition

On October 9, 1986, we received a petition in proper form filed by Wyman-Gordon Company. In compliance with the filing requirements of § 353.36 of the Commerce Regulations (19 CFR 353.36), the petition alleged that imports of the subject merchandise from the FRG are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Tariff Act of 1930, as amended (the Act), and that these imports are causing material injury, or threaten material injury to, a United States industry.

Initiation of Investigation

Under section 732(c) of the Act, we must determine, within 20 days after a petition is filed, whether it sets forth the allegations necessary for the initiation of an antidumping duty investigation and, further, whether it contains information reasonably available to the petitioner supporting the allegations.

We examined the petition on certain forged steel crankshafts from the FRG and have found that it meets the requirements of section 732(b) of the Act. Therefore, in accordance with section 732 of the Act, we are initiating an antidumping duty investigation to determine whether certain forged steel crankshafts from the FRG are being, or are likely to be, sold in the United States at less than fair value.

Scope of Investigation

The products covered by this investigation are forged carbon or alloy steel crankshafts with a shipping weight between 40 and 750 pounds, whether machined or unmachined. These products are currently classified under items 660.6713, 660.6727, 660.6747, 660.7113, 660.7127, and 660.7147 of the *Tariff Schedules of the United States Annotated (TSUSA)*. Neither cast crankshafts nor forged crankshafts with shipping weights of less than 40 pounds or greater than 750 pounds are subject to this investigation.

United States Price and Foreign Market Value

Petitioner based United States price on sales or offers, C.I.F., delivered, duty paid, by a German manufacturer. Deductions were made for foreign inland freight and insurance, ocean freight and marine insurance, U.S. customs duties, U.S. brokerage and handling charges, U.S. inland freight and insurance, and other selling expenses incurred in the United States, and the cost of a U.S. seller's inventory to arrive at an ex-factory packed price.

Because petitioner was unable to provide information on home market or third contry market selling prices in Germany, petitioner based foreign market value on constructed value. German material, labor, and power costs were provided. Depreciation, maintenance and other factory overhead were calculated using ratios based on petitioner's experience. To the sum of materials and fabrication costs, petitioner added the statutory minimums of ten and eight percent for general expenses and profit respectively.

Based on this method of comparison, petitioner alleges an average dumping margin of 28.29 percent.

Notification of ITC.

Section 732(d) of the Act requires us to notify the ITC of this action and to provide it with the information we used to arrive at this determination. We will notify the ITC and make available to it all nonprivileged and nonproprietary information. We will also allow the ITC access to all privileged and proprietary information in our files, provided it confirms that it will not disclose such information either publicly or under an administrative protective order without the consent of the Deputy Assistant Secretary for Import Administration.

Preliminary Determination by ITC

The ITC will determine by November 24, 1986, whether there is a reasonable indication that imports of certain forged steel crankshafts from the FRG are causing material injury, or threaten material injury to, a United States industry. If its determination is negative, the investigation will terminate; otherwise, it will proceed according to the statutory procedures.

Gilbert B. Kaplan,

Deputy Assistant Secretary for Import Administration

October 29, 1986.

[FR Doc. 86-25121 Filed 11-5-86; 8:45 am]

BILLING CODE 3510-DS-M

National Oceanic and Atmospheric Administration

Coastal Zone Management; Federal Consistency Appeal by Ronald Lafferty From an Objection by the New Jersey Department of Environmental Protection

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of Appeal and Stay.

On October 17, 1986, Ronald Lafferty filed a notice of appeal from an objection by the New Jersey Department of Environmental Protection (DEP) under section 307(c)(3)(A) of the Coastal Zone Management Act. The DEP objected to appellant's bulkhead constructed at 306 51st Street, Avalon, New Jersey, without a permit form the Army Corps of Engineers.

Appellant and the DEP are currently negotiating in an attempt to resolve the inconsistencies of the bulkhead with the New Jersey Coastal Zone Management Program. During these negotiations, this appeal is stayed for four months. This stay can be extended on a showing of good cause. If negotiations are successful, appallant may withdraw his appeal. If the parties are unable to settle their differences, either on their own or with the assistance of the National Oceanic and Atmospheric Administration, the appeal may be resumed at the request of the parties, or on the Secretary of Commerce's motion. A briefing schedule and request for

public comments will be issued at that time.

FOR ADDITIONAL INFORMATION CONTACT: L. Pittman, Office of the General Counsel, 1825 Connecticut Avenue, NW., Suite 603, Washington, DC 20235; (202) 673–5200.

[Federal Domestic Assistance Catalog No. 11.419 Coastal Zone Management Program Administration]

Dated: November 3, 1986.

Daniel W. McGovern,

General Counsel, National Oceanic and Atmospheric Administration.

[FR Doc. 86–25116 Filed 11–5–86; 8:45 am]

BILLING CODE 3510-08-M]

Coastal Zone Management; Federal Consistency Appeal by the County of San Mateo

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Withdrawal of appeal.

SUMMARY: On October 17, 1986, the Secretary of Commerce granted the request of the County of San Mateo, California, to withdraw its appeal filed under section 307(c)(3)(A) of the Coastal Zone Management Act, 16 U.S.C. 1456(c)(3)(A). The County had appealed an objection by the California Coastal Commission to the construction of a fence in Princeton-by-the-Sea. The fence was built to block vehicle access to a marsh adjacent to Princeton Harbor. The Commission objected to the fence because it also blocked beach access in violation of the California Coastal Management Program.

The parties to this appeal requested informal mediation assistance from the National Oceanic and Atmospheric Administration's Office of Ocean and Coastal Resource Management. The appeal was stayed during mediation, which was successful, with the County agreeing to construct six new parking spaces adjacent to the fenced area. The County then requested permission to withdraw its appeal.

FOR FURTHER INFORMATION CONTACT: L. Pittman, NOAA Office of General Counsel, 1825 Connecticut Avenue, NW., Suite 603, Washington, DC 20235, (202) 673–5200.

[Federal Domestic Assistance Catalog No. 11.419, Coastal Zone Management Program Administration.]

Dated: October 31, 1986.

Daniel W. McGovern,

General Counsel, National Oceanic and Atmospheric Administration.

[FR Doc. 86–25047 Filed 11–5–86; 8:45 am]

BILLING CODE 3510-08-M

[Modification No. 2 to Permit No. 443]

Marine Mammal Permit Modification; Southwest Fisheries Center

Correction

In FR Doc. 86–23880 appearing on page 37624 in the issue of Thursday, October 23, 1986, make the following corrections:

On page 37624, in the first column, in paragraph "5.", in the first line, "point" should read "permit", and in the last line, "1988" should read "1989".

BILLING CODE 1505-01-M

Mid-Atlantic Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Mid-Atlantic Fishery Management Council will convene a public meeting, November 18–19, 1986, at the Holiday Inn, Oceanfront at 39th Street, Virginia Beach, VA (telephone: 804–428–1711), to consider Amendment #7 to the Surf Clam and Ocean Quahog Fishery Management Plan; to consider joint venture applications for 1987; to review river herring bycatch information, as well as to discuss other fishery management matters. The public meeting may be lengthened or shortened depending upon progress on agenda items. The Council also may convene a closed session (not open to the public) to discuss personnel and/or national security matters. For further information, contact John C. Bryson, Executive Director, Mid-Atlantic Fishery Management Council, Federal building, 300 South New Street, Room 2115, Dover, DE 19901; telephone: (302) 674–2331.

Dated: November 3, 1986.

Richard B. Roe,

Director, Office of Fisheries Management, National Marine Fisheries Service.

[FR Doc. 86–25048 Filed 11–5–86; 8:45 am]

BILLING CODE 3510-22-M

National Technical Information Service

Intent To Grant Exclusive Patent License

The National Technical Information Service (NTIS), U.S. Department of Commerce, intends to grant to Lehn & Fink Products Group, Sterling Drug, Inc., having a place of business in Montvale, New Jersey, an exclusive right to manufacture, use and sell cockroach-repellent compositions embodied in the inventions entitled "Cockroach Repellents," U.S. Patent Applications No. 6–625,266 and S.N. 6–625,329 and "Insect Repellents," U.S. Patent Application S.N. 6–625,328. The patent rights in these inventions have been assigned to the United States of America.

The proposed license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 41 CFR 101–4.1. The proposed license may be granted unless, within sixty days from the date of this published Notice, NTIS receives written evidence and argument which establishes that the grant of the proposed license would not serve the public interest.

Inquiries, comments and other materials relating to the proposed license must be submitted to the Office of Federal Patent Licensing, NTIS, Box 1423, Springfield, VA 22151.

Douglas J. Campion,

Patent Licensing Specialist, Office of Federal Patent Licensing, U.S. Department of Commerce, National Technical Information Service.

[FR Doc. 86–25058 Filed 11–5–86; 8:45 am]

BILLING CODE 3510-04-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Import Limits for Certain Cotton and Man-Made Fiber Textiles and Textile Products Produced or Manufactured in Thailand

November 3, 1986.

The Chairman of the Committee for the Implementation of Textile Agreements (CITA), under the authority contained in E.O. 11651 of March 3, 1972, as amended, has issued the directive published below to the Commissioner of Customs to be effective on November 7, 1986. For further information contact Kathy Davis, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377–4212.

Background

The Governments of the United States and Thailand have agreed in consultations to further amend their Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of July 27 and August 8, 1983, as previously amended and extended, to drop the import restraint limit for men's and boys' other wool coats in Category 434 during 1986, and to establish, among other things, new specific limits for cotton yarns in Categories 300 and 301, woven fabrics of man-made fibers in Category 611, and

polypropylene bags in part of Category 669 (only TSUSA number 385.5300), produced or manufactured in Thailand and exported, in the case of Categories 300 and 301, during the twelve-month period which began on January 1, 1986 and extends through December 31, 1986; in the case of Category 611, during the six month period which began on June 1, 1986 and extends through December 31, 1986, and in the case of Category 669 pt., duirng the four-month period which began on September 1, 1986 and extends through December 31, 1986. In the letter which follows this notice the Chairman of CITA directs the Commissioner of Customs to establish these new specific limits.

A description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983, (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1986).

William H. Houston III,

Chairman, Committee for the Implementation of Textile Agreements.

November 3, 1986.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Mr. Commissioner: This directive further amends, but does not cancel, the directive of November 27, 1985, as previously amended, which established limits for certain categories of cotton, wool and man-made fiber textiles and textile products, produced or manufactured in Thailand and exported during the agreement year which began on January 1, 1986.

Effective on November 7, 1986, the directive of November 27, 1985, as previously amended, is hereby further amended to establish the following limits for cotton textiles in Categories 300 and 301:

Category	12-mo restraint limit [1]
300	5,000,000 pounds.
301 pt.[2]	5,000,000 pounds.
301 pt.[3]	1,000,000 pounds.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1985, May 31, 1986, or August 31, 1986, as applicable.
[2] In Category 301, only TSUSA numbers 300.6026 and 300.6028.
[3] In Category 301, all TSUSA numbers in the category except those listed in footnote 2.

Also effective on November 7, 1986, the following limits should be established for man-made fiber textile products in Categories 611 and 669 pt.:

Category	Restraint limit [1]	Date of export period
611	2,300,000 square yards.	June 1 to December 31, 1986.
669 pt.[2]	850,000	September 1 to December 31, 1986.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1985, May 31, 1986, or August 31, 1986, as applicable.
[2] In Category 669, only TSUSA number 385.5300.

Textile products in the foregoing categories which have been exported to the United States prior to January 1, 1986 (Categories 300 and 301), prior to June 1, 1986 (Category 611), or prior to September 1, 1986 (Category 669 pt.) shall not be subject to this directive.

Textile products in all of the foregoing categories which have been released from the custody of the U.S. Customs Service under the provisions of 19 U.S.C. 1448(b) or 1484(a)(1)(A) prior to the effective date of this directive shall not be denied entry under this directive.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553.

William H. Houston III,
Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 86-25117 Filed 11-5-86; 8:45 am]
BILLING CODE 3510-DR-M

Request for Public Comment on Bilateral Textile Consultations With the Government of Turkey on Categories 350 and 605pt.

November 3, 1986.

On September 30, 1986, the United States Government, under Article 3 of the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as extended by Protocols dated December 15, 1977, December 22, 1981 and July 31, 1986, requested the Government of Turkey to enter into consultations concerning exports to the United States of certain cotton and man-made fiber textile products, produced or manufactured in Turkey.

The purpose of this notice is to advise that, if no solution is agreed upon in consultations with Turkey, the Committee for the Implementation of Textile Agreements may later establish limits for the entry and withdrawal from warehouse for consumption of cotton dressing gowns in Category 350 and man-made fiber handknitting yarns in Category 605pt. (only T.S.U.S.A. numbers 310.9310 and 310.9320), produced or manufactured in Turkey and exported to the United States during the twelve-month period which began on September 30, 1986 and extends through September 29, 1987 at levels of 64,972 dozen (Category 350) and 747,011 pounds (Category 605pt.).

Summary market statements for these categories follow this notice.

Anyone wishing to comment or provide data or information regarding the treatment of these categories is invited to submit such comments or information in ten copies to Mr. William H. Houston III, Chairman, Committee for the Implementation of Textile Agreements, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230. Because the exact timing of the consultations is not yet certain, 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 3100, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, DC, and may be obtained upon written request.

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 agreement or the implementation thereof is not a waiver in any respect of the exemption contained in 5 U.S.C. 553(a)(1) relating to matters which constitute "a foreign affairs function of the United States."

A description of the cotton, wool and man-made fiber textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on December 13, 1982 (47 FR 55709), as amended on April 7, 1983 (48 FR 15175), May 3, 1983 (48 FR 19924), December 14, 1983 (48 FR 55607), December 30, 1983 (48 FR 57584), April 4, 1984 (49 FR 13397), June 28, 1984 (49 FR 26622), July 16, 1984 (49 FR 28754), November 9, 1984 (49 FR 44782), and in Statistical Headnote 5, Schedule 3 of the Tariff Schedules of the United States Annotated (1986).

William H. Houston III,

Chairman, Committee for the Implementation of Textile Agreements.

Turkey—Market Statement

Category 350—Cotton Dressing Gowns and Robes—September 1986

Summary and Conclusions

U.S. imports of Category 350 from Turkey were 69,878 dozen during the year ending July 1986 over three and one-half times the 19,513 dozen imported a year earlier. During the first seven months of 1986, imports from Turkey were 43,692 dozen, a threefold increase over the 14,178 dozen imported during the same period of 1985 and eight percent more than the amount imported during the full year 1985. Turkey is the fifth largest supplier and the largest uncontrolled supplier of Category

350 imports, accounting for ten percent of 1986 imports.

The U.S. market for Category 350 has been disrupted by imports. The sharp and substantial increase of imports from Turkey has contributed to this disruption.

U.S. Production and Market Share

U.S. production of Category 350 declined by 11 percent from 680 thousand dozen in 1983 to 605 thousand dozen in 1985. The U.S. producers' share of the market fell from 60 percent in 1983 to 47 percent in 1985.

U.S. Imports and Import Penetration

U.S. imports of Category 350 grew from 461 thousand dozen in 1983 to 676 thousand dozen in 1985, a 47 percent increase. Imports continue to grow in 1986. Category 350 imports are up 20 percent in the first seven months of 1986. The ratio of imports to domestic production increased from 68 percent in 1983 to 112 percent in 1985.

Duty-Paid Value and U.S. Producers' Price

Approximately 88 percent of Category 350 imports form Turkey during the first seven months of 1986 entered under TSUSA No. 381.5020—men's and boys' cotton dressing gowns and robes, except corduroy, not knit and TSUSA No. 384.4000—women's, girls' and infants' cotton dressing gowns and robes, except corduroy, not knit. These dressing gowns and robes entered the U.S. at duty-paid landed values below the U.S. producer price for comparable dressing gowns and robes.

Turkey—Market Statement

Category 605 Pt.—Man-Made Fiber Handknitting Yarns—September 1986

Summary and Conclusions

U.S. imports of Category 605-Pt.—man-made fiber handknitting yarns—from Turkey totaled 985,050 pounds during the year-ending July 1986. This is nearly four and half times the amount imported during the same period a year earlier. During the first seven months of 1986, imports of handknitting yarns from Turkey were 920,344 pounds, nearly five times the amount imported during the comparable period of 1985 and almost 3 and a half time the level imported during calendar year 1985. Turkey is the third largest supplier of handknitting yarns accounting for 14.5 percent of total U.S. imports in 1986.

The sharp and substantial increase of low-valued imports from Turkey are severely disrupting the U.S. market for man-made fiber handknitting yarns.

U.S. Production and Market Share

U.S. production of handknitting yarns in 1985 was 18 percent below the 1983 level. During the first six months of 1986, production dropped 15 percent below the level of the comparable period of 1985.

U.S. producers' share of the market for domestically produced and imported man-made fiber handknitting yarns declined from 93 percent in 1983 to 81 percent during the first six months of 1986.

Import and Import Penetration

U.S. imports of man-made fiber handknitting yarns more than doubled in 1985 reaching 6.9 million pounds. Imports in 1986 continue to increase at a substantial rate. Imports for the first seven months were up 72 percent above the January–July 1985 level.

The ratio of imports to domestic production during the first six months of 1986 was 23.8 percent, more than 3 times the 7.6 percent of 1983.

Duty Paid Values and U.S. Producers' Price

Approximately 90 percent of Category 605 Pt. man-made fiber handknitting yarns from Turkey during the first seven months of 1986 entered under TSUSA No. 310.9320—man-made fiber handknitting yarn, over 90 cents per pound. These yarns are entered at landed duty paid values below the U.S. producers' price for comparable handknitting yarns.

[FR Doc. 86-25118 Filed 11-5-86; 8:45 am]

BILLING CODE 3510-DR-M

DEPARTMENT OF DEFENSE

Department of the Air Force

Air Force Activities for Conversion to Contract

ACTION: Notice.

The Air Force recently determined that the satellite Supply function at Kelly AFB, TX, will be examined for possible conversion to contract.

For further information contact Ms. Karen Johnson, HQ ESC/XPMQ, Kelly AFB, TX, telephone (515) 925-2271.

Patsy J. Conner,

Air Force Federal Register, Liaison Officer.

[FR Doc. 86-25065 Filed 11-5-86; 8:45 am]

BILLING CODE 3910-01-M

Public Information Collection Requirement Submitted to OMB Review

ACTION: Public Information Collection Requirement Submitted to OMB Review.

SUMMARY: The Department of Defense has submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Each entry contains the following information: (1) Type of submission; (2) Title of Information Collection and Form Number, if applicable; (3) Abstract statement of need for and the uses to be made of the information collected; (4) Type of Respondent; (5) An estimate of the number of responses; (6) An estimate of the total number of hours needed to provide the information; (7) To whom comments regarding the information collection are to be forwarded; and (8) The point of contact from whom a copy of the information proposal may be obtained.

Revision

Arrears of Pay Designation and/or Annuity Beneficiary Changes

AF form 114 will request or update arrears of apy (AOP) designation information from Air Force retiree and use the information to automate and expedite AOP payments to beneficiaries when the retiree dies.

Individuals

Responses: 3,000; Burden Hours: 150.

ADDRESSES: Comments are to be forwarded to Mr. Edward Springer, Office of Management and Budget, Desk Officer, Room 3235, New Executive Office Building, Washington, DC 20503, and Mr. Daniel J. Vitiello, DOD Clearance Officer, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, telephone number (202) 746-0933.

SUPPLEMENTARY INFORMATION: A copy of the information collection proposal may be obtained from Ms. June Parsons, AFAFC/RP, Denver, CO 80279-5000, telephone number (303) 370-7458.

Patricia H. Means,

OSD Federal Register Liaison Officer, Department of Defense.

October 31, 1986.

[FR Doc. 86-25077 Filed 11-5-86; 8:45 am]

BILLING CODE 3810-01-M

USAF Scientific Advisory Board

October 30, 1986.

The USAF Scientific Advisory Board Ad Hoc Committee on Minuteman III Penetration Aids will meet at Headquarters Ballistic Missile Office, Norton AFB CA on November 24-25, 1986 from 8:00 a.m. to 5:00 p.m.

The purpose of the meeting is to review, discuss and evaluate the effectiveness of penetration aids proposed for the Minuteman III.

The meeting concerns matters listed in section 552b(c) of Title 5, United States Code, specifically subparagraph (1) thereof, and accordingly, will be closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at 202-697-8845.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 86-25059 Filed 11-5-86; 8:45 am]

BILLING CODE 3910-01-M

DEPARTMENT OF EDUCATION

National Board of the Fund for the Improvement of Postsecondary Educational; Meeting

AGENCY: National Board of the Fund for the Improvement of Postsecondary Education, ED.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the proposed agenda of a forthcoming meeting of the National Board of the Fund for the Improvement of Postsecondary Education. This notice also describes the functions of the Board. Notice of this meeting is required under the Federal Advisory Committee Act (Pub. L. 92–463), section 10(a)(2)).

DATE: December 4, 1986 at 9:00 a.m. through December 6, 1986 at 12:00 p.m.

ADDRESS: Washington Hilton, 1919 Connecticut Avenue, NW., Washington, DC 20009.

FOR FURTHER INFORMATION CONTACT: Charles Karelis, Director, Fund for the Improvement of Postsecondary Education, 7th & D Streets, SW., Washington, DC 20202 (202) 245–8091.

SUPPLEMENTARY INFORMATION: The National Board of the Fund for the Improvement of Postsecondary Education is established under section 1003 of the Higher Education Amendments of 1980, Title X (20 U.S.C. 1135a–1). The National Board of the Fund is established to "advise the Secretary and the Director of the Fund for the Improvement of Postsecondary Education . . . on the selection of projects under consideration for support by the Fund in its competitions."

The meeting of the National Board will be open to the public. The proposed agenda includes:

—An orientation and introduction of new Board members;
—A discussion and review of the past year;
—Development and discussion of policies and priorities for the coming year.
—Observation and participation in the Fund for the Improvement of Postsecondary Education Annual Project Directors' Meeting.

Records shall be kept of all Board proceedings, and shall be available for public inspection at the Fund for the Improvement of Postsecondary Education, 7th & D Streets, SW., Room 3100, Washington, DC 20202 from the hours of 8:00 a.m. to 4:30 p.m. weekdays, except Federal Holidays.

C. Ronald Kimberling,

Assistant Secretary for Postsecondary Education.

[FR Doc. 86–25098 Filed 11–5–86; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Energy Information Administration

Renewal of the Charter of The American Statistical Association Committee on Energy Statistics

Pursuant to the Federal Advisory Committee Act (Pub. L. 92–463), I hereby certify that the renewal of the charter of the American Statistical Association Committee on Energy Statistics is in the public interest in connection with the performance of duties imposed on the Department of Energy by law. This determination follows consultation with the Committee Management Secretariat of the General Services Administration, pursuant to 41 CFR Subpart 101–6.1007.

The purpose of the committee is to provide advice on a continuing basis to the Administrator of the Energy Information Administration (EIA), including:

1. Periodic reviews of elements of EIA information collection and analysis programs and the provision of recommendations;

2. Advice on priorities of technical and methodological issues in the planning, operation, and review of EIA statistical programs; and

3. Advice on matters concerning improved energy modeling and forecasting tools, particularly regarding their functioning, relevancy, and results.

Further information concerning this committee can be obtained from Gloria Decker (202–252–8990).

Dated: October 31, 1986.

Charles Tierney,

Advisory Committee Management Officer.

[FR Doc. 86–25127 Filed 11–15–86; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[SWH–FRL–3106–5]

Solid Waste Disposal; Household Hazardous Waste; State Programs

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability of reports on household hazardous waste and state solid waste (subtitle D) programs.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is today announcing the availability of two reports. The first report is entitled "A Survey of Household Hazardous Waste and Related Collection Programs." This report defines household hazardous waste (HHW); summarizes existing information regarding the presence of HHW in residential waste; and discusses the impacts of HHW on homeowners, solid waste collection and disposal personnel, and the environment. Information about HHW collection programs conducted at the State and local levels is also included in the report. The second report is entitled "Census of State and Territorial Subtitle D Non-Hazardous Waste Programs." This report summarizes the results of a mail survey of State and Territorial non-hazardous (solid) waste regulatory programs. Data from all the States and six Territories are reported. State organization and available resources for Subtitle D programs are given. Numbers and basic characteristics of landfills, land application units, and surface impoundments are included, as well as information on regulations and enforcement patterns.

ADDRESS: The reports are available for viewing at all EPA libraries and in the EPA RCRA docket room, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, from 9:30 a.m. to 3:30 p.m., Monday thru Friday, except legal holidays; telephone: (202) 475–9327. The public may copy a maximum of 50 pages of material from any one regulatory docket at no cost. Additional copies cost 20 cents per page. Limited copies of the HHW report are available, while supplies last, from the EPA RCRA/Superfund Hotline at (800) 424–9346 ((202) 382–3000 in Washington, DC). These documents are available for purchase from the National Technical Information Service (NTIS), U.S. Department of Commerce, Springfield, VA 22161, at (703) 487–4600: "A Survey of Household Hazardous Waste and Related Collection Programs" (EPA/530–SW–86–038, NTIS No.: PB–87–108–072, $18.95 hardcopy, $6.50 microfiche) and "A Census of State and Territorial Subtitle D Non-Hazardous Waste Programs" (EPA/530–SW–86–039, NTIS No.: PB–87–108–080, $24.95 hardcopy, $6.50 microfiche).

FOR FURTHER INFORMATION CONTACT: For general information, call the RCRA Hotline at (800) 424–9346 ((202) 382–3000 in Washington, DC). For technical

information on the HHW report contact, Gerry Dorian, Office of Solid Waste (WH-565E), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 382-4688. For information on the State Survey report, contact Allen Geswein, (202) 382-4687, at the same address.

SUPPLEMENTARY INFORMATION: In 1979, under the authority of sections 1008(a)(3) and 4004(a) of Subtitle D of the Resource Conservation and Recovery Act (RCRA), EPA promulgated the "Criteria for Classification of Solid Waste Disposal Facilities and Practices" (40 CFR Part 257). These Criteria include environmental performance standards that are used for determining which solid waste disposal facilities and practices pose a reasonable probability of adverse effects on human health or the environment. Those facilities that violate the Criteria are deemed "open dumps." The Criteria are enforced by the States or through citizen suits.

In 1984, Congress passed the Hazardous and Solid Waste Amendments (HSWA), which include several major provisions regarding the solid waste regulatory program. The Amendments, require EPA to submit a report to Congress by November 8, 1987, that addresses whether the current Criteria (40 CFR Part 257) are adequate to protect human health and the environment, and whether additional authorities are needed to enforce the Criteria. Further, EPA is required to revise the Criteria by March 31, 1988, for facilities that may receive hazardous household waste or small quantity generator (SQG) hazardous waste. HWSA also requires the States to have a permit program for the existing Criteria by November 1987, and to have a revised permit program 18 months after the revised Criteria are promulgated.

In response to these statutory mandates, the Agency is currently gathering extensive data for both the report to Congress and the Criteria revisions. The two reports being made publicly available today are the result of two of these data collection efforts.

Household Hazardous Waste Report

The report entitled, "A Survey of Household Hazardous Waste and Related Collection Programs," contains the results of a study of household hazardous waste that addressed the following topics: (1) The definition of HHW; (2) the quantities of HHW in the municipal waste of stream; (3) the impacts of HHW on homeowners, solid waste collection and disposal personnel, and the environmental; and (4) HHW collection programs conducted at the State and local levels. Included in the review of collection programs was an examination of the liability of operators and sponsors of HHW collection programs under RCRA and the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA).

As part of the study, a standard definition of HHW was developed. Lists of household products that may be considered household hazardous wastes, when discarded, were prepared based on this definition. For example, certain products within the following broad classes of materials could be considered HHW when discarded: drain openers, oven cleaners, wood and metal cleaners and polishes, automotive oil and fuel additives, grease and rust solvents, carburetor and fuel injection cleaners, air conditioning refrigerants, starter fluids, paint thinners, paint strippers and removers, adhesives, herbicides, pesticides and fungicides/wood preservatives. The report describes the criteria used in the definition and the limitations of the analysis. The study also found that there is very little data on the quantities of HHW in residential wastes. However, the limited studies conducted to date indicate that HHW is a small portion of all residential wastes.

The key results regarding the impacts of HHW on the environment, refuse personnel, and homeowners are summarized in the report. Although homeowners are assumed to have been injured due to the presence of HHW in their homes, no data were available to show a direct correlation. However, a number of communities across the nation have reported injuries to sanitation workers that have been caused by HHW. These indicences are often associated with materials that splash or spill during compaction, containers that explode, or materials that emit toxic fumes.

Much recent activity has focused on HHW collection programs. These programs enlist homeowners' cooperation in taking HHW to collection centers where the wastes are identified, packaged, and transported to secure waste disposal facilities. The number of these programs has grown rapidly, with over 30 States having conducted a collection program. Information on these programs, gathered from several sources, is summarized in the report.

A major element of all programs has been public education related to identification of HHW and developing an awareness of the environmental consequences of improper disposal. Problems currently associated with these programs include relatively low participation, high disposal costs, and sponsor liability concerns.

State Survey Report

The report entitled, "Census of State and Territorial Subtitle D Non-Hazardous Waste Programs," summarizes the findings of a mail survey of State and Territorial non-hazardous waste regulatory programs. The survey focused on three key areas: (1) State organization and resources; (2) number and characteristics of landfills, land application units, and surface impoundments; and (3) characteristics of the regulatory program (e.g., regulations, inspections, violations).

The report is organized in six major parts. Part I contains the introduction to the report, the study methodology, and a description of the statistical reliability of the data. Part II describes State organizational structures and resources for the Subtitle D program. Part III provides information on the total number and basic characteristics (owership, acreage, amount of waste received, monitoring systems, design and operational controls) of Subtitle D waste facilities. Part IV provides data on Subtitle D regulatory programs, including information on regulation and enforcement patterns. Part V contains information with respect to the number and quantity of Subtitle D facilities that receive exempted small quantity generator hazardous waste. Part VI provides a summary and conclusions of the report.

There are four appendices to the report. Appendix A provides the responses to a survey question concerning Statewide landfill capacity problems. Appendix B contains data tables with estimates of landfill tipping fees. The cover letters that accompanied the questionnaire are in Appendix C. Appendix D is a copy of the questionnaire used for the survey.

Examples of some of the key survey results contained in the report are as follows:

(1) Approximately 227,000 Subtitle D facilities are located at 120,000 establishment;

(2) The total number of Subtitle D disposal facilities includes: 16,416 landfills (of which 9,300 are municipal waste landfills), 18,889 land application units (LAUs), and 191,822 surface impoundments;

(3) Roughly 16 percent of all Subtitle D facilities, or 36,000, are reported to receive hazardous wastes from households or small quantity generators;

(4) Very few facilities have extensive design and operational controls and very few facilities have systems to monitor releases; and

(5) State Subtitle D regulations and resources vary by State and Territory.

Dated: October 27, 1986.

J.W. McGraw,

Acting Assistant Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. 86-25101 Filed 11-5-86; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notice; Acquisition of Banks or Bank Holding Companies

The notificants listed in this notice have applied for the Board's approval under the Change in Bank Control Act (12 U.S.C. 1817(j) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors.

Comments regarding these applications must be received not later than November 21, 1986.

A. **Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *The Citizens National Bank of Bowling Green Employee Stock Ownership Plan and Related Trust,* Bowling Green, Kentucky; to acquire 16.58 percent of the voting shares of Trans Financial Bancorp, Inc., Bowling Green, Kentucky, and thereby indirectly acquire The Citizens National Bank of Bowling Green, Bowling Green, Kentucky.

B. **Federal Reserve Bank of Minneapolis** (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Arnold B. Chace, Jr.,* Malcolm G. Chace, III, Malcolm G. Chace III Trust, Malcolm G. Chace, Jr. Trust, Jane Chace Trust, Jonathan Chace Clay Trust, Eliot Chace Trust, Christian Nolen Trust, Arnold B. Chace III Trust, Leigh Fibers, Inc., and William R. Dimeling to acquire 83.2 percent of the voting shares of Escrow Corporation of America, Inc., Pennock, Minnesota, and thereby indirectly acquire State Bank of Pennock, Pennock, Minnesota; and Heritage Bank, National Association, Willmar, Minnesota.

2. *David G. Smith,* to acquire 51.13 percent, and Keith G. Eltreim, to acquire 48.87 percent of the voting shares of Jasper Investment Company, Inc., Jasper, Minnesota, and thereby indirectly acquire Jasper State Bank, Jasper, Minnesota.

Board of Governors of the Federal Reserve System, October 31, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-25084 Filed 11-5-86; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program, Board of Scientific Counselors, Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the National Toxicology Program (NTP) Board of Scientific Counselors, U.S. Public Health Service, in the Conference Center, Building 101, South Campus, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina, on November 25, 1986.

The meeting will be open to the public from 8:30 a.m. until adjournment on November 25. The preliminary agenda with *approximate* times are as follows:

8:30 a.m.-9:00 a.m.—Report of the Director

9:00 a.m.-9:30 a.m.—Overview of the NIEHS Intramural Research Program

9:30 a.m.-10:00 a.m.—Overview of the NTP

10:15 a.m.-11:45 a.m.—Review of Chemicals Nominated for NTP Studies.

(Ten chemicals will be reviewed. Of these, five were reviewed by the NTP Chemical Education Committee (CEC) on April 29, 1986, and listed in the **Federal Register,** Volume 51, No. 111, p. 21020, June 10, 1986: (1) Cobalt naphthenate; (2) Di(2-ethylhexyl) sebecate; (3) Methylcyclopentadienyl manganese tricarbonyl; (4) 2-Methylquinoline; and (5) 4-Methylquinoline. The remaining five chemicals, which are benzodiazepine drugs, were reviewed by the CEC on September 16, 1986, and listed in the **Federal Register,** Volume 51, No. 197, pp. 36479-36480, October 10, 1986: (1) Chlordiazepoxide; (2) Clorazepate; (3) Diazepam; (4) Flurazepam; and (5) Oxazepam.)

12:30 p.m.-4:45 p.m.—NIEHS Cellular and Genetic Toxicology Branch—Short-term Assay Evaluation.

I. Introduction.

II. Comparison of *In Vitro* Assay Results with Rodent Carcinogenicity.

III. Comparative Evaluation of Short-term *In Vivo* Assay.

IV. Statistical Aspects.

V. Strategies for Testing and Other Implications of the Evaluation.

The Executive Secretary, Dr. Larry G. Hart, Office of the Director, National Toxicology Program, P.O. Box 12233, Research Triangle Park, North Carolina 27709, telephone (919) 541-3971, FTS 629-3971, will have available a roster of Board members and other program information prior to the meeting and summary minutes subsequent to the meeting.

Dated: October 30, 1986.

David P. Rall,

Director, National Toxicology Program.

[FR Doc. 86-25087 Filed 11-5-86; 8:45 am]

BILLING CODE 4140-01-M

Reestablishments

Pursuant to the Federal Advisory Committee Act, Pub. L. 92-463 (5 U.S.C., Appendix 2), the Office of the Assistant Secretary for Health announces the reestablishment by the Secretary, DHHS, with concurrence by the General Services Administration, of the following advisory committees:

Designation: Health Care Technology Study Section.

Purpose: The Study Section shall advise the Secretary and make recommendations to the Director, National Center for Health Services Research and Health Care Technology Assessment, on research grant applications in medicine, technology assessment, the information sciences, decision sciences (operations research, industrial engineering, health care administration), communications technology, bioengineering, and related fields as applied to hospital-based ambulatory, and community health care. The members of this Study Section shall survey, as scientific leaders, the status of research in their fields.

Designation: Health Services Research and Developmental Grants Review Committee.

Purpose: The Committee shall advise the Secretary and make recommendations to the Director, National Center for Health Services Research and Health Care Technology Assessment, on research grant applications of two general types. One

type of application involves primarily analysis and the use of statistical, economic, and other theoretical approaches to examine problems associated with the delivery of health services. The other type of application involves the analysis of data that derive from both large and small-scale experiments and demonstrations which are designed to test more cost-effective or efficient ways to provide health services.

Authority for the Health Care Technology Study Section will expire on June 30, 1988, and the authority for the Health Services Research and Developmental Grants Review Committee will expire on September 30, 1988, unless the Secretary, DHHS, with the concurrence of the General Services Administration, formally determines that continuance is in the public interest.

Dated: October 23, 1986.

John E. Marshall,

Director, National Center for Health Services Research and Health Care Technology Assessment.

[FR Doc. 86-25078 Filed 11-5-86; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. D-86-824; FR-2300]

Office of the Regional Administrator—Regional Housing Commissioner, Fort Worth Regional Office; Designation

AGENCY: Department of Housing and Urban Development.

ACTION: Designation of order of succession.

SUMMARY: The Regional Administrator—Regional Housing Commissioner is designating officials who may serve as Acting Regional Administrator—Regional Housing Commissioner during the absence, disability, or vacancy in the position of the Regional Administrator—Regional Housing Commissioner.

EFFECTIVE DATE: This designation is effective October 8, 1986.

FOR FURTHER INFORMATION CONTACT: Ann Hallan, Director, Management and Budget Division, Office of Administration, Fort Worth Regional Office, Department of Housing and Urban Development, 1600 Throckmorton, P.O. Box 2905, Forth Worth, Texas 76113-2905, Telephone (817) 885-5451 (this is not a toll-free number).

Designation

Each of the officials appointed to the following positions is designated to serve as Acting Regional Administrator—Regional Housing Commissioner during the absence, disability, or vacancy in the position of the Regional Administrator—Regional Housing Commissioner, with all the powers, functions, and duties redelegated or assigned to the Regional Administrator—Regional Housing Commissioner: Provided that no official is authorized to serve as Acting Regional Administrator unless all preceding listed officials in this designation are unavailable to act by reason of absence, disability, or vacancy in the position:

1. Deputy Regional Administrator;
2. Regional Counsel;
3. Director, Office of Community Planning and Development;
4. Director, Office of Administration;
5. Director, Office of Housing;
6. Director, Office of Fair Housing and Equal Opportunity; and
7. Director, Office of Public Housing.

This designation supersedes the designation published at 44 FR 19043 on July 5, 1984.

Authority: Delegation of Authority 27 FR 4319 (1962); section 9(c), Department of Housing and Urban Development Act, 42 U.S.C. 3531 note; and Interim Order II, 31 FR 815 (1966).

Sam R. Moseley,

Regional Administrator—Regional Housing Commissioner, Region VI.

[FR Doc. 86-25134 Filed 11-5-86; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-060-07-4213-24; CA-13968]

Filing an Airport Lease Application, Serial Number CA-13968, San Bernardino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of filing an airport lease application.

SUMMARY: Notice is hereby given that on May 10, 1983, Marlton P. Forest filed an application for an airport lease at the Giant Rock landing strip in San Bernardino County, California pursuant to the Act of May 24, 1928 (45 Stat. 728; 49 U.S.C. 211-214) as amended (55 Stat. 621, 49 U.S.C. 211) and the regulations thereunder (43 CFR Part 2911). That filing segregated the following public lands from all other appropriations under the public land laws effective May 10, 1983.

San Bernardino Meridian

T. 3N., R. 6E.,
Sec. 19, E½E½,
Sec. 20, S½NW¼, SW¼,
Sec. 21, W½NE¼, NW¼.
Containing 640 acres.

Comments may be sent to the Area Manager, Bureau of Land Management, 150 Coolwater Lane, Barstow, CA 92311. Serial number CA-13968 must be included in the comments to identify the pending application.

Dated: October 30, 1986.

Bary A. Freet,

Acting District Manager.

[FR Doc. 86-25129 Filed 11-5-86; 8:45 am]

BILLING CODE 4210-40-M

[OR-030-07-4322-02: GP7-020]

Vale District Grazing Advisory Board; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: The Vale District Grazing Advisory Board will meet December 9 in the Vale District Office. The meeting agenda will include discussion of proposed 1987 range improvement projects, Rangeland Program Summary updates for the Baker, Northern and Southern Malheur Resource Areas, and a review of the current status of remanded grazing decisions. The advisory board will also be briefed on the Cold Springs wild horse roundup, 1986 wildfire rehabilitation, and the Vale district's policy on supplemental grazing use.

DATE: The meeting will be held Tuesday, December 9, beginning at 9:00 a.m. in the Vale District Office conference room.

ADDRESSES: The Vale District Office is located at 100 East Oregon Street, Vale, Oregon, 97918.

FOR FURTHER INFORMATION CONTACT: Barry Rose, Public Affairs Specialist, Vale District Office, 503-473-3144.

David Lodzinski,

Associate District Manager

[FR Doc. 86-25130 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-33-M

[AZ-010-87-4322-02; 1784-010]

Arizona Strip District Grazing Board; Meeting

ACTION: Notice of meeting.

SUMMARY: The Arizona Strip District Grazing Board will meet at 8:30 A.M. on Tuesday, December 2, 1986 at the Holiday Inn, 850 Bluff Street, St. George, Utah. The primary topics for consideration are FY 1987 rangeland improvements and antelope release update.

FOR FURTHER INFORMATION CONTACT: G. William Lamb, District Manager, 196 E. Tabernacle, St. George, Utah 84770, (801) 673-3545.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Interested persons may make oral statements at 9 A.M. or file written statements for the Board's consideration.

G. William Lamb,

Arizona Strip District Manager.

[FR Doc. 86-25060 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-32-M

[AZ-010-87-4332-02; 1784-010]

Arizona Strip District Advisory Council; Meeting

ACTION: Notice of meeting.

SUMMARY: The Arizona Strip District Advisory Council will meet at 8:30 A.M. on Thursday, December 4, 1986 at the Holiday Inn, 850 Bluff Street, St. George, Utah. Primary topics on agenda are on-going District programs and discussion of issues related to minerals, cultural resources; wildlife and wilderness management.

FOR FURTHER INFORMATION CONTACT: G. William Lamb, District Manager, 196 E. Tabernacle, St. George, Utah 84770, (801) 673-3545.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Interested persons may make oral statements at 2 p.m. or file written statements for the Council's consideration.

G. William Lamb,

Arizona Strip District Manager.

[FR Doc. 86-25061 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-32-M

[NV-030-07-4322-02]

Carson City District Grazing Advisory Board; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Carson City District Grazing Advisory Board.

DATE: December 11, 1986—10:00 a.m. to 3:30 p.m.

DATES: Conference Room, 1535 Hot Springs Road, Suite 300, Carson City, Nevada.

FOR FURTHER INFORMATION CONTACT: Phil Anderson, Carson City District, Bureau of Land Management, 1535 Hot Springs Road, Suite 300, Carson City, Nevada 89701 (702) 882-1631.

SUPPLEMENTARY INFORMATION: This will be the first meeting for the newly elected Carson City District Grazing Advisory Board. The charter of the Advisory Board provides that the Board will advise the Bureau of Land Management (BLM) District Manager in the development of Allotment Management Plans, all phases, and in the expenditure of Range Betterment Funds. The agenda of this meeting will include election of officers, discussion of the Carson City Range Program for the 1987 fiscal year, a brief discussion of current allotment management plans, plus those new plans for 1987 fiscal year, and the status of the land use plans as they pertain to the grazing program and the projects that will be funded by 1987 range betterment funds. The meeting is open to the public. Any person may attend, file a written statement by mail or appear before the board at 2:00 p.m.

James W. Elliott,

District Manager.

[FR Doc. 86-25069 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-HC-M

[MT-020-06-4410-02]

Miles City District Advisory Council; Meeting

AGENCY: Bureau of Land Management, Miles City District Office, Interior.

ACTION: Notice of Meeting.

SUMMARY: Notice is hereby given in accordance with Pub. L. 92-463 that a meeting of the Miles City District Advisory Council will be held Wednesday, December 10, 1986, at 10 a.m. in the conference room at the Miles City District, Bureau of Land Management Resource Area Offices, Miles City Plaza, Miles City, Montana 59301.

The agenda is as follows:

1. Status of access and easement acquisition program.
2. Report on "Access in Montana".
3. Status of Montana BLM Wilderness Designation Process.
4. Consideration of resolution on membership apportionment of National Public Lands Advisory Council.

The meeting is open to the public. The public may make oral statements before the Advisory Council or file written statements for the Council's consideration. Depending upon the number of persons wishing to make an oral statement, a person time limit may be established.

Summary minutes of the meeting will be maintained in the Bureau of Land Management District Office and will be available for public inspection and reproduction during regular business hours within 30 days following the meeting.

FOR FURTHER INFORMATION CONTACT: District Manager, Miles City District, Bureau of Land Management, P.O. Box 940, Miles City, Montana 59301

Nat Millenbach,

District Manager.

[FR Doc. 86-25072 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-DN-M

[AZ-040-07-4322-02]

Safford District Advisory Council and Grazing Advisory Board; Joint Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Meeting.

SUMMARY: Notice is hereby given in accordance with Pub. L. 92-463 and 94-579 and 43 CFR Part 1780, that meetings of the Safford District Advisory Council and the Safford District Grazing Advisory Board will be held. Both the Council and Board meetings will be in conjunction with a field tour of the Lazy B Ranch. The tour will start at the Safford District Office.

DATE: Monday, December 15, 1986; 10:00 a.m.

ADDRESS: Safford District Office, 425 E. 4th Street, Safford, Arizona.

FOR FURTHER INFORMATION CONTACT: Pete Zwaneveld, Public Affairs Specialist or Jack Rietz, District Range Conservationist Safford District Office, 425 East 4th Street, Safford, Arizona 85546. Telephone (602) 428-4040.

SUPPLEMENTARY INFORMATION: The agenda for the meeting includes the following items: Field tour of the Lazy B Ranch to observe various grazing management systems, including Holistic Resource Management; Management Update; and Business from the floor.

The concurrent meetings are open to the public. Council and Board members will meet at the Safford District Office, 425 East 4th Street, Safford, Arizona, at 10:00 a.m. From there they will depart via BLM-provided vehicles for a tour of the Lazy B Ranch. Members of the public may accompany the tour but must provide their own transportation. Written statements may be filed for

either the Council's or Board's consideration. A management update and business from the floor will take place during the lunch stop. The tour is expected to return to Safford by 5:00 p.m.

Summary minutes of the meetings will be maintained in the District Office and will be available for public inspection and reproduction (during regular business hours) within 30 days following the meeting.

Dated: October 31, 1986.

Vernon L. Saline,

Acting District Manager.

[FR Doc. 86-25071 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-32-M

[AA-6980-A, AA-6980-B, AA-6980-C]

Alaska Native Claims Selection; Huna Totem Corp.

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of section 14(b) of the Alaska Native Claims Settlement Act of December 18, 1971, 43 U.S.C. 1601, 1613(b), will be issued to Huna Totem Corporation for approximately 1,534.42 acres. The lands involved are in the vicinity of Hoonah, Alaska.

U.S. Survey No. 2594

Cooper River Meridian, Alaska

T. 43 S., R. 60 E;
T. 43 S., R. 61 E;
T. 43 S., R. 62 E;
T. 44 S., R. 63 E;

A notice of the decision will be published once a week, for four (4) consecutive weeks, in the JUNEAU EMPIRE. Copies of the decision may be obtained by contacting the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513 ((907) 271-5960).

Any party claiming a property interest which is adversely affected by the decision, an agency of the Federal government or regional corporation, shall have until December 8, 1986, to file an appeal. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management, Division of Conveyance Management (960), address identified above, where the requirements for filing an appeal may be obtained. Parties who do not file an appeal in accordance with the requirements of 43 CFR Part 4, Subpart E, shall be deemed to have waived their rights.

Steven L. Willis,

Section Chief, Branch of ANCSA Adjudication.

[FR Doc. 86-25056 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-JA-M

[CA-010-07-4322-10]

Public Use Restriction (Extension); California

AGENCY: Bureau of Land Management, Interior.

ACTION: Extension of temporary vehicle use restrictions in the Short Canyon Area within Kern County in the Caliente Resource Area, Bakersfield District, California.

SUMMARY: This action extends restrictions on vehicle use on BLM-administered public land in the Short Canyon Area in Kern County, California, due to flood-caused damage. Maps of the affected area are available at the Caliente Resource Area Office, 520 Butte Street, Bakersfield, California. All vehicle use in this area is prohibited, except for administrative and rehabilitative purposes. Persons allowed to drive in the area will be designated by an authorized officer. This closure will continue to apply until December 30, 1986, or will open earlier if conditions permit.

The public lands affected by this closure are located in portions of T.26S., R.35E., M.D.M., Sections 20, 21, 22, 26, 27, 28, 29, 32, 33, 34, and 35.

SUPPLEMENTARY INFORMATION: Due to extensive flooding that occurred during July and August 1984 and severe storms in August 1986, massive amounts of sandy soils have been eroded and deposited in the Short Canyon Area. These recently deposited soils, as well as eroded hillside soils, and loss of soil-holding vegetation, represent a potential hazard in that they are highly vulnerable to further erosion and subsequent massive soil movement. This situation directly effects commercial and residential developments in the area. In order to stabilize the eroded area, a temporary vehicle closure will be maintained so that vegetation can be reestablished to protect these fragile soils. Authority for this vehicle closure is contained in CFR Title 43, Chapter II, Part 8364.1(a).

DATES: This vehicle closure is effective from November 16, 1987 through December 30, 1987, unless conditions permit an early opening.

FOR FURTHER INFORMATION CONTACT: Glenn Carpenter, Caliente Resource Area Manager, Caliente Resource Area, Bureau of Land Management, 520 Butte Street, Bakersfield, California 93305; (805) 861-4236.

Dated: October 29, 1986.

Katherine G. McPeters,

Acting Caliente Resource Area Manager.

[FR Doc. 86-25057 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-40-M

[AZ-020-07-4212-13; A-22309]

Realty Action; Exchange of Mineral Estate; Arizona

The following described federal mineral estate has been determined to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716:

Gila and Salt River Meridian

T. 19 N., R. 25 E.,
Section 30: NE¼SW¼.
Comprising 40 acres.

In exchange for the federal mineral estate described above, the United States will acquire the following privately owned mineral estate:

T. 19 N., R. 24 E.,
Section 27, SW¼SW¼.
Comprising 40 acres.

The purpose of this exchange is to acquire the mineral estate underlying a parcel of land that is to be added to Petrified Forest National Park. The above described federal mineral estate is not encumbered by mining claims. The mineral estate to be acquired by the United States from Santa Fe Mining, Inc., is also unencumbered.

Based on leasable and locatable mineral potential reports, it has been determined that the overall potential mineral value of the private and federal mineral estates are approximately equal.

Publication of this notice shall segregate the federal minerals, as described in this notice, from appropriation under the mining laws. This segregative effect shall terminate upon the issuance of a patent or two years from the date of this notice, or upon publication of a Notice of Termination.

Detailed information concerning the exchange, including the locatable mineral potential and the leasable mineral potential reports, can be obtained from the Phoenix Resource Area Manager, 2015 West Deer Valley Road, Phoenix, Arizona 85027. For a period of forty-five (45) days, from the date of this notice, interested parties may submit comments to the Phoenix

District Manager, Bureau of Land Management, 2015 West Deer Valley Road, Phoenix, Arizona 85027. Objections will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any objections, this realty action will become the final determination of the Department of the Interior.

Dated: October 30, 1986.

Marlyn V. Jones,

District Manager.

[FR Doc. 86-25070 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-32-M

[CA-060-07-4211-07-NCBG; CA-19159]

Realty Action; Exchange of Public and Private Lands in Riverside and San Diego Counties, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of realty action—exchange of Public and Private Lands, CA 19159.

SUMMARY: The following described public lands have been determined to be suitable for disposal by exchange under section 206 of the Federal Land Policy and Management Act of October 21, 1976 (43 U.S.C. 1716):

Legal Description and Reservation

Riverside County, San Bernardino Meridian, California

T. 8S., R. 2E.,
Sec. 14: NW¼ NW¼.—A-1
T. 7S., R. 3 E.,
Sec. 18: E½ E½, SE¼ SE¼.—A-1

San Diego County, San Bernardino Meridian, California

T. 11S., R. 1W.,
Sec. 29: Lot 14.
Sec. 31: Lot 6.
Sec. 32: Lots 8, 9, 11, 12, 13.—A-1
T. 9S., R. 2W.,
Sec. 4: SW¼ NE¼, SE¼ NW¼, N½ SW¼.—A-1,2;B
T. 11S., R. 3W.,
Sec. 9: Lots 9 & 16.—A-1
T. 12S., R. 2E.,
Sec. 26: NW¼ NW¼.—A-1
T. 18S., R. 7E.,
Sec. 2: N½ NW¼, SW¼ NE¼, N½ SE¼ NW¼, NE¼ SW¼.—A-1;B

Containing 470.53 acres, more or less.

In exchange for these lands, the United States will acquire the following described non-federal lands in Riverside County from The Nature Conservancy:

San Bernardino Meridian, California

T. 4S., R. 7E.,
Sec. 8: All.

Containing 640.00 acres, more or less.

SUPPLEMENTARY INFORMATION: The purpose of the exchange is to acquire a portion of the non-federal lands within the proposed 13,030 acre preserve for the Coachella Valley fringe-toed lizard. The lizard is federally listed as threatened and State listed as endangered. The Bureau of Land Management's goal is to acquire approximately 6,700 acres within the preserve. The acres being acquired do not constitute habitat for the lizard, but provide a sand source required for the continuing production of active sand dune areas that are critical habitat for the lizard. Other state and federal agencies will acquire the remaining portions of the preserve. The public interest will be well served by completing this exchange.

The values of the lands to be exchanged are approximately equal; full equalization of values will be achieved through acreage adjustment, or by cash payment in an amount not to exceed 25 percent of the value of the lands being transferred out of federal ownership.

Lands to be transferred from the United States will be subject to:

A-1. A reservation to the United States of a right-of-way for ditches and canals constructed by the authority of the United States; Act of August 30, 1890 (26 Stat. 391, 43 U.S.C. 945).

A-2. A right-of-way for a water tank and pipeline granted to Anthony DiMaggio pursuant to the Act of October 21, 1976 (43 U.S.C. 1761); Grant No. CA 18124.

B. All the Geothermal Steam and associated Geothermal Resources shall be reserved to the United States, together with the right to prospect for, mine and remove the minerals. A more detailed description of this reservation, which will be incorporated in the patent document is available for review at this BLM office.

Publication of this notice in the **Federal Register** segregates the public lands from operation of the public land laws and the mining law, except for mineral leasing. The segregative effect will end upon issuance of patent or two years from the date of publication, whichever occurs first.

For detailed information concerning this exchange, including the planning documents, environmental assessment and land report, contact Peter A. Kempenich, BLM Indio Resource Area Office, 1900 E. Tahquitz-McCallum Way, Suite B-1, Palm Springs, California 92262.

For a period of 45 days after publication of this Notice in the **Federal Register**, interested parties may submit comments to the District Manager, California Desert District, 1695 Spruce Street, Riverside, California 92507. Any adverse comments will be evaluated by the State Director, who may vacate or modify this realty action and issue a final determination. In the absence of any action by the State Director, this realty action will become the final determination of the Department of the Interior.

Dated: October 30, 1986.

Bary A. Freet,

Acting District Manager.

[FR Doc. 86-25131 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-40-M

[WY-920-07-4111-15-7001; W-95566]

Proposed Reinstatement of Terminated Oil and Gas Lease, Wyoming

October 30, 1986.

Pursuant to the Provisions of Pub. L. 97-451, 96 Stat. 2462-2466, and Regulation 43 CFR 3108.2-3(a) and (n)(1), a petition for reinstatement of oil and gas lease W-95566 for lands in Natrona County, Wyoming was timely filed and was accompanied by all the required rentals accruing from the date of termination.

The lessee has agreed to the amended lease terms for rentals and royalties at rates of $5 per acre, or fraction thereof, per year and 16-2/3 percent, respectively.

The lessee has paid the required $500 administrative fee and $106.25 to reimburse the Department for the cost of this **Federal Register** notice. The lessee has met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease W-95566 effective July 1, 1986, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Patricia J. Wattles,

Acting Chief, Leasing Section.

[FR Doc. 85-25073 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-22-M

[WY-920-07-4111-15-7001; W-70060-A]

Proposed Reinstatement of Terminated Oil and Gas Lease, Wyoming

October 30, 1986.

Pursuant to the provisions of Pub. L. 97-451, 96 Stat. 2462-2466, and Regulation 43 CFR 3108.2-3(a) and (b)(1), a petition for reinstatement of oil and gas lease W-70060-A for lands in

Converse County, Wyoming was timely filed and was accompanied by all the required rentals accruing from the date of termination.

The lessee has agreed to the amended lease terms for rentals and royalties at rates of $7 per acre, or fraction thereof, per year and 16⅔ percent, respectively.

The lessee has paid the required $500 administrative fee and $106.25 to reimburse the Department for the cost of this Federal Register notice. The lessee has met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease W-70060-A effective August 1, 1986, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Patricia J. Wattles,

Acting Chief, Leasing Section.

[FR Doc. 86-25074 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-22-M

[WY-920-07-4111-15-7001; W-90534]

Proposed Reinstatement of Terminated Oil and Gas Lease, Wyoming

October 29, 1986.

Pursuant to the provisions of Pub. L. 97-451, 96 Stat. 2462-2466, and Regulation 43 CFR 3108.2-3(a) and (b)(1), a petition for reinstatement of oil and gas lease W-90534 for lands in Big Horn County, Wyoming was timely filed and was accompanied by all the required rentals accruing from the date of termination.

The lessee has agreed to the amended lease terms for rentals and royalties at rates of $5 per acre, or fraction thereof, per year and 16⅔ percent, respectively.

The lessee has paid the required $500 administrative fee and $106.25 to reimburse the Department for the cost of this Federal Register notice. The lessee has met all the requirements for reinstatement of the lease as set out in section 31 (d) and (e) of the Mineral Lands Leasing Act of 1920 (30 U.S.C. 188), and the Bureau of Land Management is proposing to reinstate lease W-90534 effective February 1, 1986, subject to the original terms and conditions of the lease and the increased rental and royalty rates cited above.

Patricia J. Wattles,

Acting Chief, Leasing Section.

[FR Doc. 86-25075 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-22-M

Fish and Wildlife Service

Issuance of Permit for Marine Mammals

On August 4, 1986, a notice was published in the Federal Register (51(149) FR 27918) that an application had been filed with the Fish and Wildlife Service by Vancouver Public Aquarium (PRT-709567) for a permit to take and export two Alaskan sea otters (*Enhydra lutris lutris*) for public display.

Notice is hereby given that on October 22, 1986, as authorized by the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), and the Endangered Species Act (16 U.S.C. 1539), the Fish and Wildlife Service issued the requested permit subject to certain conditions set forth therein.

The permits are available for public inspection during normal business hours at the Fish and Wildlife Service's Office in Room 605, 1000 North Glebe Road, Arlington, Virginia 22201.

Dated: October 31, 1986.

R.K. Robinson,

Chief, Federal Wildlife Permit Office.

[FR Doc. 86-25115 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-55-M

Minerals Management Service

Outer Continental Shelf (OCS) Oil and Gas Information Program

Notice. Availability of 1986 Outer Continental Shelf Information Program (OCSIP) Documents for the Atlantic, Pacific, and Gulf of Mexico Regions, and the OCS National Compendium.

Summary: The OCSIP has recently published the following documents in compliance with the OCS Lands Act Amendments of 1978 and 30 CFR 252.4:

MMS 86-0017 *OCS National Compendium.* "Outer Continental Shelf Oil and Gas Information through 1984"

MMS 86-0060 *Pacific Summary Report/Index: November 1984-May 1986*

MMS 86-0084 *Gulf of Mexico Summary Report/Index: November 1984-June 1986*

MMS 86-0071 *Atlantic Summary/Index: January 1985-June 1986*

In an effort to publish a more cost effective document, the OCSIP has made an evolution of format changes during the past year, as can be seen in the document title variations listed above. The resulting format for 1987 should provide a more succinct reference tool for State and local planners, as well as to Federal Government managers.

While still reporting on the standard topics, the OCSIP is striving to eliminate parallel coverage so that the documents will be easier to read and cheaper to publish, yet still be as information and up-to-date as possible. The first format change combined the subregional documents of the Alaska (Arctic, Bering, Gulf of Alaska) and Atlantic (North, Mid, and South) Regions into one document for each region, instead of three.

Another format change further combined the regional summary reports and the regional indexes into one document for each region; i.e., Summary Report/Index.

The standard topics still include the following:

(1) Offshore oil and gas resources.

(2) Magnitude and timing of OCS development.

(3) Oil and gas transportation strategies.

(4) Nature and location of onshore support facilities.

(5) Appendixes of OCS-related studies and issues, Federal and State agency directories, Federal depository libraries, and leasing procedure descriptions.

The *OCS National Compendium* (MMS 86-0017) is a consolidated volume of historical data taken from past OCSIP Summary Reports and Indexes, which provides a national overview as well as allowing regional comparisons. Where information was available, worldwide offshore data have been included for comparison.

To obtain: Copies of the documents may be obtained free of charge from the OCS Information Program, Office of Offshore Information and Publications, Minerals Management Service, 1951 Kidwell Drive, Suite 601, Mail Stop 642, Vienna, Virginia 22180. Telephone (703) 285-2280.

FOR FURTHER INFORMATION CONTACT: Douglas L. Slitor, Chief, OCS Information Program, Minerals Management Service, 1951 Kidwell Drive, Suite 601, Mail Stop 642, Vienna, Virginia 22180. Telephone (703) 285-2285.

Dated: October 28, 1986.

John Goll,

Acting Associate Director for Offshore Minerals Management.

[FR Doc. 86-25066 Filed 11-5-86; 8:45 am]

BILLING CODE 4310-MR-M

Office of Surface Mining Reclamation and Enforcement

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirements should be made within 30 days directly to the Bureau clearance officer and to the Office of Management and Budget Interior Department Desk Officer, Washington, DC 20503, telephone 395–7313.

Title: State Regulatory Authority: Inspection and Enforcement, 30 CFR Part 840.

Abstract: This information collection requirement is authorized by section 521 of Pub. L. 95–87. This provision requires the regulatory authority to submit and maintain inspection records for public review. This information is necessary to meet the public participation provisions of the Act. Public review assures the public that the State is meeting the requirements of the Act and approved State regulatory program.

Bureau Form Number: None.

Frequency: Quarterly, monthly and on occasion.

Description of Respondents: State Regulatory Authorities.

Annual Responses: 144,408.

Annual Burden Hours: 216,804.

Bureau clearance officer: Darlene Grose Boyd 202–343–5447.

Dated: August 13, 1986.

Donald L. Hinderliter,

Acting, Assistant Director for Budget and Administration.

[FR Doc. 86–25108 Filed 11–5–86; 8:45 am]

BILLING CODE 4310–05–M

INTERSTATE COMMERCE COMMISSION

[Docket No. AB–271X]

Chicago & Illinois Midland Railway Company; Exemption; Abandonment in Christian County, IL

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Interstate Commerce Commission exempts from the requirements of prior approval under 49 U.S.C. 10903, *et seq.*, the abandonment by Chicago & Illinois Midland Railway Company of its "B&O connection track" (track Nos. 6 and 11), a distance of approximately 1.5 miles in Taylorville, Christian County, IL, subject to standard labor protective conditions and the filing of a notice of environment and energy matters on the designated State agency in Illinois.

DATES: This exemption will be effective on December 8, 1986. Petitions to stay must be filed by November 17, 1986, and petitions for reconsideration must be filed by November 26, 1986.

ADDRESSES: Send pleadings referring to Docket No. AB–271X to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423

(2) Petitioner's representative: William G. Harvey, P.O. Box 139, Springfield, IL 62705

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar (202) 275–7245.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to T.S. InfoSystems, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423, or call 289–4357 (DC Metropolitan area) or toll free (800) 424–5403.

Decided: October 30, 1986.

By the Commission, Chairman Gradison, Vice Chairman Simmons, Commissioners Sterrett, Andre, and Lamboley.

Noreta R. McGee,

Secretary.

[FR Doc. 86–25082 Filed 11–5–86; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF JUSTICE

Lodging of Consent Decree in Clean Air Act Enforcement Action

In accordance with Departmental Policy, 28 CFR 50.7 38 FR 19029, notice is hereby given that a consent decree in *United States* v. *Osceola Farms Co.* was lodged with the United States District Court for the Southern District of Florida on October 24, 1986. The proposed consent decree requires Osceola Farms to comply with applicable Clean Air Act requirements governing emissions of particular matter, implement certain operation and maintenance procedures for three years, and pay a civil penalty of $85,000.

The Department of Justice will receive for thirty (30) days from the publication date of this notice, written comments relating to the decree. Comments should be addressed to the Assistant Attorney General, Land and Natural Resources Division, Department of Justice, Washington, DC 20530, and refer to *United States* v. *Osceola Farms Co.*, 90–5–2–1–870.

The consent decree can be examined at the office of the United States Attorney, 155 S. Miami Avenue, Room 500, Miami, Florida 33130, the Region IV Office of the Environmental Protection Agency, 345 Courtland Street, NE., Atlanta, Georgia, and at the Environmental Enforcement Section, Land and Natural Resources Division, U.S. Department of Justice, (Room 1515), Ninth and Pennsylvania Avenue, NW., Washington, DC 20530. Copies of the consent decree can be obtained in person or by mail from the Environmental Enforcement Section at the above address.

F. Henry Habicht, II,

Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 86–25063 Filed 11–5–86; 8:45 am]

BILLING CODE 4410–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–440]

Cleveland Electric Illuminating Co., et al.; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from a portion of the requirements of Appendix E to 10 CFR Part 50 to the Cleveland Electric Illuminating Company (CEI), Duquesne Light Company, Ohio Edison Company, Pennsylvania Power Company, and Toledo Edison Company (the licensees) for the Perry Nuclear Power Plant, Unit No. 1, located at the licensees' site in Lake County, Ohio. The exemption was requested by the licensees by letter from CEI dated October 30, 1986.

Environmental Assessment

Identification of Proposed Action: The exemption will permit the licensees, following the Commission's issuance of a full power operating license for the facility, to operate the unit above 5% of its rated power without conducting another offsite full participation emergency preparedness exercise prior to May 1988.

Section IV.F.1 of 10 CFR Part 50, Appendix E, requires that a full participation execrise of the offsite

emergency preparedness plans be conducted within 1 year prior to operation above 5% of rated power. The Perry emergency plan was previously exercised on April 15, 1986, with state and local government participation. However, the need for this exemption has arisen because the Federal Emergency Agency (FEMA), in its report dated September 5, 1986, has characterized the April 1986 exercise as demonstrating full participation for Ashtabula, Geauga and Lake Counties of Ohio, but partial participation for the State of Ohio.

The Need for the Proposed Action: The proposed exemption is needed to permit the licensee to proceed with operation above 5% of rated power prior to conducting another offsite emergency preparedness exercise. The next exericse with full participation at the State and County level is presently scheduled for May 1988. An alternative possibility is to upgrade an onsite exercise planned for May 1987 to include full offsite participation. However, neither date would be timely for Perry Unit 1, which is expected to be ready by mid to late November 1986 for operation above 5% of rated power.

Environmental Impact of the Proposed Action: The exemption would not affect the environemtal impact of the facility because the level of emergency preparedness will not be degraded by its issuance. Both FEMA and the NRC concluded from the April 1986 exercise that the results provide reasonable assurance of adequate offsite emergency preparedness relative to the Perry Plant. Therefore, the proposed exemption does not involve a significant radiological environmental impact. In addition, the action would have no effect on nonradiological environmental impacts associated with the Perry Plant.

Alternative to the Proposed Action: Because the staff has concluded that there is no significant impact associated with the proposed exemption, any alternative to the exemption will have either no environmental impact or greater environmental impact.

Alternative Use of Resources: This action does not involve the use of resources not previously considered in connection with the "Final Environmental Statement Related to the Operation of Perry Nuclear Power Plant, Units 1 and 2," dated August 1982.

Agencies and Persons Consulted: The NRC staff consulted FEMA regarding its September 5, 1986 report. No other agencies or persons were contacted.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed exemption.

Based upon the environmental assessment, we conclude that the proposed action will not have a significant effect on the quality of the human environment.

For details with respect to this action, see the request for exemption dated October 30, 1986, which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the Perry Public Library, 3753 Main Street, Perry, Ohio 44081.

Dated at Bethesda, Maryland, this 3rd day of November 1986.

Walter R. Butler,

Director, BWR Project Directorate No. 4, Division of BWR Licensing.

[FR Doc. 86-25133 Filed 11-5-86; 8:45 am]

BILLING CODE 7590-01-M

Advisory Committee on Reactor Safeguards, Subcommittee on Spent Fuel Storage; Meeting

The ACRS Subcommittee on Spent Fuel Storage will hold a meeting on November 21, 1986, Room 1046, 1717 H Street, NW., Washington, DC.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Friday, November 21, 1986—8:30 a.m. Until the Conclusion of Business

The Subcommittee will continue its review of 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High Level Radioactive Waste" and Monitored Retrievable Storage (MRS).

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Mr. Owen Merrill (telephone 202/634-1414) between 8:15 a.m. and 5:00 p.m. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., whicy may have occurred.

Dated: November 3, 1986.

Morton W. Libarkin,

Assistant Executive Director for Project Review.

[FR Doc. 86-25113 Filed 11-5-86 8:45 am]

BILLING CODE 7590-01-M

Proposed Availability of FY 1987 Funds for Financial Assistance To Enhance Technology Transfer and Dissemination of Nuclear Energy Process and Safety Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC), Office of Nuclear Regulatory Research announces proposed availability of FY 1987 funds to support professional meetings symposia, conferences, national and international commissions and publications for the expansion, exchange and transfer of knowledge, ideas and concepts directed toward the research necessary to provide a technology base to assess the safety of nuclear power (hereinafter called project).

Projects will be funded through grants.

EFFECTIVE DATE: November 1, 1986 through September 30, 1987.

ADDRESS: U.S. Nuclear Regulatory Commission, Attn: Grants Officer, Division of Contracts, Office of Administration, Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: The cognizant NRC grant official is Mr. Ronald Thompson, telephone (301) 492-4322.

SUPPLEMENTARY INFORMATION:

A. Scope and Purpose of this Announcement

Pursuant to section 31.a. and 141.b. of the Atomic Energy Act of 1954, as amended, the NRC's Office of Nuclear Regulatory Research proposes to support educational institutions, nonprofit institutions, state and local governments, and professional societies through providing funds for expansion, exchange and transfer of knowledge, ideas and concepts directed toward the research program. The program includes, but is not limited to, support of professional meetings, symposia, conferences, national and international commissions, and publications. The primary purpose of this will be to stimulate research to provide a technological base for the safety assessment of systems and subsystems technologies used in nuclear power applications. The results of this program will be to increase public understanding relating to nuclear safety, to enlarge the funds of theoretical and practical knowledge and technical information, and ultimately to enhance the protection of the public health and safety.

B. Eligible Applicants

Educational institutions, nonprofit entities, state and local governments and professional societies are eligible to apply for a grant under this announcement.

C. Research Proposals

A research proposal should describe: (i) The objectives and scientific significance of the proposed meeting, symposium, conference, or commission; (ii) the methodology to be proposed or discussed, and its suitability; (iii) the qualifications of the participants and the proposing organization; and (iv) the level of financial support required to perform the proposed effort.

Proposals should be as brief and concise as is consistent with communication to the reviewers. Neither unduly elaborate applications nor voluminous supporting documentation is desired.

State and local governments shall submit proposals utilizing the standard forms specified in Office of Management and Budget (OMB) Circular A-102, Attachment M. Nonprofit organizations, universities, and professional societies shall submit proposals utilizing the standard forms stipulated on OMB Circular A-110, Attachment M.

The format used for project proposals should give a clear presentation of the proposed project and its relation to the specific objectives contained in this notice. Each proposal should follow the format outlined below unless the NRC specifically authorizes exception.

1. Cover Page. The Cover Page should be typed according to the following format (submit separate cover pages if the proposal is multi-institutional):

Title of Proposal—To include the term "conference," "symposium," "workshop," or other similar designation to assist in the identification of the project;

Location and Dates of Conferences, Symposium, Workshop, etc.;

Name of Principal Participants;

Total Cost of Proposal;

Period of Proposal;

Organization or Institution and Department;

Required Signatures:

Principal Participants:

Name:_____
Date:_____
Address:_____
Telephone No.:_____

Required Organization Approval:
Name:_____
Date:_____
Address:_____
Telephone No.:_____

Organization Financial Officer:
Name:_____
Date:_____
Address:_____
Telephone No.:_____

2. Project Description. Each proposal shall provide, in ten pages or less, a complete and accurate description of the proposed project. This section should provide the basic information to be used in evaluating the proposal to determine its priority for funding.

Applicants must identify other proposed sources of financial support for a particular project.

The information provided in this section must be brief and specific. Detailed background information may be included as supporting documentation to the proposal.

The following format shall be used for the project description:

(a) Project Goals and Objectives:

The project's objectives must be clearly and unambiguously stated.

The proposal should justify the project including the problems it intends to clarify and the development it may stimulate.

(b) Project Outline:

The proposal should show the project format and agenda, including a list of principal areas or topics to be addressed.

(c) Project Benefits:

The proposal should indicate the direct and indirect benefits that the project seeks to achieve and to whom these benefits will accrue.

(d) Project Management:

The proposal should describe the physical facilities required for the conduct of the project. Further, the proposal should include brief biographical sketches of individuals responsible for planning the project.

(e) Project Costs:

Nonprofit organizations shall adhere to the cost principles set forth in OMB Circular A-122; Educational Institutions shall adhere to the cost principles set forth in OMB Circular A-21; and state and local governments shall adhere to the cost principles set forth in OMB Circular A-87.

The proposal must provide a detailed schedule of project costs, identifying in particular:

(1) Salaries—in proportion to the time or effort directly related to the project;

(2) Equipment (rental only);

(3) Travel and Per Diem/Subsistence in relation to the project;

(4) Publication Costs;

(5) Other Direct Costs (specify)—e.g., supplies or registration fees;

Note.—Dues to organizations, federations or societies, exclusive of registration fees, are not allowed as a charge.

(6) Indirect Costs (attach negotiated agreement/cost allocation plan); and

(7) Supporting Documentation. The supporting documentation should contain any additional information that will strengthen the proposal.

D. Proposal Submission and Deadline

This program announcement is valid for the period of November 1, 1986 to September 30, 1987. Proposal submissions shall be one signed original and six copies.

E. Funds

For Fiscal Year 1987, the U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research anticipates making $75,000–$100,000 available for funding the project(s) mentioned hearing.

The NRC anticipates that approximately 5 to 10 projects will be funded. Further, the NRC anticipates that its average support will be $5,000–$15,000 per project.

F. Evaluation Process

All proposals received as a result of this announcement will be evaluated by an NRC review panel.

G. Evaluation Criteria

The award of NRC grants is discretionary. Generally, projects are supported in order to merit to the extent permitted by available funds.

Evaluation of proposals will employ the following criteria:

1. Potential usefulness of the proposed project for the advancement of scientific knowledge;

2. Clarity of statement of objectives, methods, and anticipated results;

3. Range of issues covered by the meeting agenda;

4. Qualifications and experience of project speakers; and

5. Reasonableness of estimated cost in relation to anticipated results.

H. Disposition of Proposals

Notification of award will be made by the Grants Officer and organizations whose proposals are unsuccessful will be so advised.

I. Proposal Instructions and Forms

Questions concerning the preceding information, copies of application forms, and applicable regulations shall be obtained from or submitted to: U.S. Regulatory Commission; Attn: Grants Officer, Division of Contracts, AR–2223, Office of Administration, Washington, DC 20555.

The address for hand-carried applications is: U.S. Regulatory Commission; Attn: Grants Officer, Division of Contracts, Office of Administration, Room 2223, 4550 Montgomery Avenue, Bethesda, MD 20814

Nothing in this solicitation should be construed as committing the NRC to dividing available funds among all qualified applicants.

Dated at Washington, DC this 29th day of October 1986.

For the U.S. Nuclear Regulatory Commission.

Ronald D. Thompson,

Chief, Contract Negotiation Branch No. 2, Division of Contracts, Office of Administration.

[FR Doc. 86–25044 Filed 11–5–86; 8:45 am]

BILLING CODE 7590-01-M

PEACE CORPS

Notification of Extension Request of Peace Corps' Form PC 1532, Volunteer Reference Form

ACTION: Notification of extension request of Peace Corps' form PC 1532, volunteer reference form.

SUMMARY: The information collection from described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Peace Corps is requesting a three-year extension approval of the form.

ADDRESS: Interested persons are invited to submit comments regarding this form by name. These comments should be sent to Francine Picoult, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Room 3235, Washington, DC 20503. Comments should be received on or before January 5, 1987.

FOR FURTHER INFORMATION CONTACT: James Duke, Management Analyst, Office of Volunteer Recruitment and Selection, Peace Corps, 806 Connecticut Avenue, NW., Room M–900 Washington, DC 20526, telephone (202) 254–8387. This is not a toll-free number. For a copy of the form contact Mr. Duke.

SUPPLEMENTARY INFORMATION: Individuals applying for Peace Corps Volunteer service furnish names and addresses of persons having knowledge of their qualifications for such service. Reference forms sent to the listed individual for those applicants basically qualified and nominated for Peace Corps Volunteer service. Information furnished by the referents is used as a part of the determination process in selecting and placing applicant/nominees in volunteer projects. Peace Corps has no other means of obtaining this type of appraisal of an applicant's capabilities for volunteer service.

List of Subjects: Volunteers, Privacy Act
Form Title: Peace Corps Volunteer Reference Form
Office: Volunteer Recruitment and Selection
Form Number: PC 1532
Frequency of Submission: On occasion
Affected Public: Individuals listed as references by Peace Corps Volunteer applicants
Estimated Burden Hours: 35,000 per annum

This is not a proposal to which 44 U.S.C. 3504(h).

This notice is issued in Washington, DC on November 3, 1986.

Linda Rae Gregory,

Associate Director for Management.

Robert E. McClendon,

Certifying Officer, Peace Corps.

[FR Doc. 86–25055 Filed 11–5–86; 8:45 am]

BILLING CODE 6051-01-M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of reporting requirements submitted for review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the Federal Register notifying the public that the agency has made such a submission.

DATE: Comments should be submitted by November 28, 1986. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Copies of survey, request for clearance (S.F. 83), supporting statement, instructions, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Elizabeth M. Zaic, Small Business Administration, 1441 L Street, NW., Room 200, Washington, DC 20416, Telephone: (202) 653–6623

OMB Reviewer: Patricia Aronsson, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503, Telephone: (202) 395–7231

Title: Erroneous Penalties Assessed by IRS Associated with Payroll Taxes

Frequency: On-time, non-recurring

Description of Respondents: SBA is conducting a study to determine the reasons for the large number of erroneous penalty assessments made by IRS on small businesses with respect to employment returns and the number of small businesses which pay the erroneous assessment instead of challenging them. This data will be collected from small businesses by a mail questionnaire.

Annual Responses: 3,200

Annual Burden Hours: 96

Type of Request: New

Elizabeth M. Zaic,

Deputy Director, Office of Administrative Services, Small Business Administration.

[FR Doc. 86–25109 Filed 11–5–86; 8:45 am]

BILLING CODE 8025-01-M

[Disaster Loan Area No. 2255 Amdt. No. 1]

Missouri; Declaration of Disaster Loan Area

The above-numbered Declaration (51 FR 37532) is hereby amended to include the entire county of Jackson County, Missouri, due to torrential rains, flash flooding and flooding which occurred on September 17, 1986. All other information remains the same; i.e., the

termination date for filing applications for physical damage is the close of business on December 15, 1986, and for economic injury until the close of business on July 15, 1987.

Dated: October 29, 1986.

Charles L. Heatherly,

Acting Administrator.

[FR Doc. 86-25096 Filed 11-5-86; 8:45 am]

BILLING CODE 8025-01-M

[License No. 05/05-0173]

Madison Capital Corp.; Surrender of License

Notice is hereby given that Madison Capital Corporation, 102 State Street Madison, Wisconsin 53703 has surrendered its License to operate as a small business investment company under the Small Business Investment Act of 1958, as amended (the Act). Madison Capital Corporation was licensed by the Small Business Administration on December 9, 1983.

Under the authority vested by the Act and pursuant to the Regulations promulgated thereunder, the surrender was accepted on October 16, 1986 and accordingly, all rights, privileges, and franchises derived therefrom have been terminated.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: October 27, 1986.

Robert G. Lineberry,

Deputy Associate Administrator for Investment.

[FR Doc. 86-25049 Filed 11-5-86; 8:45 am]

BILLING CODE 8025-01-M

[Application No. 01/01-0340]

Monarch—Narragansett Ventures, Inc.; Application for a License To Operate as a Small Business Investment Company

Notice is hereby given that an application has been filed with the Small Business Administration (SBA) pursuant to § 107.102 of the SBA Regulations (13 CFR 107.102 (1986)) by Monarch—Narragansett Ventures, Inc., (Applicant) One Financial Plaza, Springfield, Massachusetts 01102, for a license to operate as a small business investment company (SBIC) under the provisions of the Small Business Investment Act of 1958, as amended (the Act), (15 U.S.C. 661 et seq.) and the Rules and Regulations promulgated thereunder.

The officers, directors and shareholders of the Applicant are as follows:

Name	Title or relationship	Percentage of shares owned
George W. Siguler, One Financial Plaza, Springfield, MA 01102.	President, Director.	
James M. Durham, One Financial Plaza, Springfield, MA 01102.	Treasurer, Director.	
Gordon N. Oakes, Jr., One Financial Plaza, Springfield, MA 01102.	Director	
Raymond A. Terfera, Esq., One Financial Plaza, Springfield, MA 01102.	Clerk	
Michael J. Romanowski, One Financial Plaza, Springfield, MA 01102.	Manager	
Monarch-Narragansett Corporation, One Financial Plaza, Springfield, MA 01102.	Shareholder	99.991
Monarch Capital Corporation, One Financial Plaza, Springfield, MA 01102.	Shareholder	.009

Monarch Capital Corporation is a publicly traded holding company and sole shareholder of Monarch-Narragansett Corporation.

The Applicant, a Massachusetts corporation, will begin operations with approximately $10,000,000 paid in capital and paid in surplus.

The Applicant will conduct its activities primarily in the Commonwealth of Massachusetts but will consider investments in businesses in other areas of the United States.

Matters involved in SBA's consideration of the application include the general business reputation and character of the proposed owners and management, and the probability of successful operations of the company under their management including adequate profitability and financial soundness, in accordance with the Small Business Investment Act of 1958, as amended, and the SBA Rules and Regulations.

Notice is further given that any person may, not later than 30 days from the date of publication of this Notice, submit written comments on the proposed Applicant. Any such communication should be addressed to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street, NW., Washington, DC 20416.

A copy of the Notice will be published in a newspaper of general circulation in Springfield, Massachusetts.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: October 30, 1986.

John L. Werner,

Acting Deputy Associate Administrator for Investment.

[FR Doc. 86-25051 Filed 11-5-86; 8:45 am]

BILLING CODE 8025-01-M

Senior Executive Service Performance Review Boards List of Members

AGENCY: Small Business Administration.

ACTION: Listing of personnel serving as members of this agency's senior executive service performance review boards.

SUMMARY: Pub. L. 95-454 dated October 13, 1978, (Civil Service Reform Act of 1978) requires that Federal Agencies publish notification of the appointment of individuals who serve as members of that agency's Performance Review Boards (PRB). The following is a listing of those individuals currently serving as members of this Agency's PRB:

1. James P. Gallogly, Assistant Administrator for Information Resources Management;
2. Edwin T. Holloway, Associate Administrator for Finance and Investment;
3. Janice E. Wolfe, District Director, Washington;
4. Monika Edwards Harrison, Associate Administrator for Procurement Assistance;
5. Robert H. Miller, Regional Administrator, Philadelphia;
6. Richard L. Osbourn, Director of Personnel, (Non-voting Technical Advisor); and
7. George H. Robinson, Director of Equal Employment Opportunity and Compliance, (Non-voting Equal Employment Advisor);
8. Martin D. Teckler, Deputy General Counsel;
9. June M. Nichols, Regional Administrator, Atlanta
10. Robert J. Moffitt, Deputy Associate Administrator for Procurement Assistance;
11. Albert J. Prendergast, Director of Program Analysis and Review;
12. Wilfredo J. Gonzales, Associate Administrator for Minority Small Business and Capital Ownership Development;
13. Robert G. Lineberry (Alternate), Deputy Associate Administrator for Investment;
14. Renald Morani, Deputy Inspector General, Veterans Administration;
15. Joseph J. Genovese, Assistant Inspector General for Auditing, Department of Transportation; and

16. Lawrence Dempsey (Alternate), Assistant Inspector General for Investigations, General Services Administration.

Dated: October 31, 1986.

Charles L. Heatherly,

Acting Administrator.

[FR Doc. 86-25050 Filed 11-5-86; 8:45 am]

BILLING CODE 6025-01-M

DEPARTMENT OF STATE

[Public Notice CM-8/1019]

Overseas Schools Advisory Council; Meeting

The Overseas Schools Advisory Council, Department of State, will hold its Executive Committee meeting on Wednesday, December 17, 1986, 9:30 a.m., in Conference Room 1107, Department of State Building, Washington, DC.

Agenda items scheduled for discussion are as follows:

I. Welcome and Introduction of Participants.

II. Greetings from the Department of State.

III. Results of Surveys and Reports Concerning Schools Fund-Raising Drives and Activities of Regional School Associations.

IV. Council Programs of Educational Assistance:

(a) Final Report of 1985 Program and Initial Progress Report on 1986 Program.

(b) Recommendations of Council's Evaluation Committee Regarding Projects submitted by Regional Overseas Schools Associations for 1987 Program.

(c) Council's Efforts in Securing Necessary Contributions for 1986 and 1987 Programs.

V. Council's Communications with U.S. Corporations and Foundations.

VI. Election of Council Chairman and Vice Chairman.

Access to the State Department is controlled, therefore members of the public desiring to attend the meeting should call Ms. Joyce Bruce, Office of Overseas Schools, Department of State, Washington, DC, Area Code 703-235-9600, prior to December 17. The public may participate in discussions at the Chairman's instructions.

Dated: October 30, 1986.

Ernest N. Mannino,

Executive Secretary, Overseas Schools Advisory Council.

[FR Doc. 86-25064 Filed 11-5-86; 8:45 am]

BILLING CODE 4710-24-M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement; Multnomah County, OR

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project in Multnomah County, Oregon.

FOR FURTHER INFORMATION CONTACT: Elton Chang, Environmental Coordinator and Safety Programs Engineer, Federal Highway Administration, Equitable Center, Suite 100, 530 Center NE., Salem, Oregon 97301. Telephone: (503) 399-5749.

SUPPLEMENTARY INFORMATION: The FHWA in cooperation with the Oregon Department of Transportation will prepare an environmental impact statement (EIS) on a proposal to reconstruct a 4.3 mile section of I-84 between 181st Avenue and the Troutdale Interchange. The project would widen the roadway to six lanes and reconstruct the interchanges. The interchanges may be replaced at locations that are different from the existing interchange locations. The project is located in east Multnomah County and passes through the cities of Wood Village and Fairview. The proposed improvement is considered necessary to provide for the existing and projected traffic demand and a safe and efficient highway meeting modern design standards.

Alternatives under consideration include (1) widen the roadway and replace the interchanges in essentially the same locations; (2) widen the roadway, reconstruct two of the interchanges, and redesign the third interchange as a full instead of a partial interchange; (3) widen the roadway and relocate one or two of the interchanges to new locations; and (4) taking no action.

Information describing the proposed action and soliciting comments will be sent to the appropriate Federal, State and local agencies. Public meetings will be held during project development, and a public hearing will be held. No formal scoping meeting is planned at this time.

Comments or questions concerning this proposed action, and the EIS, should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The provisions of Executive Order 12372, "Intergovernmental Review of Federal Programs" apply to this program)

Issued on: October 24, 1986.

Elton H. Chang,

Environmental Coordinator/Safety Program Engineer, Oregon Division, Salem, Oregon.

[FR Doc. 86-25067 Filed 11-5-86; 8:45 am]

BILLING CODE 4910-22-M

Environmental Impact Statement; Multnomah County, OR

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project in Multnomah County, Oregon.

FOR FURTHER INFORMATION CONTACT: Elton Chang, Environmental Coordinator and Safety Programs Engineer, Federal Highway Administration, Equitable Center, Suite 100, 530 Center NE., Salem, Oregon 97301. Telephone: (503) 399-5749.

SUPPLEMENTARY INFORMATION: The FHWA in cooperation with the Oregon Department of Transportation will prepare an environmental impact statement (EIS) on a proposal to improve traffic flow and safety on a 1.9 mile section of I-5 (Pacific Highway) in Portland, Oregon. The proposed improvements are intended to minimize the number of on-and-off-ramps entering and leaving the freeway; to provide standard acceleration and deceleration lanes; and to provide standard weave and merge distances associated with the ramps through a system of collector-distributor frontage roads and braided ramps. The proposed improvement is considered necessary to provide for the existing and projected traffic demand and a safe and efficient highway meeting modern design standards.

Alternatives under consideration include different ramp locations and different local street patterns. An alternative that would not include any action is also being considered.

Information describing the proposed action and soliciting comments will be sent to the appropriate Federal, State and local agencies. Public meetings will be held during project development, and a public hearing will be held. No formal scoping meeting is planned at this time.

Comments or questions concerning this proposed action, and the EIS, should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research,

Planning and Construction. The provisions of Executive Order 12372, "Intergovernmental Review of Federal Programs" apply to this program)

Issued on October 24, 1986.

Elton H. Chang,

Environmental Coordinator/Safety Prgm Engineer, Oregon Division, Salem, Oregon.

[FR Doc. 86-25068 Filed 11-5-86; 8:45 am]

BILLING CODE 4910-22-M

National Highway Traffic Safety Administration

[Docket No. IP86-06; Notice 2]

Motor Vehicle Safety Standards; Marina Mobili, Inc.; Grant of Petition for Determination of Inconsequential Noncompliance

This notice grants the petition by Marina Mobili, Inc. of Moonachie New Jersey, to be exempted from the notification and remedy requirements of the National Highway Traffic and Motor Vehicle Safety Act (15 U.S.C. 1381 *et seq.*) for an apparent noncompliance with 49 CFR 571.115, Motor Vehicle Safety Standard No. 115, *Vehicle Identification Number.* The basis of the petition was that the noncompliance is inconsequential as it relates to motor vehicle safety.

Notice of the petition was published on May 7, 1986, and an opportunity afforded for comment (51 FR 16944).

Paragraphs S3 and S4.2 of Federal Motor Vehicle Standard No. 115, *Vehicle Identification Number,* give the definition of vehicle identification numbers and requirement of the standard respectively. "A vehicle identification number is a series of Arabic number and Roman letters which is assigned to a motor vehicle for identification purposes." Standard No. 115 requires that the vehicle identification number consist of seventeen (17) characters.

The petitioner determined that 50 mopeds (motor driven cycles) manufactured in 1981 do not comply with Standard No. 115 requirements because of the use of an abbreviated vehicle identification number.

Marina Mobili stated that, due to the small number of Negrini mopeds involved, it believes the abbreviated vehicle identification number on these vehicles is an inconsequential noncompliance as it relates to motor vehicle safety.

Marina Mobili also argued that recalls would have detrimental effects because:

"a. The original certification level contains the month and year of manufacture as well as the vehicle identification number. The new labels would have to be sent out with the date of manufacture space blank, making it necessary for the customer to imprint this information into the new certification label.

b. Most Department of Motor Vehicle Offices would become suspect of a moped having been stolen after the old certification plate had been removed and a new label installed.

c. Some of the Gazelle III mopeds affected by the noncompliance are being used in States that require moped registration. These units would already be registered under the original abbreviated vehicle identification number. Changing the vehicle identification number on these units would create a great deal of confusion at the various Department of Motor Vehicle Offices and in turn, create problems for the consumer."

No comments were received on the petition.

The agency has recognized, in past instances of noncompliances with Standard No. 115, the problems that removal and reissuance of VINs would cause. Because the population of affected vehicle is small, and their VINs are sufficient to identify them in the event the manufacturer wishes to recall them, the manufacturer has met its burden of persuasion that the noncompliance herein described is inconsequential as it relates to motor vehicle safety, and its petition is granted.

(Sec. 102, Pub. L. 93-492, 88 Stat. 1470 (15 U.S.C. 1417); delegation of authority at 49 CFR 1.50 and 49 CFR 501.8)

Issued on October 31, 1986.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc 86-25085 Filed 11-5-86; 8:45 am]

BILLING CODE 4910-59-M

VETERANS ADMINISTRATION

Agency Form Under OMB Review

AGENCY: Veterans Administration.

ACTION: Notice.

The Veterans Administration has submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document contains an extension and lists the following information: (1) The department or staff office issuing the form, (2) the title of the form, (3) the agency form number, if applicable, (4) how often the form must be filled out, (5) who will be required or asked to report, (6) an estimate of the number of responses, (7) an estimate of the total number of hours needed to fill out the form, and (8) an indication of whether section 3504(h) of Pub. L. 96-511 applies.

ADDRESSES: Copies of the form and supporting documents may be obtained from Patti Viers, Agency Clearance Officer (732), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233-2146. Comments and questions about the items on the list should be directed to the VA's OMB Desk Officer, Joe Lackey, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503, (202) 395-7316.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 60 days of this notice.

Dated: November 3, 1986.

By direction of the Administrator.

Robert W. Schultz,

Director, Office of Information Management and Statistics.

Extension

1. Department of Veterans Benefits
2. Claim for Disability Insurance Benefits
3. VA Form 29-357
4. On occasion
5. Individuals or households
6. 13,250 responses
7. 26,500 hours
8. Not applicable

1. Department of Veterans Benefits
2. Certification of Loan Disbursement Manufactured Home
3. VA Form 26-8646
4. On occasion
5. Businesses or other for-profit
6. 1,200 responses
7. 300 hours.
8. Not applicable

Revision

1. Department of Veterans Benefits
2. Application for Guaranty of Loan to Purchase Manufactured Home and/or Lot
3. VA Form 26-8641
4. On occasion
5. Individuals or households; Businesses or other for-profit
6. 1,050 responses
7. 788 hours
8. Not applicable

Extension

1. Department of Veterans Benefits
2. Supplemental Information for Change of Program or Reenrollment After Unsatisfactory Progress or Conduct
3. VA Form 22-8873
4. On occasion

5. Individuals or households
6. 31,743 responses
7. 10,581 hours
8. Not applicable

[FR Doc. 86-25088 Filed 11-5-86; 8:45 am]
BILLING CODE 8320-01-M

Voluntary Service National Advisory Committee, Availability of Annual Report

Notice is hereby given that the Annual Report of the Veterans Administration Voluntary Service National Advisory Committee Annual Meeting for 1985 has been issued.

The report summarizes activities of the annual meeting which was held in Reno, Nevada, October 24 through 27, 1985.

It is available for public inspection at two locations:

Library of Congress, Serial and Government Publications Reading Room, LM 133, Madison Building, Washington, DC 20540

and

Veterans Administration, Voluntary Service (135), Veterans Service Unit, Room 132, 810 Vermont Avenue, NW., Washington, DC 20420

Dated: October 30, 1986.

By direction of the Administrator.

Rosa Maria Fontanez,

Committee Management Officer.

[FR Doc. 25054 Filed 11-5-86; 8:45 am]
BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 51, No. 215
Thursday, November 6, 1986

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

COUNCIL ON ENVIRONMENTAL QUALITY

November 4, 1986.

TIME AND DATE: 10:00 a.m., Thursday, November 13, 1986.

PLACE: Conference Room First Floor, 722 Jackson Place, NW., Washington, DC.

MATTERS TO BE CONSIDERED:

1. Continuation of Sunshine Act Meeting begun on Wednesday, November 12, 1986. 51 FR 39943 (1986). Because of the number of people who will be participating in the Sunshine Act meeting on the lead agency issue for the proposed PortAmerica project, the Council will reconvene on Thursday, November 13.

CONTACT PERSON FOR MORE INFORMATION: Dinah Bear, General Counsel, Council on Environmental Quality, 722 Jackson Place, NW., Washington, DC 20006.

A. Alan Hill,

Chairman.

[FR Doc. 86-25221 Filed 11-4-86; 2:10 pm]

BILLING CODE 3125-01-M

2

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 3:25 p.m. on Friday, October 31, 1986, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to: (1) Receive bids for the purchase of certain assets of and the assumption of the liability to pay deposits made in Republic Bank, Blanchard, Louisiana, which was closed by the Commissioner of Financial Institutions for the State of Louisiana on Friday, October 31, 1986; (2) accept the bid for the transaction submitted by American Bank & Trust Company in Monroe, Monroe, Louisiana, an insured State nonmember bank; (3) approve the application of American Bank & Trust Company in Monroe, Monroe, Louisiana, for consent to purchase certain assets of and assume the liability to pay deposits made in Republic Bank, Blanchard, Louisiana, and for consent to establish the six offices of Republic Bank as branches of American Bank & Trust Company in Monroe; and (4) provide such financial assistance, pursuant to section 13(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1823(c)(2)), as was necessary to facilitate the purchase and assumption transaction.

In calling the meeting, the Board determined, on motion of Director C.C. Hope, Jr. (Appointive), seconded by Director Robert L. Clarke, (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: November 3, 1986.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 86-25178 Filed 11-4-86; 11:13 am]

BILLING CODE 6714-01-M

3

FEDERAL ENERGY REGULATORY COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: October 29, 1986, 51 FR 39607.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: November 3, 1986, 10:00 a.m.

CHANGE IN THE MEETING: The meeting will be held in Hearing A, 825 North Capitol, NE., Washington, DC 20426.

Lois D. Cashell,

Acting Secretary.

[FR Doc. 86-25186 Filed 11-4-86; 12:07 pm]

BILLING CODE 6717-02-M

4

NATIONAL COMMISSION ON LIBRARIES AND INFORMATION SCIENCE

DATE AND TIME: November 19-20, 1986.

PLACE: Sheraton National Hotel, Concourse II Meeting Room, Columbia Pike and Washington Boulevard, Arlington, Virginia 22204.

STATUS: Open.
November 19, 9:00 a.m. to 4:30 p.m.
November 20, 9:00 a.m. to 4:30 p.m.

MATTERS TO BE DISCUSSED:
Introduction of New NCLIS Chairman and Executive Director
Chairman's Report
Approval of August 1986 Minutes
Executive Director's Report
—FY 1986 Final Program Report
—Administrative Matters
—FY 1987 Program Plans
NCLIS Program Objectives: FY 1986-1988
Committee Reports
—1989 National Conference
—Bicentennial
—Budget and Finance
—Program Review
—Public Affairs
Guest Speakers on Preservation:
Warren Haas, Council on Library Resources (CLR)
Peter Sparks, Library of Congress
Meeting Reports
—Information in the Economy
—Chief Officers of State Library Agencies (COSLA)
—White House Conference on Library and Information Services Taskforce (WHCLIST)
Guest Speakers on the Information Age Bill:
Jane Bortnick, Congressional Research Service (CRS)
John Clement, American Federation of Information Processing Societies (AFIPS)
Ralph Petta, Senator Nunn's Office
Milton Wessell, Association of Data Processing Service Organizations (ADAPSO)
ALA President's Committee on Library Services to Minorities
Old Business
New Business

CONTACT: Vivian J. Arterbery, Executive Director (202) 382–0840.2

SUBMITTED:

Jane D. McDuffie,

Staff Assistant.

October 30, 1986.

[FR Doc. 86–25150 Filed 11–4–86; 10:03 am]

BILLING CODE 7527–01–M]

5

NATIONAL TRANSPORTATION SAFETY BOARD

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 51 FR 40106, November 4, 1986.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 9 a.m., Thursday, November 13, 1986.

CHANGE IN MEETING: The following items have been added to the agenda and will be discussed in open session:

2. *Depositions:* Request for staff-conducted depositions regarding the collision of CSX Transportation Company freight train Extra 7593 with standing camp cars, Frenchton, West Virginia, September 3, 1986.

3. *Depositions:* Request for staff-conducted depositions regarding the bus/truck collision, I–295, Carney's Point, New Jersey, September 29, 1986.

CONTACT PERSON FOR MORE INFORMATION: H. Ray Smith (202) 382–6525.

H. Ray Smith,

Federal Register Liaison Officer.

November 4, 1986.

[FR Doc. 86–25230 Filed 11–4–86; 3:23 pm]

BILLING CODE 7533–01–M

6

POSTAL RATE COMMISSION

TIME AND DATE: 10:00 a.m. on November 19, 1986.

PLACE: Conference Room, 1333 H Street, NW., Suite 300, Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED: To consider motions to dismiss the Complaint of the Sacramento Bee et al., which is Docket No. C86–2.

CONTACT PERSON FOR MORE INFORMATION: Charles L. Clapp, Secretary, Postal Rate Commission, Room 300, 1333 H Street, NW., Washington, DC 20268–0001, Telephone (202) 789–6840.

Charles L. Clapp,

Secretary.

[FR Doc. 86–25248 Filed 11–4–86; 4:03 pm]

BILLING CODE 7715–01–M

7

SECURITIES AND EXCHANGE COMMISSION

Agency Meetings

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meetings during the week of November 10, 1986:

A closed meeting will be held on Wednesday, November 12, 1986, at 2:30 p.m. An open meeting will be held on Thursday, November 13, 1986, at 10:00 a.m., in Room 1C30.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Peters, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Wednesday, November 12, 1986, at 2:30 p.m., will be:

Institution of administrative proceedings of an enforcement nature.

Institution of injunctive actions.

Settlement of administrative proceeding of an enforcement nature.

Opinion.

The subject matter of the open meeting scheduled for Thursday, November 13, 1986, at 10:00 a.m., will be:

1. Consideration of whether to solicit comment on proposed amendments to two Commission rules that would result in the designation as National Market System ("NMS") Securities of almost all listed securities, as well as the over-the-counter securities that currently are designated as NMS Securities, and on proposed companion rule changes filed by the National Association of Securities Dealers, Inc. For further information, please contact Andrew Feldman at (202) 272–2414.

2. Consideration of whether to adopt an amendment to Rule 31a–2 under the Investment Company Act of 1940 which would allow investment companies to store certain required records on magnetic tape, disk, or other computer storage medium. For further information, please contact John McGuire at (202) 272–7317.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Patrick Daugherty at (202) 272–3077.

Shirley E. Hollis,

Assistant Secretary.

October 31, 1986.

[FR Doc. 86–25197 Filed 11–4–86; 1:22 pm]

BILLING CODE 8010–01–M

federal register

Thursday
November 6, 1986

Part II

Department of Labor

48 CFR Part 2901, Etc.
Acquisition Regulation Concerning Competition in Contracting; Interim Rule

DEPARTMENT OF LABOR

48 CFR Parts 2901, 2902, 2903, 2905, 2906, 2909, 2913, 2914, 2915, 2916, 2917, 2919, 2933, 2943, and 2949

Acquisition Regulation Concerning Competition in Contracting

AGENCY: Department of Labor.

ACTION: Interim rule; request for comments.

SUMMARY: This rule amends the Department of Labor Acquisition Regulation (DOLAR) to implement the Competition in Contracting Act of 1984 and Federal Acquisition Circular 84–5. The rule also makes editorial changes to the DOLAR.

DATES: The effective date of this rule is November 6, 1986, in order to effect implementation of the procedures under Federal Acquisition Circular 84–5. Written comments must be received on or before December 8, 1986 to be considered in the formulation of a final rule.

ADDRESS: Interested parties should submit written comments to Mr. Theodore Goldberg, Room S–1522, Office of Procurement and Grant Policy, Directorate of Administrative and Procurement Programs, Office of the Assistant Secretary for Administration and Management, United States Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Mr. Adam W. Hare. Telephone: (202) 523-9174.

SUPPLEMENTARY INFORMATION: The Department of Labor (DOL) has determined that this rule concerns agency procedures. These procedures are required for the DOL's implementation of the changes made to the Federal Acquisition Regulation resulting from the Competition in Contracting Act of 1984 (CICA), Pub. L. 98–369.

The purpose of this rule is to conform the DOLAR to revisions made to the FAR for implementing the Competition in Contracting Act of 1984. The FAR revisions were implemented under Federal Acquisition Circular 84–5. The rule also makes editorial changes to the DOLAR and implements revised procedures for filing protests with the General Accounting Office (GAO) and new procedures for filing automatic data processing protests with the General Services Administration Board of Contract Appeals (GSBCA) as required by CICA. Revisions were made to the FAR to implement the new bid protest procedures under Federal Acquisition Circular 84–6 dated January 15, 1985, and Federal Acquisition Circular 84–9 dated June 20, 1985. Prior notice and opportunity for public comment on this rule would be impracticable and contrary to the public interest in view of the need to implement the new protest procedures in as timely a manner as possible. In accordance with 5 U.S.C. 553(b)(3) (A) an (B), the Department has determined that prior notice and comment may be omitted. On the same basis, the Department has found good cause to make these regulations effective upon publication under 5 U.S.C. 553(d)(3).

Public Comment

Section 22 of the Office of Federal Procurement Policy Act, 41 U.S.C. 418(b), requires a 30 day notice and comment period for significant procurement regulations. Section 22(d) provides for the waiver of that period if urgent and compelling circumstances make compliance impracticable. In such cases, the regulation may be effective on a temporary basis where provision is made for a 30 day public comment period beginning on the date of notice of the temporary regulation. The Department has determined that the need to implement the new protest procedures in a timely manner constitutes urgent and compelling circumstances permitting the issuance of this regulation on a temporary basis with provision for a 30 day comment period.

Regulatory Impact

This rule does not have the financial or other impact to make it a major rule, and, therefore, the preparation of a regulatory impact analysis is not necessary. See Executive Order No. 12291, 3 CFR, 1981 Comp., p. 127, 5 U.S.C. 601 note.

The rule appears not to have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) because it imposes no new requirements which would require such entities to change their business practices, incur additional costs or otherwise affect their competitive position.

The Department of Labor has notified the Chief Counsel for Advocacy, Small Business Administration, and made the certification pursuant to 5 U.S.C. 605(b), that the rule will not have a significant economic impact on a substantial number of small entities. The rule revises existing Department-wide acquisition regulations and contains no new requirements on small entities beyond those prescribed by the Competition in Contracting Act of 1984.

Paperwork Reduction Act

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

List of Subjects in 48 CFR Parts 2901, 2902, 2903, 2905, 2906, 2909, 2913, 2914, 2915, 2916, 2917, 2919, 2933, 2943 and 2949

Government procurement.

For the reasons set out in the preamble, Chapter 29 of Title 48 of the Code of Federal Regulations is amended as set forth below.

Signed at Washington, DC, this 29th day of October, 1986.

Thomas K. Delaney,

Procurement Executive.

Thomas C. Komarek,

Assistant Secretary for Administration and Management.

PART 2901—DEPARTMENT OF LABOR ACQUISITION REGULATION SYSTEM

1. The Authority citation for 48 CFR Part 2901 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

2. The heading for Part 2901 is revised to read as set forth above.

3. Section 2901.603–1 is amended as follows:

a. In paragraph (a)(3), the words, "input for" are removed from the second sentence;

b. In paragraph (d)(8)(i), the word "copiers" in the last sentence is revised to read "copier"; and

c. Paragraphs (d)(4)(iii), (d)(9), (f)(2), (g)(2), and (g)(3) are revised to read as follows:

2901.603–1 General.

* * * * *

(d) * * *

(4) * * *

(iii) The purchase, lease, or renewal of lease(s) of ADP equipment, software and services costing $100,000 or less without prior approval of the Directorate of Information Resources Management (DIRM), OASAM. Requirements shall not be fragmented in order to circumvent this $100,000 threshold. ADP equipment, software or services costing more than $100,000 require prior approval of DIRM. Prior approval of DIRM for ADP equipment, software, or services costing less than $100,000 is also required when costs involved exceed GSA blanket delegation thresholds granted under FIRMR 201–23.104.

* * * * *

(9) The Director, National Capital Service Center, OASAM, or an officer acting in that capacity, is delegated authority and responsibility for acquisition of all property and services on behalf of DOL activities except for those contracting and grant responsibilities designated above. This includes (except for the Mine Safety and Health Administration (MSHA)) acquisition authority for the purchase, lease, and renewal of lease(s) of all ADP equipment, software and all ADP services where Agencies have obtained prior approval from the Directorate of Information Resources Management (DIRM), OASAM, as appropriate.

* * * * *

(f) * * *

(2) The Director, Directorate of Information Resources Management (DIRM), OASAM, or an officer acting in that capacity, is responsible for:

(i) Reviewing and providing prior approval for the purchase, lease or renewal of lease(s) of ADP equipment, software and services costing $100,000 or more (the purchase price is to be used to determine inclusion in this paragraph regardless of whether the item is to be purchased or leased) and for all ADP services. Requirements shall not be fragmented in order to circumvent this $100,000 threshold. Reviews involving lower amounts will be made when costs involved exceed GSA blanket delegation thresholds granted under FIRMR 201-23.104.

(ii) Providing oversight, including periodic system reviews, to promote efficient and effective management of information technology resources.

(iii) Reviewing ADP procurement requests for compliance with procurement policies, standards, and regulations.

(iv) Representing DOL and agencies in DOL in liaison with GSA and OMB on ADP matters.

(v) Developing and publishing policies and guidelines for managing information technology resources.

* * * * *

(g) * * *

(2) *Automated data processing (ADP).* The following requirements and limitations exist for the purchase or lease of ADP equipment, software and services:

(i) Authority to issue purchase orders and contracts is limited only to those officials in paragraph (b) with procurement responsibility explicitly including this authority.

(ii) Acquisition of ADP equipment, software and services costing $100,000 or more requires prior approval of DIRM, OASAM.

(iii) Acquisition of ADP equipment, software and services costing less than $100,000 do not require prior approval of DIRM, OASAM, unless costs involved exceed GSA blanket delegation thresholds granted under FIRMR 201-23.104. However, agencies are responsible for complying with FIRMR documentation requirements.

(3) *Records equipment.* The purchase of records equipment; defined as file cabinets, shelf files, visible files, mechanized files, files guides, folders, jackets, wallets, and similar items used in the creation and maintenance of records and in mail handling requires special authority. Federal Property Management Regulation 101-11.306 as implemented by the Department of Labor Manual Series (DLMS-1) requires that: Form DL 1-194 be completed by the Agency Records Officer and forwarded to the Departmental Records Officer, DIRM, OASAM, for approval prior to acquisition. Regional Administrators—OASAM are delegated this approval authority for their respective regions. In keeping with GSA Bulletins FPMR B-120 and B-122 which discourage the use of legal-size files, no new legal size records equpment is to be purchased.

* * * * *

4. A new section 2901.603-74 is added to read as follows:

2901.603-74 Legal review and assistance.

Proposed acquisitions may be subject to legal review by the Office of the Solicitor of Labor. Internal DOL procedures are contained in the Department of Labor Manual Series (DLMS-2, Chapter 900, Section 910). Copies of the DLMS Chapter may be obtained upon written request from the Office of Procurement and Grant Policy, Directorate of Procurement and Grant Management, Office of the Assistant Secretary for Administration and Management, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

PART 2902—DEFINITION OF WORDS AND TERMS

5. The Authority citation for Part 2902 is revised to read as follows and the separate Authority citations following the sections in Part 2902 are removed:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

6. Section 2902.101 is amended by adding definitions for "Head of procuring activity" and for "Procuring activity", and by revising the definitions for "Automated Data Processing (ADP)" and "Procurement Executive", as follows:

2902.101 Definitions.

* * * * *

"Automated Data Processing (ADP)," as used throughout this document, is defined as Information Technology. Information Technology means the merging of three technologies: automated data processing, office automation and telecommunications. Information technology resources include automated data processing (ADP) equipment, software, maintenance, related supplies, services, general purpose facilities for office automation, and data and integrated voice/data telecommunications services, facilities, and equipment.

* * * * *

"Head of procuring activity" means the Assistant Secretary for Administration and Management; the Assistant Secretary for Employment and Training; the Assistant Secretary for Mine Safety and Health, and the Director, National Capital Service Center.

* * * * *

"Procurement Executive" means the Director, Directorate of Procurement and Grant Management, and is synonymous with the term "Senior Procurement Executive" defined at FAR Subpart 2.1. Responsibilities of the Procurement Executive include appointing the DOL advocate for competition.

"Procuring activity" means the Office of the Assistant Secretary for Administration and Management; the Employment and Training Administration; the Mine Safety and Health Administration; and the National Capital Service Center.

PART 2903—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

7. The Authority citation for Part 2903 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

2903.204 [Amended]

8. Section 2903.204(a) is amended by revising the word "Afer" in the first sentence to read "After".

PART 2905—PUBLICIZING CONTRACT ACTIONS

9. The Authority citation for Part 2905 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(C).

10. A new Subpart 2905.2 is added to read as follows:

Subpart 2905.2—Synopsis of Proposed Contract Actions

2905.202 Exceptions.

The Procurement Executive is authorized to make the determination prescribed in FAR 5.202(b). A written determination documenting the reasons why advance notice is not appropriate or reasonable shall be submitted by the HCA to the Director, Directorate of Procurement and Grant Management, for appropriate action including communication with the officials listed in FAR 5.202(b).

11. A new Part 2906 is added to 48 CFR Chapter 29, to read as follows:

PART 2906—COMPETITION REQUIREMENTS

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 2906.2—Full and Open Competition After Exclusion of Sources

2906.202 Establishing or maintaining alternative sources.

The Procurement Executive is authorized to make the determination prescribed in FAR 6.202(b). A written determination shall be submitted by the HCA to the Director, Directorate of Procurement and Grant Management.

Subpart 2906.3—Other Than Full and Open Competition

2906.303 Justifications.

2906.303–1 Requirements.

(a) As prescribed in the Department of Labor Manual Series (DLMS) 2, Chapter 830, any proposed noncompetitive aquisitions in excess of the small purchases limitation must be fully justified, submitted to the DOL Procurement Review Board and approved by the Assistant Secretary for Administration and Management and, in the case of research contracts, by the Assistant Secretary for Policy.

(b) The contracting officer is responsible for assuring that proposed acquisitions below the dollar level specified in paragraph (a) of this section are in compliance with FAR and DOLAR requirements regarding competition.

Subpart 2906.5—Competition Advocates

2906.501 Requirement.

(a) The Competition Advocate for the Department of Labor is the Director, Office of Procurement and Grant Policy, Directorate of Procurement and Grant Management, OASAM.

(b) The head of the agency has delegated the authority to the Procurement Executive to appoint the Agency and Procuring Activity Competition Advocates. The Procurement Executive has delegated authority to the Head of the Procuring Activity to appoint Procuring Activity Competition Advocates.

PART 2909—CONTRACTOR QUALIFICATIONS

12. The Authority citation for Part 2909 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

13. Section 2909.105–1 is amended by revising paragraph (b) to read as follows:

2909.105–1 Procedures.

* * * * *

(b) Contracting officers may obtain credit reports prior to the issuance of any loan, loan guarantee, contract or grant through the credit bureau service. The National Capital Service Center will award a contract for the credit bureau service for use by all DOL contracting activities until such services become available through an established GSA Federal Supply Schedule.

PART 2913—SMALL PURCHASE AND OTHER SIMPLIFIED PURCHASE PROCEDURES

14. The Authority citation for Part 2913 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

2913.403 [Amended]

15. Section 2913.403 is amended by revising the word "System" in the first sentence to read "Series".

2913.503–70 [Amended]

16. Section 2913.503–70 is amended by revising the word "orignal" in the first sentence of the second paragraph to read "original".

PART 2914—SEALED BIDDING

17. The Authority citation for Part 2914 continues to read:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

18. The part heading of Part 2914 is revised to read as set forth above.

19. Sections 2914.404 and 2914.404–1 are added to read as follows:

2914.404 Rejection of bids.

2914.404–1 Cancellation of invitations after opening.

The head of the contracting activity (HCA) is authorized to make the written determination required by FAR 14.404–1(c).

20. Section 2914.407–8 is revised to read as follows:

2914.407–8 Protests against award.

See DOLAR subpart 2933.1, "Protests".

PART 2915—CONTRACTING BY NEGOTIATION

21. The Authority citation for Part 2915 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subparts 2915.1, 2915.2, and 2915.3 [Removed]

22. Part 2915 is amended by removing Subparts 2915.1, 2915.2 and 2915.3.

23. Section 2915.608 is added to read as follows:

2915.608 Proposal evaluation.

The head of contracting activity (HCA) is authorized to make the determination required by FAR 15.608(b).

PART 2916—TYPES OF CONTRACTS

24. The authority citation for Part 2916 continues to read; as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

25. A new Subpart 2916.3 is added to read as follows:

Subpart 2916.3—Cost-Reimbursement Contracts

§ 2916.306 Cost-plus-fixed-fee contracts.

The Contracting Officer is authorized to approve the determination establishing the basis for application of the statutory price or fee limitation prescribed in FAR 16.306(c)(2).

PART 2917—SPECIAL CONTRACTING METHODS

26. The Authority citation for Part 2917 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c)

27. Section 2917.502 is revised to read as follows:

2917.502 General.

The head of the contracting activity is authorized to make the determination prescribed in FAR 17.502 in accordance

with the requirements contained in FAR 17.503.

PART 2919—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

28. The Authority citation for Part 2919 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

2919.202-1 [Amended]

29. Section 2919.202–1 is amended as follows:

a. In paragraph (a), the dollar amount "$2,500" is revised to read "$10,000".

b. In paragraph (b), the word "and" is added at the end thereof; and

c. In paragraph (c), the words "synopsis message; and" are revised to read "synopsis message.".

PART 2933—PROTESTS, DISPUTES, AND APPEALS

30. The Authority citation for Part 2933 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

31. The part heading for Part 2933 is revised to read as set forth above.

32. Part 2933 is amended by adding a new subpart 2933.2, to read as follows:

Subpart 2933.2—Disputes and Appeals

2933.003, 2933.003-70, 2933.009, 2933.011 and 2933.012 [Redesignated]

33. Sections 2933.003, 2933.003–70, 2933.009, 2933.011 and 2933.012 are redesignated in the new Subpart 2933.2, with redesignated section numbers as set forth in the following table:

Old Section:	*New Section (In Subpart 2933.2)*
2933.003	2933.203
2933.003–70	2933.203–70
2933.009	2933.209
2933.011	2933.211
2933.012	2933.212

2933.203 [Amended]

34. In paragraph (a) of newly redesignated section 2933.203, the citation "33.003(b)" is revised to read "33.203(b)".

2933.211 [Amended]

35. In the first sentence of newly redesignated section 2933.211, the phrase "The written decision required by FAR 33.011 (a)(4) shall include, in the paragraph listed under FAR 33.011(a)(4)(v)," is revised to read "The written decision required by FAR 33.211(a)(4) shall include, in the paragraph listed under FAR 33.211(a)(4)(v),".

36. Part 2933 is amended by adding a new Subpart 2933.1 consisting of sections 2933.102 through 2933.105, to read as follows:

Subpart 2933.1—Protests

2933.102 General.

The Director, Office of Procurement and Grant Policy, Directorate of Procurement and Grant Management, shall be responsible for coordinating bid protests filed with the General Accounting Office (GAO). All communications relative to protests filed with GAO or GSBCA shall be coordinated with the Director, Office of Procurement and Grant Policy. Bid protests concerning automatic data processing (ADP) acquisitions filed with the General Services Administration Board of Contract Appeals (GSBCA) shall be coordinated by the contracting officer.

2933.103 Protests to the DOL Agency.

When protests are filed with a DOL Agency and received before award, the contracting office shall obtain the advice of the Director, Office of Procurement and Grant Policy, before making the determination under FAR 33.103(a).

2933.104 Protests to the GAO.

(a) *Notice of protest.* Upon being advised telephonically by GAO or the receipt of a protest before or after award, the Office of Procurement and Grant Policy shall inform the appropriate contracting officer and request preparation of the protest report required by FAR 33.104(a)(2). For GAO protests concerning ADP acquisitions, the Office of Procurement and Grant Policy shall also inform the Director, Directorate of Information Resources Management, who, in turn, shall notify the appropriate DOL Agency Information Resources Management (IRM) contact. As required by FAR 33.104(a)(3) and 4 CFR 21.3, the contracting officer shall promptly notify all interested parties, including offerors (or the contractor, if the protest is after award) involved in or affected by the protest, that a protest has been filed with GAO and the basis for the protest. A written record of such notification shall be placed in the contract file. After receiving a copy of the protest from GAO and its request for an administrative report, the Office of Procurement and Grant Policy will promptly furnish the same to the contracting officer. The contracting officer shall promptly transmit by letter a copy of the protest to all interested parties previously notified and include a statement requiring furnishing of views and information directly to GAO. Copies of cover letters shall be sent to the Director, Office of Procurement and Grant Policy. Cover letters shall set forth a specified period of time for submission of comments (see FAR 33.104(a)(3)) and include instructions that any comments submitted to GAO should also be submitted simulaneously to the contracting officer and the Director, Office of Procurement and Grant Policy. Materials submitted by the protester may be withheld from interested parties in accordance with 4 CFR 21.3(b).

(b) *Submission of report.* (1) All personnel shall handle protests on a priority basis. Within 25 work days after receipt by the Office of Procurement and Grant Policy of GAO's telephonic notice of the protest, or within 10 work days after receipt from GAO of a determination to use the express option, a complete report shall be submitted to GAO (see FAR 33.104(a)(2)). If the specific circumstances of the protest require a longer period, the head of the contracting activity shall immediately notify the Office of Procurement and Grant policy which shall request, in writing, an extension of the time period in accordance with 4 CFR 21.3(d).

(2) In addition to the requirements of FAR 33.104(a)(2), the report responsive to the protest shall be appropriately titled and dated; shall cite the GAO file number; and shall be signed by the contracting officer or the contracting officer's representative. Reports shall be prepared with the assistance of the Office of the Solicitor of Labor. If appropriate, the report shall contain a statement regarding any urgency for the acquisition and the extent to which a delay in award may result in significant performance difficulties or additional expense to the Government. If award is not urgent, a statement shall be included giving an estimate of the length of time an award may be delayed without significant expense or difficulty in performance. The head of the contracting activity shall submit an original and one copy of the contracting officer's report to the Director, Office of Procurement and Grant Policy, with a forwarding letter to GAO signed by the Assistant Secretary for Administration and Management. When the letter and report are dated and transmitted to GAO, the Director, Office of Procurement and Grant Policy, will inform the contracting officer. The contracting officer will then distribute copies of the report to all interested parties.

(c) *Notice to GAO.* The Assistant Secretary for Administration and

Management shall submit the report required by FAR 33.104(f). The report shall be submitted to the Comptroller General through the Director, Office of Procurement and Grant Policy, and the Director, Directorate of Procurement and Grant Managemnent. For decisions concerning ADP acquisitions, the report shall also be submitted through the Director, Directorate of Information Resources Management.

2933.105 Protests to General Services Administration Board of Contract Appeals.

(a) *Notice of protest.* Immediately upon receipt of a copy of a protest to the General Services Administration Board of Contract Appeals (GSBCA), the contracting officer shall inform the Office of Procurement and Grant Policy, the Directorate of Information Resources Management, and the Office of the Solicitor of Labor. The contracting officer shall, within 1 work day after receipt of a copy of the protest, provide oral or written notice to all parties required to be notified by FAR 33.105(a)(2) and shall provide the GSBCA with a written list of all such parties to whom notice was provided within 5 work days after receipt of a copy of the protest. A copy of all notifications to interested parties and related correspondence with GSBCA shall be maintained in the contract file and a copy of the list of interested parties notified shall be provided to the Office of Procurement and Grant Policy simultaneously with submission to the GSBCA.

(b) *Submission of protest file.* An original and one copy of a protest file (see FAR 33.105(b)) plus one copy for each interested party which has a notice of intervention or a motion to intervene in accordance with the requirements of Rule 5(a)(3) of GSBCA Rules of Procedure (48 CFR 6101.5(a)(3)) shall be prepared by the contracting officer. The protest file shall be organized to comply with the requirements of Rule 4(b) of the GSBCA Rules of Procedure (48 CFR 6101.4(b)). The contracting officer shall submit the file to the GSBCA within 10 work days after filing of the protest and shall also send copies to the Director, Office of Procurement and Grant Policy, and to each interested party.

(c) *Hearings.* The Solicitor of Labor, or the Solicitor's representative, is responsible for representing the contracting officer at all stages of proceedings on suspension of the agency's delegation of procurement authority (see FAR 33.105(d)), at all stages of proceedings on the merits of the protest (see FAR 33.105(e)), and with respect to any other proceedings which may be heard by the GSBCA. The head of the contracting activity shall be responsible for executing the determination required by FAR 33.105(d)(1). The Office of the Solicitor shall notify the contracting officer and the Directorate of Information Resources Management of the results of such proceedings, including any hearing.

PART 2943—CONTRACT MODIFICATIONS

37. The Authority citation for Part 2943 is revised to read as follows, and the separate Authority citations for sections in the part are removed:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

38. Part 2943 is amended by adding a new subpart 2943.3 to read as follows:

Subpart 2943.3—Forms

2943.301 Use of forms.

FAR 43.301(a)(1)(vi) requires the use of Standard Form 30 (SF–30) to effect any obligation or deobligation of contract funds after award. The SF–30 also shall be used to deobligate funds when effecting contract closeout for a cost reimbursement contract when obligated funds exceed the final contract costs. In such an instance, the SF–30 may be issued as an administrative modification on a unilateral basis if the contractor's financial release has been separately obtained.

PART 2949—TERMINATION OF CONTRACTS

39. The Authority citation for Part 2949 continues to read as follows:

Authority: 5 U.S.C. 301; 40 U.S.C. 486(c).

Subpart 2949.1—General Principles

40. Part 2949.1 is amended by revising the subpart heading to read as set forth above

[FR Doc. 86–24855 Filed 11–5–86; 8:45 am]
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Federal Register

Thursday
November 6, 1986

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 868, 874, 878, and 886
Medical Devices; Ear, Nose, and Throat Devices; Final Rule, Proposed Rule and Withdrawal of Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868 and 874

[Docket No. 78N-1549]

Ear, Nose, and Throat Devices; General Provisions and Classifications of 47 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 47 devices: 45 ear, nose, and throat devices and 2 anesthesiology devices. The preamble to this rule responds to comments received on the proposed regulations classifying these devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: December 8, 1986.

FOR FURTHER INFORMATION CONTACT: David A. Segerson, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-8185.

SUPPLEMENTARY INFORMATION:

Table of Contents

A. Background

In the **Federal Register** of January 22, 1982 (47 FR 3280-3325), FDA published a proposed rule containing general provisions applicable to the classification of ear, nose, and throat devices and individual proposed regulations classifying 67 ear, nose, and throat devices into one or more of three regulatory classes: class I (general controls), class II (performance standards), and class III (premarket approval).

In the final rule, FDA is classifying 47 devices, with 14 devices in class I, 26 devices in class II, 5 devices in class III, 1 device in either class I or class II (depending upon its construction), and 1 device in either class II or class III (depending upon its intended use).

For several reasons, there is a difference between the number of devices covered by the proposal (67) and the number of devices covered by the final rule (47). First, FDA has grouped 23 devices that were the subjects of proposed regulations into 9 generic types of devices, resulting in 14 fewer devices. Second, FDA is postponing classification of six devices pending review of additional data. Third, FDA is announcing its decision on a reclassification petition for the microsurgical argon laser for use in otology and is codifying the reclassification of this device into class II for certain intended uses; however, the device remains in class III for other intended uses. Fourth although FDA proposed that the transdermal stimulator (§ 874.5850, Docket No. 78N-1636) be classified into class III (47 FR 3280) as part of the ear, nose, and throat device classification proceeding, the agency later determined that the device is an investigational device not in commercial distribution before May 28, 1976, the enactment date of the amendments. Because the device was not in commercial distribution, the transdermal stimulator is classified into class III by statute as provided in section 513(f) of the act (21 U.S.C. 360c), without the need for agency publication of a classification regulation for the device.

Two proposed ear, nose, and throat devices, the tracheostomy tube and tube cuff (class II) and the tracheal tube cleaning brush (class I), are being codified with anesthesiology devices in 21 CFR Part 868. Therefore, in this final rule, FDA is classifying 45 ear, nose, and throat devices and 2 anesthesiology devices.

Elsewhere in the issue of the **Federal Register**, FDA is publishing a notice withdrawing the proposed regulations that are unnecessary due to the decisions described above.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule proposing to exempt from the requirement of premarket notification, with limitations, four class I ear, nose, and throat devices.

Classification of medical devices in commercial distribution is required by section 513 (21 U.S.C. 360c) of the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301-392). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. 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 III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. For a class III device that was not considered a new drug before the amendments and that either was in commercial distribution before May 28, 1976, or that is substantially equivalent to a device that was in commercial distribution before that date, each application for premarket approval must be submitted to FDA on or before June 28, 1989, or within 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. Devices that FDA previously regarded as new drugs, or newly offered devices that are not substantially equivalent to a device that was in commercial distribution before the amendments, are classified by statute into class III and already are required to have in effect an approved application for premarket approval. See sections 520(1) and 513(f) of the act (21 U.S.C. 360j(l) and 360c(f)).

The preamble to the proposed rule described the development of the general provisions and the proposed regulations classifying ear, nose, and throat devices and the activities of the FDA advisory committee that makes recommendations to FDA concerning the classification of ear, nose, and throat devices. FDA provided a period of 60 days for interested persons to submit written comments on the proposals. The deadline was later extended to July 1, 1982. The comments received and FDA's responses to the comments are discussed in section "K. Summaries of Comments and FDA's Responses to Comments" of this preamble.

In April 1985, H.R. 2177 (99th Cong. 1st Sess.) was introduced in the U.S. House of Representatives. The bill is a legislative proposal of the Department of Health and Human Services. Among other things, the bill would (1) and amend the act to eliminate the statutory category of class II, (2) make the establishment of a performance standard one of the several general controls that may be made applicable to a device, and (3) streamline the procedure for establishing standards set out in section 514 of the act. If this bill becomes law, there will be only two

categories of devices, class I (general controls) and class II (premarket approval, formerly class III). Class II devices would be redesignated as class I devices. Because this legislation includes transitional provisions that translate classifications under the current law to classifications under the proposed law, FDA is continuing its issuance of classification rules under the current law and has established a policy, described below, to set priorities for the establishment of performance standards for class II devices.

B. FDA's Priorities for Establishing Performance Standards

In the **Federal Register** of October 23, 1985 (50 FR 43060), FDA published a notice, "Policy Statement; Class II Medical Devices," announcing its policy for setting priorities for initiating proceedings to establish performance standards for medical devices classified into class II. Under the amendments, FDA is required to establish performance standards for class II devices. At this time, however, FDA does not have the resources to establish performance standards for all of the devices already classified (or being classified) in class II.

In the notice of October 23, 1985, FDA announced it will consider the following factors when setting priorities for establishing performance standards for class II devices:

1. The seriousness of questions concerning the safety and effectiveness of the device; the risks associated with use of the device; the significance of a device to the public health; and the present and projected use of the device.
2. The recommendations of FDA's advisory committees.
3. The inpact of an FDA guideline or recommendation.
4. The effect of a Federal standard or other regulatory controls under an authority other than the act.
5. The impact of voluntary standards.
6. The impact of activities authorized under the general controls provisions of the act.
7. The effect of dissemination of information and education efforts.
8. The sufficiency of voluntary corrective actions.
9. Valid scientific evidence developed since classification.
10. The existence of a petition for reclassification.
11. The impact of any other factors that affect a device's safety or effectiveness.

C. Changes in the Name of the Ear, Nose, and Throat Device Advisory Committee

FDA has periodically restructured its advisory panels for device classification. Most recently, on April 14, 1984, FDA established the Ear, Nose, and Throat Devices Panel (see 49 FR 17446; April 24, 1984). The new panel performs the same functions with respect to ear, nose, and throat devices as did its predecessors, the Ear, Nose, and Throat Device Classification Panel (1976–1978) and the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel (1978–1984).

D. Grouping of Similar Devices

In response to comments and to simplify and clarify the regulations, in the final rule FDA has grouped 23 proposed ear, nose, and throat devices into 9 generic types of devices. The term "generic type of device" is defined in 21 CFR 860.3(i) to mean a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness. Consequently, similar regulatory controls are appropriate to provide reasonable assurance of the safety and effectiveness of these devices. The devices being grouped are identified below under the heading in the preamble entitled "J. List of Ear, Nose, and Throat Devices." Each generic type of ear, nose, and throat device being classified is identified with both the docket number used for that device in the proposed regulations and the section number of the Code of Federal Regulations at which its classification is being codified. A device listed under the heading "J. List of Ear, Nose, and Throat Devices" that is not identified with a section number is being grouped into the generic type of device with a section number that is listed directly before it. Thus, for example, *Air caloric stimulator* and *Water caloric stimulator* are being grouped into the generic type of device *Air or water caloric stimulator* (§ 874.1800).

E. Devices Not Being Classified at This Time

FDA is postponing classification of the following six generic types of ear, nose, and throat devices in order to review additional data on electrical safety. Because similar ear, nose, and throat devices are being grouped as described above, the six generic types of devices encompass devices that were the subjects of eight proposed regulations. The following is a list of the six generic types of devices that are not being classified in the final rule. FDA is considering classifying these six devices in class I.

Docket No.	Device
78N-1552	Short increment sensitivity index (SISI) adapter.
78N-1565	Air or water caloric stimulator.
78N-1622	Laryngostroboscope.
78N-1624	Otoscope.
78N-1630	Ear, nose, and throat examination and treatment unit.
78N-1631	Powered nasal irrigator.

F. Changes in Classifications in Final Regulations

Based upon consideration of the comments received and on additional consideration of all information before the agency, FDA has placed several devices that are listed below in different classes from those proposed. FDA's reasons for adopting classifications for these devices that differ from the proposal are provided in this preamble under the heading "K. Summaries of Comments and FDA's Responses to Comments."

Secs.	Device	Proposed class	Final class
874.1060	Acoustic chamber for audiometric testing.	II	I
874.1100	Earphone cushion for audiometic testing.	II	I
874.3300	Hearing aid	II	I, II
874.3450	Partial ossicular replacement prothesis.	II, III	II
874.3495	Total ossicular replacement prosthesis.	II, III	II
874.3630	Ear, nose, and throat porous polyethylene synthetic polymer material.	III	II
874.3880	Tympanostomy tube	II, III	II
874.4140	Ear, nose, and throat bur.	II	I
874.4420	Ear, nose, and throat manual surgical instrument.	II	I
874.5840	Antistammering device.	II	I

FDA believes that it is unnecessary to issue a new proposal concerning these decisions. The purpose of publishing a proposal and soliciting comments is to enable the agency to determine whether its proposed classification of a device was correct. After reviewing the comments submitted on a proposal, or upon reconsideration, the agency may determine that its proposed classification is incorrect. Persons interested in the classification process should anticipate that in a final regulation a device may be placed in a class different from the one originally proposed. This possibility was specifically identified in the proposed

general regulations for ear, nose, and throat devices (see 47 FR 3280; January 22, 1982). Persons who disagree with a final classification for a device may petition for reclassification of the device under Subpart C of Part 860.

G. Minor Changes or Clarifications

Occasionally the agency has made minor changes in the name of a generic type of device or its identification to clarify the final regulation. Additionally, the agency is adding new § 874.3 in Subpart A to explain the various effective dates for premarket approval requirements for devices classified into class III. FDA also is adding a new paragraph (c) in the classification regulation for each device classified into class III to declare, where applicable, the effective date for premarket approval requirements for the device.

H. Reclassification of the Microsurgical Argon Laser

Postamendments devices that are not substantially equivalent to devices in commercial distribution before May 28, 1976, are classified by statute into class III under section 513(f)(1) of the act (21 U.S.C 360c(f)(1)). In response to a petition received by FDA under section 513(f)(2) of the act and Part 860 of the regulations, FDA may reclassify a new device into class I or class II.

On October 15, 1980, FDA received a petition (Docket No. 81P-0115) under section 513(f) of the act requesting the agency to reclassify the petitioner's Model 770 argon laser with microsurgical attachments for use in otolarynogological surgery from class III to class II. On December 4, 1980, FDA received a petition (Docket No. 80P-0501) under section 513(e) of the act (21 U.S.C. 360(e)) requesting the agency to reclassify the petitioner's Model 9005 argon laser with microsurgical attachments for use in otology from class III to class II. In the **Federal Register** of May 11, 1982 (47 FR 20188), FDA published the recommendations of the Ear, Nose, and Throat Devices Section of the Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel that both of these devices be reclassified from class III to class II and treated as one generic type of device. The agency provided a period of 30 days (extended to 60 days by notice of July 2, 1982 (47 FR 29004)) for interested persons to submit written comments on the recommendations. No written comments were received. FDA agreed with the section's recommendations that the device be reclassified. Further, the Section recommended, and FDA agrees, that the labeling for the device include a comprehensive description of the techniques, risks, and hazards which accompany use of the device, as well as a discussion on how the attendant risks and hazards can be avoided. In accordance with section 513(f)(2)(C)(i) of the act and 21 CFR 860.134(b)(6) of the regulations, FDA partially approved and partially denied the petitions and, by orders in the form of letters dated November 19, 1982, and sent to each petitioner, reclassified the microsurgical argon laser for use in otology from class III to class II. However, the microsurgical argon laser for other uses, including use in laryngology and general use in otolaryngology, remains in class III and may not be commercially distributed without an approved application for premarket approval.

FDA is codifying the reclassification into class II of the microsurgical argon laser for use in otology at § 874.4490(a). FDA's orders reclassifying the device for certain uses into class II and the regulation apply to any microsurgical argon laser for use of otology that is substantially equivalent to the reclassified device. FDA determines substantial equivalence of new devices by reviewing premarket notification submissions under section 510(k) of the act and Subpart E of Part 807.

I. Classification Regulations Published to Date

The following table shows the current structure of the advisory committees involved with the classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel name	Publication date in FEDERAL REGISTER
Circulatory System Devices Panel	Mar. 9, 1979, 44 FR 13284-13434 (proposals); Feb. 5, 1980, 45 FR 7904-7971 (final regulations).
Clinical Chemistry and Clinical Toxicology Devices Panel.	Feb. 2, 1982, 47 FR 4802-4929 (proposals).
Hematology and Pathology Devices Panel.	Sept. 11, 1979, 44 FR 53063 (proposals); Sept. 12, 1980, 45 FR 60576-6051 (final regulations).
General Hospital and Personal Use Devices Panel.	Aug. 24, 1979, 44 FR 49844-49954 (proposals); Oct. 21, 1980 45 FR 69678-69737 (final regulations).
Gastroenterolgy-Urology Devices Panel.	Jan. 23, 1981, 46 FR 7562-7641 (proposals); Nov. 23, 1983, 48 FR 53012-53029 final regulations).
Immunology Devices Panel	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982, 47 FR 50614-50640 (final regulations).
Microbiology Devices Panel	Do.
Obstetrics-Gynecology Devices Panel.	Apr. 3, 1979, 44 FR 19894-19971 (proposals); Feb. 26, 1980, 45 FR 12682-12720 (final regulations).
Radiologic Devices Panel	Jan. 29, 1982, 47 FR 4406-4451 (proposals).
Ophthalmic Devices Panel	Jan. 26, 1982, 47 FR 3694-3749 (proposals).
Ear, Nose, and Throat Devices Panel.	Jan. 22, 1982, 47 FR 3280-3325 (proposals); (Nov. 6, 1986 (final regulations)l
Dental Devices Panel	Dec. 30, 1980, 45 FR 85962-86168 (proposals).
Anesthesiology and Respiratory Therapy Devices Panel.	Nov. 2, 1979, 44 FR 63292-63426 (proposals); July 16, 1982, 47 FR 31130-31150 (final regulations).
Neurological Devices Panel	Nov. 23, 1978, 43 FR 54640-55732 (proposals); Sept. 4, 1979, 44 FR 51726-51778, (final regulations).
Orthopedic and Rehabilitation Devices Panel (Physical Medicine Devices).	Aug. 28, 1979, 44 FR 50458-50537 (proposals); Nov. 23, 1983, 48 FR 53032-53054 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Orthopedic Devices).	July 2, 1982, 47 FR 29052-29140 (proposals).
General and Plastic Surgery Devices Panel.	Jan. 19, 1982, 47 FR 2810-2853 (proposals).

J. List of Ear, Nose, and Throat Devices

The list below shows for each ear, nose, and throat device the section of the Code of Federal Regulations at which the classification of that device is being codified (or will be codified), the docket number of the corresponding proposed classification regulation (where applicable), the final classification of the device, and an identification (yes or no) of whether public comments were received on the proposed regulation. If no comments were received, generally FDA is adopting the proposed regulation without a change in classification. The list includes the six generic types of ear, nose, and throat devices for which final classification is being postponed. For each of these six devices, the section number of the Code of Federal Regulations is in parentheses, the name of the device is identified with footnote "1," and no final classification is provided.

Section	Device	Docket No.	Class	Comments
	SUBPART B—DIAGNOSTIC DEVICES			
874.1050	Audiometer	78N-1550	II	Yes.
874.1060	Acoustic chamber for audiometric testing	78N-1551	I	Yes.
(874.1070)	Short increment sensitivity index (SISI) adapter [1]	78N-1552		Yes.
874.1080	Audiometer calibration set	78N-1553	II	Yes.
874.1090	Auditory impedance tester	78N-1554	II	Yes.
874.1100	Earphone cushion for audiometric testing	78N-1555	I	Yes.
874.1120	Electronic noise generator for audiometric testing	78N-1556	II	Yes.
874.1325	Electroglottograph	78N-1558	II	Yes.
874.1500	Gustometer	78N-1561	I	No.
(874.1800)	Air or water caloric stimulator [1]	78N-1565		
	Air caloric stimulator	78N-1565		Yes.
	Water caloric stimulator	78N-1566		Yes.
874.1820	Surgical nerve stimulator/locator	78N-1567	II	Yes.
874.1925	Toynbee diagnostic tube	78N-1568	I	No.
	SUBPART D—PROSTHETIC DEVICES			
874.3300	Hearing aid	78N-1569	I, II	Yes.
874.3310	Hearing aid calibrator and analysis system	78N-1570	II	Yes.
874.3320	Group hearing aid or group auditory trainer	78N-1571	II	Yes.
874.3330	Master hearing aid	78N-1572	II	Yes.
874.3375	Battery-powered artificial larynx	78N-1573	I	No.
874.3400	Tinnitus masker	78N-1574	III	No.
874.3430	Middle ear mold	78N-1576	II	Yes.
874.3450	Partial ossicular replacement prosthesis	78N-1577	II	
	Partial ossicular replacement prosthesis	78N-1577		Yes.
	Porous polyethylene partial ossicular replacement prosthesis	78N-1637		Yes.
874.3495	Total ossicular replacement prosthesis	78N-1578	II	
	Total ossicular replacement prosthesis	78N-1578		Yes.
	Porous polyethylene total ossicular replacement prosthesis	78N-1639		Yes.
874.3540	Prosthesis modification instrument for ossicular replacement surgery	78N-1579	I	No.
874.3620	Ear, nose, and throat synthetic polymer material	78N-1583	II	
	Ear, nose, and throat polyamide mesh or foil synthetic polymer material	78N-1583		Yes.
	Ear, nose, and throat porous polyethylene synthetic polymer material	78N-1584		Yes.
874.3695	Mandibular implant facial prosthesis	78N-1588	II	Yes.
874.3730	Laryngeal prosthesis (Taub design)	78N-1589	II	Yes.
874.3760	Sacculotomy tack (Cody tack)	78N-1591	II	Yes.
874.3820	Endolymphatic shunt	78N-1593	II	Yes.
874.3850	Endolymphatic shunt tube with valve	78N-1594	III	Yes.
874.3880	Tympanostomy tube	78N-1595	II	
	Tympanostomy tube	78N-1595		Yes.
	Porous polyethylene tympanostomy tube	78N-1641		Yes.
874.3930	Tympanostomy tube with semipermeable membrane	78N-1596	III	Yes.
	SUBPART E—SURGICAL DEVICES			
874.4100	Epistaxis balloon	78N-1599	I	No.
874.4140	Ear, nose, and throat bur	78N-1601	I	Yes.
874.4175	Nasopharyngeal catheter	78N-1602	I	No.
874.4250	Ear, nose, and throat electric or pneumatic surgical drill	78N-1604	II	Yes.
874.4350	Ear, nose, and throat fiberoptic light source and carrier	78N-1606	II	Yes.
874.4420	Ear, nose, and throat manual surgical instrument	78N-1609	I	
	Bronchial, tracheal, or esophageal surgical instrument	78N-1607		Yes.
	Surgical instrument for the ear	78N-1608		Yes.
	Ear, nose, and throat multiple-use surgical instrument	78N-1609		Yes.
	Laryngeal surgical instrument	78N-1610		Yes.
	Pharyngeal surgical instrument	78N-1611		Yes.
	Nasal and paranasal sinus surgical instrument	78N-1612		Yes.
874.4490	Microsurgical argon laser [2]	80P-0501 and 81P-0115	II, III	
874.4500	Ear, nose, and throat microsurgical carbon dioxide laser	78N-1613	II	Yes.
874.4680	Bronchoscope (flexible or rigid) and accessories	78N-1616	II	
	Bronchoscope (flexible or rigid)	78N-1616		Yes.
	Ear, nose, and throat endoscopic accessory [3]	78N-1617		Yes.
	Laryngeal-bronchial telescope	78N-1625		Yes.
874.4710	Esophagoscope (flexible or rigid) and accessories	78N-1619	II	Yes.
874.4720	Mediastinoscope and accessories	78N-1620	II	Yes.
(874.4750)	Laryngostroboscope [1]	78N-1622		
	External Laryngostroboscope	78N-1622		No.
	Laryngostroboscope (patient-contacting)	78N-1643		Yes.
874.4760	Nasopharyngoscope (flexible or rigid) and accessories	78N-1623	II	Yes.
(874.4770)	Otoscope [1]	78N-1624		Yes.
868.5800 (Proposed 874.4800)	Tracheostomy tube and tube cuff	78N-1626	II	
	Tracheostomy tube	78N-1626		Yes.
	Tracheostomy tube cuff	78N-1626		Yes.
868.5795 (Proposed 874.4910)	Tracheal tube cleaning brush	78N-1627	I	No.
	SUBPART F—THERAPEUTIC DEVICES			
874.5220	Ear, nose, and throat drug administration device	78N-1629	I	No.
(874.5300)	Ear, nose, and throat examination and treatment unit [1]	78N-1630		Yes.
874.5350	Suction antichoke device	78N-1597	III	No.
874.5370	Tongs antichoke device	78N-1598	III	No.
(874.5550)	Powered nasal irrigator [1]	78N-1631		Yes.
874.5800	External nasal splint	78N-1634	I	No.
874.5840	Antistammering device	78N-1635	I	Yes.

[1] Classification postponed.
[2] Not proposed; classification results from reclassification petitions.
[3] The endoscopic accessories formerly identified in this proposed regulation are included in the following sections of the final rule: 874.4680, 874.4710, 874.4720, and 874.4760.

K. Summaries of Comments and FDA's Responses to Comments

FDA is responding to comments received on the proposed regulations that were published in the **Federal Register** of January 22, 1982 (47 FR 3280–3325).

1. Comments stated a review of manufacturers' complaint files and of reports in FDA's device experience network show no adverse experience reports for a number of devices. For these reasons, the comments said the devices listed below should be classified into class I, rather than class II or class III as proposed.

Section	Device	Class proposed, by FDA
874.3430	Middle ear mold	II
874.3450	Partial ossicular replacement prosthesis.	II
874.3760	Sacculotomy tack (Cody tack).	II
874.3880	Tympanostomy tube	II
874.3930	Tympanostomy tube with semipermeable membrane.	III

FDA disagrees with the comments regarding the devices above. The reports in FDA's device experience network (DEN) are submitted voluntarily to FDA. FDA believes that the adverse experience reports in DEN and the data in complaint files of manufacturers may not reflect the actual levels of adverse experiences with devices. See the preamble to FDA's reproposed rule on medical device reporting (May 27, 1983; 48 FR 24014 at 24016). In the **Federal Register** of September 14, 1984 (49 FR 36326), FDA published a final rule requiring manufacturers and importers to report to FDA deaths and serious injuries caused or contributed to by devices (See 21 CFR Part 803). FDA believes that the data this reporting system yields are not a definitive basis for classification decisions, as manufacturers need not report adverse experiences which do not rise to the level of death or serious injury, and health professionals are not required to report adverse experiences to manufacturers. Therefore, FDA is classifying the devices listed above into the classes shown.

2. Comments questioned whether the risks to health identified in the proposed regulations for each of the devices listed below justify development of a mandatory performance standard. The comments suggested that these devices be classified into class I, rather than class II as proposed. FDA's responses to these comments are in paragraphs 2a through 2o.

2a. Section 874.1050; Audiometer.

FDA believes that a performance standard is necessary for this device to control calibration parameters, method of calibration, reference levels, test frequencies, distoration level, and masking levels. The agency believes these characteristics must be controlled by a standard to prevent misdiagnosis or injury to the patient resulting from devices of improper design or construction. Accordingly, FDA is adopting the proposed regulation without change.

2b. Section 874.1060; Acoustic chamber for audiometric testing.

FDA agrees with the comments regarding the acoustic chamber for audiometric testing. FDA now believes that the general controls of class I are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that labeling that provides adequate directions for use of the acoustic chamber for audiometric testing is sufficient to control the risk to health of asphyxiation. FDA believes that the labeling should provide adequate instructions to the operator and the patient with respect to procedures for opening the door of the acoustic chamber. FDA now believes that it is unnecessary to establish a performance standard for the device. Accordingly, FDA is adopting the proposed regulation with the classification of class I rather than class II as proposed.

2c. Section 874.1080; Audiometer calibration set.

The agency believes that a performance standard is necessary for this device to control calibration parameters to prevent erroneous measurement of hearing thresholds which could lead to a misdiagnosis and to prevent excessive sound output levels from the audiometer which may produce hearing damage in a patient. Accordingly, FDA is adopting the proposed regulation with a minor clarifying change.

2d. Section 874.1090; Auditory impedance tester.

The agency believes that a performance standard is necessary to control the static pressure produced by the device to prevent damage to the tympanic membrane and to control the sound output levels produced by the device to prevent hearing damage. Accordingly, FDA is adopting the proposed regulation without change.

2e. Section 874.1120; Electronic noise generator for audiometric testing.

The sound output level produced by the device is not under the direct control of the patient, and the patient may tolerate excessive sound levels under the mistaken belief that excessive sound levels are intentional and necessary. The agency believes that a performance standard is necessary to control the maximum sound output levels to minimize the possibility of hearing damage to the patient. Accordingly, FDA is adopting the proposed regulation with a minor clarifying change.

2f. Section 874.1325; Electroglottograph.

The agency believes that a performance standard is necessary to control the output characteristics of this device to prevent erroneous measurement of electrical impedance of the larynx which could lead to misdiagnosis and subsequent inappropriate therapy. Accordingly, FDA is adopting the proposed regulation without change.

2g. Section 874.1820; Surgical nerve stimulator/locator.

The agency believes that the output characteristics of the surgical nerve stimulator/locator need to be specified and controlled by a performance standard to assure that the electrical current will not damage nerve tissue. The agency notes that application of direct current to an area of exposed nerve may injure the nerve and cause paralysis. A standard is needed to prevent injury to the patient from devices of improper design or construction. Accordingly, FDA is adopting the proposed regulation without change.

2h. Section 874.3300; Hearing aid.

FDA agrees in part and disagrees in part with the comments urging that the hearing aid be placed in class I instead of class II as proposed. FDA agrees that the air-conduction hearing aid presents a sufficiently low risk to health of hearing loss from excessive sound output levels that the controls of class I, in conjunction with the requirements for labeling and conditions for sale for hearing aids (21 CFR 801.420 and 801.421) would provide reasonable assurance of safety and effectiveness of this kind of hearing aid. However, FDA continues to believe that a performance standard is necessary for the bone-conduction hearing aid to control the sound levels to prevent further hearing damage in a patient and to ensure effectiveness of this kind of hearing aid. A performance standard for the bone-conduction hearing aid would establish the parameters for the values of the data

elements that are required by § 801.420(c)(4) to be included in the labeling and would ensure that each bone-conduction hearing aid device is able to function within such parameters. Accordingly, in the final rule FDA is clarifying the identification of the device, classifying the air-conduction hearing aid into class I, and classifying the bone-conduction hearing aid into class II as proposed.

2i. Section 874.3310; Hearing aid calibrator and analysis system.

The agency believes that a performance standard is necessary for this device to control the accuracy of the calibration mechanism. A standard is needed to minimize erroneous calibration of a hearing aid which could cause further hearing damage in a patient from excessive sound output levels. Accordingly, FDA is adopting the proposed regulation with minor clarifying changes.

2j. Section 874.3320; Group hearing aid or group auditory trainer.

The agency believes that a performance standard is necessary for this device to control the maximum allowable sound output pressure levels to prevent further hearing damage in a patient. Accordingly, FDA is adopting the proposed regulation without change.

2k. Section 874.3330; Master hearing aid.

The agency believes that a performance standard is necessary for the master hearing aid to control its calibration of a hearing aid, because inaccurate calibration may cause the hearing aid to produce excessive sound output levels and result in further hearing damage in a patient or cause a practitioner to select the wrong hearing aid or incorrectly adjust a hearing aid for a patient. Accordingly, FDA is adopting the proposed regulation without change.

2l. Section 874.3760; Sacculotomy tack (Cody tack).

The agency believes that a performance standard is necessary for the sacculotomy tack to control the size and sharpness of the device and assure its biocompatibility with inner ear tissues and fluids. The agency believes that there is sufficient information available to develop a standard for the device (Ref. 10). Accordingly, FDA is adopting the proposed regulation with minor clarifying changes in the identification of the device.

2m. Section 874.3820; Endolymphatic shunt tube.

FDA believes that a performance standard is necessary to control the risks of possible infection and adverse tissue reaction from the use of materials that are not biologically or mechanically compatible with the body. Implantation of an endolymphatic shunt tube into the middle ear is a major surgical procedure. Accordingly, FDA is adopting the proposed regulation with clarifying changes in the name of the generic type of device and its identification to clarify that the rule also applies to silicone sheets, which serve the same purpose as shunt tubes.

2n. Section 874.3880; Tympanostomy tube.

FDA believes that references 51 through 54 cited in the proposed rule show that performance standards are necessary to control the risks to health, infection and adverse tissue reaction, that are described in the proposed regulation for the device. Further, Reference 11 cited in this final rule shows that large diameter tympanostomy tubes present the additional risk to health of permanent perforation of the tympanic membrane. Thus, to control risks associated with the device, including permanent perforation of the tympanic membrane, adverse tissue reaction, infection, or malleous erosion from devices of improper design or construction (such as use of tubes of excessively large diameter), the agency believes that a performance standard is necessary for the tympanostomy tube. Accordingly, FDA is adopting the proposed regulation with clarifying changes in the identification of the device.

2o. Section 874.5840; Antistammering device.

FDA agrees with the comments suggesting that the antistammering device be classified into class I instead of class II as proposed. FDA now believes that general controls alone are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is intended for use by persons with normal hearing acuity who have direct control of the sound output levels produced by the device. In case of excessive sound output, the user can either adjust or remove the device. Accordingly, FDA is classifying the device into class I.

3. A comment suggested that the biocompatibility of the devices listed below could be controlled through premarket notification procedures in section 510(k) of the act. The comment suggested that these devices be classified into class I, rather than class II as proposed. No medical or scientific data were presented to support the suggestion.

Section	Device	Class proposed by FDA
874.3695	Mandibular implant facial posthesis.	II
874.3730	Laryngeal prosthesis (Taub design).	II
874.3820	Sacculatomy tack (Cody tack).	II
874.3880	Tympanostomy tube	II
874.4920	Tracheostomy tube cuff	II

FDA disagrees with the comment regarding the devices above. Premarket notification procedures required by section 510(k) of the act and Subpart E of 21 CFR Part 807 apply to manufacturers of a device being introduced into commercial distribution for the first time (as defined in 21 CFR 807.81(a) (1) and (2)) or manufacturers of a commercially distributed device that is about to be significantly changed or modified (as defined in § 807.81(a)(3)). Premarket notification procedures are not intended to assure that preamendments devices and postamendments substantially equivalent devices in commercial distribution are safe and effective. FDA believes that establishment of a performance standard is necessary for each of the devices listed above to control the risks to health identified in the proposed regulations and to provide reasonable assurance of the safety and effectiveness of the devices.

4. Section 874.1100; Earphone cushion for audiometric testing.

A comment stated that premarket notification procedures would be sufficient to detect the use of new materials which may not be biocompatible and cause contact dermatitis. The comment suggested that this device be classified into class I rather than class II as proposed.

FDA agrees with the comment. FDA identified the risk to health of contact dermatitis from use of materials that may not be biocompatible. However, the device is used by a patient for only a short time period. FDA now believes that the general controls of class I are sufficient to provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is classifying the device in class I.

5. Section 874.3430; Middle ear mold.

Two comments requested that the device be placed in class I instead of class II as proposed, based upon the extensive clinical use of the device with minimal risk to patients.

FDA disagrees with the comments. FDA acknowledges the extensive clinical use over several years of middle ear molds that are implanted in the middle ear. However, the agency notes that the synthetic materials from which

middle ear molds are made have been marketed for less than 10 years. Consequently, there have not been any long-term clinical toxicology studies to determine the biocompatibility of the device at the implantation site. As stated in the proposed regulation, FDA believes that a performance standard is necessary for this device to control the risks to health of adverse tissue reaction and infection, because general controls alone are insufficient to control these risks. Accordingly, FDA is adopting the proposed regulation with a minor clarifying change.

6. Section 874.3620; Ear, nose, and throat polyamide mesh or foil synthetic polymer material; proposed class II.

A comment requested that the device be classified into class I. No medical or scientific data were presented to support the request.

FDA disagrees with the comment. The agency believes that a performance standard is necessary for this implanted device to control the risks to health of adverse tissue reaction and infection. Accordingly, FDA is adopting the proposed regulation with minor clarifying changes.

7. FDA proposed that four ear, nose, and throat prostheses be classified into class II if made of certain materials and proposed that the same four devices be classified into class III if made of porous polyethylene.

Devices Proposed for Class II

§ 874.3450 Partial ossicular replacement prosthesis
§ 874.3495 Total ossicular replacement prosthesis
§ 874.3620 Ear, nose, and throat polyamide mesh or foil synthetic polymer material
§ 874.3880 Tympanostomy tube

Devices Proposed for Class III

§ 874.3465 Porous polyethylene partial ossicular replacement prosthesis
§ 874.3510 Porous polyethylene total ossicular replacement prosthesis
§ 874.3630 Ear, nose, and throat porous polyethylene synthetic polymer material
§ 874.3910 Porous polyethylene tympanostomy tube

During open Panel meetings held on June 22, 1978; November 6, 1978; and March 19, 1979, the Panel recommended that the four devices above made of porous polyethylene (PPE) be classified into class III. At that time, the Panel believed that the general controls of class I alone would not provide sufficient control over the risks to health presented by the four devices intended to be implanted in the ear and that insufficient information was available to develop performance standards for these four devices. Based on the Panel recommendations, FDA prepared draft regulations proposing to classify the four devices made of PPE into class III. These four proposed regulations, accompanied by the other 63 ear, nose, and throat proposed classification regulations, were submitted to FDA's Office of the Commissioner for approval and publication in the **Federal Register**.

On November 3, 1981, the Panel held another public meeting to review additional data on the safety and effectiveness of the four devices. At that meeting, for the reasons set forth below, the Panel recommended that FDA classify each of the four devices made of PPE into class II instead of class III as the Panel had originally recommended. FDA's Center for Devices and Radiological Health then decided to agree with the new recommendations.

However, by the November 3, 1981, advisory committee meeting the draft proposed classification regulations to classify ear, nose, and throat devices had been submitted to FDA's Office of the Commissioner for final approval. Due to inadvertence, the draft proposed regulations were not retrieved and updated to include the results of the November 3, 1981, meeting and the Center's views, both of which now favored a proposed classification into class II. As a result, FDA's proposed classification regulations for ear, nose, and throat devices, published on January 22, 1982, did not include the Panel's November 3, 1981, recommendations that the four PPE devices be in class II or the Center's revised views as to the appropriate classification of the devices.

Although the Panel's class II recommendations were not included in the proposed regulations, FDA received a comment from a manufacturer disagreeing with the Panel's recommendations of November 3, 1981, and requesting that FDA classify the four devices into class III as proposed. FDA also received comments that agreed with the Panel's recommendations of November 3, 1981, that the devices be classified into Class II. These comments requested that FDA classify the four devices into class II instead of class III.

The comment requesting that the four devices be in class III questioned the safety of PPE as an ear implant. The comment noted that the literature on clinical use of PPE in ear surgery did not identify the material in terms of its physical and chemical characteristics. The comment also questioned the effectiveness of PPE as an implant material: the comment questioned the ability of implants made from the material to permit tissue ingrowth and stabilization. The comment summarized the results of a paper by A.G. Kerr (Ref. 6). The comment said that Dr. Kerr, in his examination of 52 patients, did not find evidence that ear implants made of PPE provided tissue ingrowth stabilization.

For the reasons set forth below, FDA now believes that sufficient evidence is available of the safety and effectiveness of the four devices made of PPE that the agency concludes that the four devices should be classified into class II, rather than class III as proposed. FDA believes that the amount of tissue ingrowth into any pores in the implant material is not a critical factor in the agency's determination of whether these implants are placed in class II or class III. FDA is discussing below the critical factors upon which classification of these ear implants is based.

FDA agrees with the comments requesting that FDA classify the four devices made of PPE into class II.

At the meeting of the Panel on March 19, 1979, Dr. Zimlak and Mr. Lurie, American Hoechst Corp., described the process used to produce PPE, the mechanical and chemical properties of PPE, and the use of additives and catalysts in production of PPE. At the same meeting, Mr. Joseph Ferri, General Polymeric Corp., described the procedures used by his company to manufacture PPE. Mr. Ferri said that no additives are used and no chemical changes occur during their conversion of polyethylene (PE) powder to porous polyethylene (PPE).

Although PPE produced through use of various additives may indeed have a different physical and chemical composition from PE, FDA believes that PPE produced without additives (as noted above) can be characterized physically and chemically to the same extent as nonporous PE. Thus, FDA believes that sufficient information is available to develop performance standards for both PE and PPE.

Dr. Shea performed a scanning electron micrograph study of a PPE implant that had been removed from the middle ear of a human patient after it had been implanted for many months (Ref. 8). The study showed interlacing fibrous tissue engaging a section of the PPE implant. Thus, some tissue invasion into the PPE implant does take place from the interlacing network of fibrous connective tissue formed by the body around the implant. The study showed that the result of the tissue invasion is a columna of living tissue with a PPE skeleton. Dr. Shea found no evidence of

either acute or chronic tissue inflammation around the implantation site.

At the Panel meeting of June 22, 1978, Dr. Shea presented data to the Panel on the results of his studies of cats involving implantation of PPE in the middle ear and in the oval window. At this meeting, Dr. Shea also presented results of clinical studies involving 225 PPE implantation procedures in the middle ears of human patients. Data from these procedures were obtained during a followup period of 12 to 28 months. Dr. Shea said that the data showed excellent results. Dr. Shea presented slides to the Panel which illustrated the acceptance of PPE by human tissue and the characteristics of the material that allow tissue ingrowth (Ref. 9).

At the Panel meeting of November 3, 1981, Myron Spector, Ph.D., University of South Carolina, presented data to the Panel on the results of implanting PPE into the middle ear of cats (Ref. 1). The studies showed that after six months of implantation the animal formed a thin fibrous tissue capsule surrounding the implanted PPE material. The fibrous capsule appeared to cover the pores of the implant, and in some areas the fibrous tissue formed a continuum with fibrous tissue within the pores of the PPE material. Dr. Spector stated that internal pores of the PPE contained fibroblasts, blood vessels, macrophages, and foreign body giant cells. Occasionally, the fibroblasts and fibrocollagenous material in the pore structure of the PPE was contiguous with the fibrous capsule itself. The fibrous capsule around the PPE was also seen to be continuous with connective tissue structures of the middle ear. Dr. Spector observed that this fibrous tissue capsule, which formed around the PPE implant, appeared to stabilize the implant in the middle ear.

At the Panel meeting of November 3, 1981, J.M. Cassell and R.E. Dehl, National Bureau of Standards, reviewed the results of their studies performed under contract from FDA to characterize the porosity of PPE (Refs. 2, 3, and 4).

Following its review of the data above, on November 3, 1981, the Panel revised its earlier recommendation. The Panel unanimously recommended that the four ear, nose, and throat devices made of PPE and intended to be implanted in the middle ear be placed in class II. The Panel recommended, however, that the labeling for the four devices made of PPE should indicate that the devices not be implanted in direct contact with fluids of the inner ear.

FDA has concluded that PPE middle ear implants are at least as safe and effective as nonporous PE implants. Sufficient scientific and technical information is available to establish a performance standard that would adequately characterize the PPE material in terms of its physical and chemical specifications. Because the chemical composition of PPE may be different from nonporous PE, FDA believes that PPE should be specified and characterized separately from PE. FDA finds that adequate valid scientific evidence is available to show that middle ear implants made of PPE facilitate, to some extent, tissue ingrowth within the pore structure of the implant that serves to improve overall stabilization of the implant. Data from studies of PPE indicate that a fibrous tissue capsule forms around the implant made of PPE which serves to stabilize the device in a manner similar to the stabilization of the device made of nonporous PE.

Accordingly, FDA is classifying the porous polyethylene partial ossicular replacement prosthesis; porous polyethylene total ossicular replacement prosthesis; ear, nose, and throat porous polyethylene synthetic polymer material; and the porous polyethylene tympanostomy tube into class II instead of class III as proposed. FDA now believes that premarket approval is unnecessary for these four devices, because performance standards established for these devices under section 514 of the act would provide reasonable assurance of the safety and effectiveness of the devices and sufficient information is available to establish such standards. FDA also believes that the general controls of class I alone are insufficient to provide reasonable assurance of the safety and effectiveness of these four devices.

In the final rule, to reduce unnecessary regulations, certain of the devices above have been grouped together. See "D. Grouping of Similar Devices" and "J. List of Ear, Nose, and Throat Devices."

8. Section 874.3850; Endolymphatic shunt tube with valve; proposed class III.

One comment stated that sufficient data are available to assure the safety and effectiveness of the device with establishment of a performance standard. The comment said that the device had been used longer than 7 years and that nearly 2,000 devices had been implanted. The comment alleged that clogging is an infrequent generic problem with endolymphatic tubes, whether valved or not, and that because there is no observable injury to inner ear structures, it is unreasonable to place the valved device in class III. The comment cites clinical data that indicate the following effectiveness rates for the device: relief of vertigo, 89 to 90 percent; hearing stabilization, 64 to 72 percent; relief of aural pressure, 60 to 70 percent; and relief of tinnitus, 35 to 49 percent. The comment recommended that the proper classification of the device should be class I or class II.

FDA disagrees with the comment and believes that the device should be classified into class III as proposed. The agency notes that the endolymphatic shunt tube with valve is a relatively new device that is intended to be implanted. Several different versions have evolved over the past few years. The valve is intended to maintain a physiologically normal endolymphatic pressure, yet little is known about what is normal pressure. If the valve becomes inoperative or clogs, FDA believes that a significant risk to health would result from buildup of fluid pressure in the inner ear. Any surgical procedure to correct a defective valve also presents additional risks to health, such as infection. For these reasons, and the reasons stated in the proposed regulation, the agency believes that the endolymphatic shunt tube with valve should be in class III. Accordingly, FDA is adopting the proposed regulation with minor clarifying changes.

9. Section 874.3930; Tympanostomy tube with semipermeable membrane; proposed class III.

A comment argued that the risks to health in the proposed regulation are identical to those for the tympanostomy tube that FDA proposed to classify into class II: (a) Perforation; (b) adverse tissue reaction; (c) infection; and (d) hearing loss. Therefore, the comment stated that these risks are not risks which support classification of the tympanostomy tube with semipermeable membrane into class III. Further, the comment noted that hearing loss, as a result of membrane blockage, has not been substantiated in the clinical literature. A second comment stated that, considering the risks to health mentioned in the proposal, a performance standard is adequate to control the safety and effectiveness of the device. The comments recommended that the device be classified into class II, rather than class III as proposed.

FDA disagrees with the comments. The agency believes that the tympanostomy tube with semipermeable membrane presents a significant risk to health that is not presented by other tympanostomy tubes: The risk of hearing

loss due to blockage of the membrane. When the Panel recommended that the device be in class III, data demonstrating the safety and effectiveness of the device were not available (47 FR 3305). The comments did not provide scientific evidence demonstrating that blockage of the membrane is no longer a risk. Accordingly, FDA is adopting the proposed regulation with minor clarifying changes.

10. Section 874.4140; Ear, nose, and throat bur; proposed class II.

Comments stated that both the physical and material properties of the device and its design have been established for many years. The comments also stated that the cutting device is intended to remove bone and tissue and that the skill of the user is most essential in the safe and effective use of the device. The risks to health of hearing damage from noise or vibration from use next to the cochlea or ossicular chain and of excessive amount of tissue removal are controllable by the user. Eccentricity and corrosion of the device can be detected by the user, and fracture of the device is unlikely to occur. Thus, the comments argued the device should be in class I, rather than class II as proposed.

FDA agrees with the comments. FDA now believes that the general controls of class I will provide reasonable assurance of the safety and effectiveness of the device. FDA believes that manufacturers' adherence to requirements of the current good manufacturing practice (CGMP) regulations in Part 820 would assure that eccentricity of the device is controlled and provide reasonable assurance that it would not fracture during use. Accordingly, FDA is adopting the proposed regulation with a change in classification from class II to class I.

11. Section 874.4250; Ear, nose, and throat electric or pneumatic surgical drill; proposed class II.

A comment stated that the risk to health of mechanical trauma caused by whip or wobble in the device is not appropriate for this generic product as this condition can only occur after attachments are affixed to the device. A comment noted that the risk of noise trauma can be controlled by checking the device for excessive output noise prior to use, and the risk of explosion can be controlled with appropriate labeling concerning use of the device in an explosive atmosphere. A comment stated that general controls would be adequate for this device, because the identified risks to health are user-related, rather than the result of manufacturing deficiencies. The comments suggested that this device be classified into class I rather than class II as proposed.

FDA disagrees with the comments. The agency believes that when the ear, nose, and throat electric or pneumatic surgical drill is being used as intended, the drill would have accessories attached and thus could present the risk of whip or wobble under normal conditions of use. For the reasons stated in the proposal, the agency believes that establishment of a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device, including control of noise output and prevention of fire or explosion when used in the presence of flammable gases. Accordingly, FDA is adopting the proposed regulation with minor clarifying changes.

12. Section 874.4340; Ear, nose, and throat fiberoptic light source and carrier; proposed class II.

Three comments suggested that electrical hazards alone should not be used as the basis for classifying a device into class II and recommended that this device be classified into class I.

FDA believes that this device should be classified into class II. When the ear, nose, and throat fiberoptic light source and carrier is connected to an used with the various endoscopes for which it is intended, a direct pathway to the thoracic cavity is established that can transmit to the patient any hazardous chassis leakage currents or fault currents. In addition, in FDA's contract problem definition study that identified hazards and performance problems associated with endoscopes and endoscopic accessories (Ref. 12), the contract report recommended that certain performance parameters and attributes of this device be addressed by a standard, such as thermal safety, eye safety, and provisions for back-up lamps. Thus, the device has characteristics other than electrical safety hazard, that warrant a peformance standard. FDA believes that general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and that it is necessary to establish a performance standard to control the attributes identified above to prevent injury to the patient from a device of improper design or construction. Accordingly, FDA is adopting the proposed regulation without change.

13. FDA proposed to classify the ear, nose, and throat manual surgical instruments listed below into class II. Comments argued that the risks to health identified in these six proposed regulations essentially are the same as the risks identified for the general and plastic surgery manual surgical instruments that FDA proposed to classify into class I. (See § 878.4800 *Manual surgical instrument for general use;* Docket No. 78N–2696; 47 FR 2810; January 19, 1982.) The comments said that a review of complaints received in FDA's device experience network during the last 3 years showed only nine complaints for the manual devices. In each of the nine reports, the device had broken during use. The comments said that these experience data show that the devices do not present risks to health that require performance standards. Comments said that some of the devices also may be included in the identification of the manual surgical instrument for general use (§ 878.4800) that FDA proposed to classify with general and plastic surgery devices. The comments therefore suggested that FDA classify the devices listed below into class I. Further, the comments suggested that the ear, nose, and throat devices listed below, which were subjects of the six separate proposed regulations, be treated as one generic type of device.

Section	Device	Class proposed by FDA
874.4400	Bronchial, tracheal, or esophageal surgical instrument.	II
874.4410	Surgical instrument for the ear.	II
874.4420	Ear, nose, and throat multiple-use surgical instrument.	II
874.4430	Laryngeal surgical instrument.	II
874.4440	Pharyngeal surgical instrument.	II
874.4450	Nasal and paranasal sinus surgical instrument.	II

FDA agrees that the risks to health identified in the proposed regulations above essentially are the same as the risks identified for general and plastic surgery manual surgical instruments that FDA proposed to classify into class I. FDA agrees that the general controls of class I, particularly the controls of the CGMP regulations in 21 CFR Part 820, would control the risks to health of unnecessary tissue trauma or device fracture and would provide reasonable assurance of the safety and effectiveness of the devices above. The agency now believes that it is unnecessary to establish performance standards for these devices. Accordingly, FDA is classifying the devices above into class I instead of class II as proposed.

FDA disagrees that some of the devices identified above are included in the devices subject to the proposed regulation for general and plastic

surgery manual surgical instruments. Nevertheless, for the reasons given above, FDA now is classifying the devices into class I.

FDA agrees that the devices above should be grouped into one generic type of device. Accordingly, FDA is treating the devices which are subjects of the six proposed regulations listed above as one generic type of device—the ear, nose, and throat manual surgical instrument (§ 874.4420)—and is classifying this device into class I. FDA also is making appropriate changes in the identification of the device.

14. Section 874.4500; Ear, nose, and throat microsurgical carbon dioxide laser; proposed class II.

A comment questioned the need for a performance standard where the possibility of an electrical hazard is involved and suggested that this device be classified into class I rather than class II as proposed. The comment provided no additional data.

FDA disagrees with the comment. The device presents risks other than electrical hazard. The agency believes that the laser beam alignment and exposure characteristics of this device must be controlled by a standard to prevent injury to the patient resulting from devices of improper design or construction. Accordingly, in the final rule FDA is adopting the proposed regulation with clarifying changes in the name and identification of the device.

15. Comments stated that the risks to health FDA identified in the proposed regulations on the devices listed below are unlikely to occur and that these risks can be controlled adequately by the general controls of class I. The comments stated that (1) the risk of tissue trauma due to corrosion or fracture of the devices can be controlled by adequate labeling; (2) electrical hazards can be controlled through appropriate safeguards that have already been established; (3) the risk of trauma as a result of a sharp edge on a device can be controlled with adequate labeling; (4) the risk of asphyxiation due to use of a device of an improper size or shape is the responsibility of the user (given appropriate labeling and sufficient information); (5) the risk of reflex stimulation from the use of a device of an improper size or shape is also within the control of the user; and (6) the risk of infection from a device that is difficult to disassemble, clean, and reassemble or from a device that is not cleaned properly is a function of user knowledge and manufacturers' labeling. The comments also argued that the risk of failure of the ventilation system which may cause the patient to receive an inadequate supply of breathing gas was not considered by FDA to be sufficiently serious to warrant an FDA contract problem definition study to recommend a standard as a solution for this problem. The comments recommended that these devices be classified into class I, rather than class II as proposed.

Section	Device	Class proposed by FDA
874.4680	Bronchoscope (flexible or rigid)	II
874.4685	Ear, nose, and throat endoscopic accessory.	II
874.4710	Esophagoscope (flexible or rigid)	II
874.4720	Mediastinoscope	II
874.4760	Nasopharyngoscope (flexible or rigid).	II

FDA disagrees with the comments. The agency notes that its contract problem definition study, which identified hazards and performance problems associated with endoscopes and endoscopic accessories (Ref. 12), recommended that certain performance characteristics of these devices be addressed by standards (image quality, tip control, protective sheath specifications, control mechanisms, withdrawal mechanisms, brittleness and durability, disassembly procedures, and lamp illumination levels). The agency believes that performance standards are necessary to control these characteristics to prevent injury to the patient resulting from a device of improper design or construction.

FDA proposed that the ear, nose, and throat endoscopic accessory be classified as a separate device. FDA is grouping the accessories that were the subjects of proposed § 874.4685 with each of the respective endoscope devices identified above, as appropriate. Accordingly, FDA is adopting the proposed regulations for the devices listed above with changes in the names of the devices and their identifications to include any accessories.

16. Section 874.4900; Tracheostomy tube; proposed class II.

Comments argued that tissue trauma due to corrosion of a metal tracheostomy tube or fracture of the device is a user's responsibility and that corrosion or fracture may result as a consequence of improper cleaning, improper care, or improper maintenance of the device. The comments recommended this device be classified into class I, rather than class II as proposed.

FDA disagrees with the comments. The agency has reviewed its device experience network reports over the past several years and finds that a significant number of problems have been reported involving tracheostomy tubes (Ref. 13). The agency believes that the general controls of class I are insufficient to control certain risks to health, such as the problems reported in FDA's proposed rule and that these risks can be controlled only by requiring manufacturers to comply with a performance standard for the device. Specific characteristics of the device for which FDA believes that a standard is necessary include integrity of the inflation system and material specifications. Accordingly, FDA is classifying the device into class II as proposed with minor clarifying changes.

L. Exemptions for Class I Devices

Exemptions From Current Good Manufacturing Practice (CGMP) Requirements

Section 513(d)(1)(2)(A) of the act allows FDA to exempt class I devices from certain requirements under the act if the agency determines that compliance with these requirements is not required to assure that the device will be safe and effective and otherwise in compliance with the act. Of the 15 devices FDA is classifying into class I in this rule, FDA is exempting manufacturers of one anesthesiology device and four ear, nose, and throat devices from the CGMP requirements with the exception of the requirements specified in 21 CFR 820.180 and 820.198 relating to records and complaint files. The exemptions apply to the tracheal tube cleaning brush (§ 868.5795), the gustometer (§ 874.1500), the battery-powered artificial larynx (§ 874.3375), the prosthesis modification instrument for ossicular replacement surgery (§ 874.3540), and the ear, nose, and throat drug administration device (§ 874.5220). However, for the reasons given in the preamble to the proposed regulations, these exemptions do not apply to devices that are labeled or otherwise represented as sterile.

As stated in the proposed rule, the agency has determined that exemption of manufacturers of any device from §§ 820.180 and 820.198 of the CGMP regulations would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The complaint file requirements of § 820.198 ensure that device manufacturers have adequate systems for complaint investigation and followup. The general requirements concerning records in § 820.180 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 an exemption from other sections of the CGMP regulations, if one has been granted, is still appropriate.

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 CGMP regulations. These petitions may be submitted in accordance with the provisions of section 520(f)(2) of the act (21 U.S.C. 360j(f)(2)). The agency announced the availability of these guidelines in a notice published in the **Federal Register** of January 18, 1980 (45 FR 3671).

Exemptions From the Requirement of Premarket Notification

FDA proposed to grant an exemption from the requirement of premarket notification for one device, the tracheal tube cleaning brush (proposed § 874.4910). FDA did not receive any comments regarding this proposed exemption. Nor did FDA receive comments urging exemptions for any of the ear, nose, and throat devices subject to other proposed regulations. In this final rule, FDA is granting an exemption from the requirement of premarket notification for the tracheal tube cleaning brush, as proposed. Elsewhere in this issue of the **Federal Register**, FDA is proposing to grant an exemption from the requirement of premarket notification, with limitations, for each four class I ear, nose, and throat devices. The preamble to that proposed rule explained FDA's criteria for granting these exemptions.

M. References

The following information has been placed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Spector, Myron, "Tissue Response to Plastipore and Proplast Otologic Implants in the Middle Ear of Cats," Division of Otolaryngology, Medical University of South Carolina.

2. Dehl, R.E.; Cassell, J. M., "Characterization of Porosity in Porous Polymeric Implant Materials," National Bureau of Standards; Summary minutes; Ear, Nose, and Throat Device Advisory Section meeting, November 2-3, 1981, Appendix J.

3. "Evaluation of Methods of Characterizing the Porosity of Porous Polymeric Implant Materials: A Review of the Current Status of Porosity Measurements," (NBSIR 81-2212), February 1981.

4. "Characterization of Porosity in Porous Polymeric Implant Materials" (NBSIR 81-2459), February 1982.

5. (Reserved)

6. Kerr, A.G., "Proplast and Plastipore," *Clinical Otolaryngology*, 6:187, 1981.

7. (Reserved)

8. Shea, J.J., et al., "Biocompatible Ossicular Implants," *Archives of Otolaryngology*, 104: 191-196, 1978.

9. Shea, J.J., "Porous Polyethylene Information," Shea Clinic; Summary minutes; Ear, Nose, and Throat Device Classification Panel meeting, June 22-23, 1978, Appendix D.

10. Cody, D.T.R., "The Shunt Operation and the Tack Operation, Long-Term Results," *Canadian Journal of Otolaryngology*, 3:3, 271-275, 1974.

11. Holt, J.J., and M.D. Herner, "Effects of Large-Bore Middle Ear Ventilation Tubes," *Journal of Otolaryngology and Head and Neck Surgery*, 88: 581-585, 1980.

12. Skreenock, J.J., D.S. Mead, and J.H. Stalker, "A Study of the Common Characteristic's, Hazards, and Performance Problems of Endoscopes and Endoscopic Accessories," Department of Health and Human Services, FDA Contract Number 223-77-5037, Task Order No. 3, Final Report, ECRI, Plymouth meeting, PA, April 1, 1981.

13. Reports of problems concerning tracheostomy tubes and cuffs, FDA's Device Experience Network, January 1984.

N. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) (April 26, 1985; 50 FR 16636) 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.

O. Economic Impact

The Food and Drug Administration has carefully analyzed the economic effects of this final rule and has determined that, if promulgated, the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this final rule has been carefully analyzed, and it has been determined that the final rule does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules classifying devices into class I generally maintain the status quo: These devices are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule, remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II also remain subject only to the general controls provisions of the act unless and until an applicable performance standard is established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket approval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules.

List of Subjects

21 CFR Part 868

Anesthesiology devices, Medical devices.

21 CFR Part 874

Ear, nose, and throat devices, medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Chapter I of Title 21 of the Code of Federal Regulations is amended in Parts 868 and 874 as follows:

PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR Part 868 is revised to read as follows:

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)); 21 CFR 5.10.

2. Part 868 is amended in Subpart F by adding new §§ 868.5795 and 868.5800 to read as follows:

Subpart F—Therapeutic Devices

§ 868.5795 Tracheal tube cleaning brush.

(a) *Identification.* A tracheal tube cleaning brush is a device consisting of a brush with plastic bristles intended to clean tracheal cannula devices after their removal from patients.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements

concerning records, and § 820.198, with respect to complaint files.

§ 868.5800 Tracheostomy tube and tube cuff.

(a) *Identification.* A tracheostomy tube and tube cuff is a device intended to be placed into a surgical opening of the trachea to facilitate ventilation to the lungs. The cuff may be a separate or integral part of the tracheostomy tube and is, when inflated, intended to establish a seal between the tracheal wall and the tracheostomy tube. The cuff is used to prevent the patient's aspiration of substances, such as blood or vomit, or to provide a means for positive-pressure ventilation of the patient. This device is made of either stainless steel or plastic.

(b) *Classification.* Class II.

3. New Part 874 is added to read as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

Subpart A—General Provisions

Subpart B—Diagnostic Devices

Subpart C—[Reserved]

Subpart D—Prosthetic Devices

Subpart E—Surgical Devices

Subpart F—Therapeutic Devices

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

Subpart A—General Provisions

§ 874.1 Scope.

(a) This part sets forth the classification of ear, nose, and throat devices intended for human use that are in commercial distribution.

(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, an ear, nose, and throat 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.

§ 874.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of

the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

Subpart B—Diagnostic Devices

§ 874.1050 Audiometer.

(a) *Identification.* An audiometer or automated audiometer is an electroacoustic device that produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders.

(b) *Classification.* Class II.

§ 874.1060 Acoustic chamber for audiometric testing.

(a) *Identification.* An acoustic chamber for audiometric testing is a room that is intended for use in conducting diagnostic hearing evaluations and that eliminates sound reflections and provides isolation from outside sounds.

(b) *Classification.* Class I.

§ 874.1080 Audiometer calibration set.

(a) *Identification.* An audiometer calibration set is an electronic reference device that is intended to calibrate an audiometer. It measures the sound frequency and intensity characteristics that emanate from an audiometer earphone. The device consists of an acoustic cavity of known volume, a sound level meter, a microphone with calibration traceable to the National Bureau of Standards, oscillators, frequency counters, microphone amplifiers, and a recorder. The device can measure selected audiometer test frequencies at a given intensity level, and selectable audiometer attenuation settings at a given test frequency.

(b) *Classification.* Class II.

§ 874.1090 Auditory impedance tester.

(a) *Identification.* An auditory impedance tester is a device that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. The device is used to determine abnormalities in the mobility of the tympanic membrane due to stiffness, flaccidity, or the presence of fluid in the middle ear cavity. The device is also used to measure the acoustic reflex threshold from contractions of the stapedial muscle, to monitor healing of tympanic membrane grafts or stapedectomies, or to monitor followup treatment for inflammation of the middle ear.

(b) *Classification.* Class II.

§ 874.110 Earphone cushion for audiometric testing.

(a) *Identification.* An earphone cushion for audiometric testing is a device that is used to cover an audiometer earphone during audiometric testing to provide an acoustic coupling (sound connection path) between the audiometer earphone and the patient's ear.

(b) *Classification.* Class I.

§ 874.1120 Electronic noise generator for audiometric testing.

(a) *Identification.* An electronic noise generator for audiometric testing is a device that consists of a swept frequency generator, an amplifier, and an earphone. It is intended to introduce a masking noise into the non-test ear during an audiometric evaluation. The device minimizes the non-test ear's sensing of test tones and signals being generated for the ear being tested.

(b) *Classification.* Class II.

§ 874.1325 Electroglottograph.

(a) *Identification.* An electroglottograph is an AC-powered device that employs a pair of electrodes that are placed in contact with the skin on both sides of the larynx and held in place by a collar. It is intended to measure the electrical impedance of the larynx to aid in assessing the degree of closure of the vocal cords, confirm larygeal diagnosis, aid behavioral treatment of voice disorders, and aid research concerning the laryngeal mechanism.

(b) *Classification.* Class II.

§ 874.1500 Gustometer.

(a) *Identification.* A gustometer is a battery-powered device that consists of two electrodes that are intended to be placed on both sides of the tongue at different taste centers and that provides a galvanic stimulus resulting in taste sensation. It is used for assessing the sense of taste.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180 with respect to general requirements concerning records, and § 820.198 with respect to complaint files.

§ 874.1820 Surgical nerve stimulator/locator.

(a) *Identification.* A surgical nerve stimulator/locator is a device that is intended to provide electrical stimulation to the body to locate and identify nerves and to test their excitability.

(b) *Classification.* Class II.

§ 874.1925 Toynbee diagnostic tube.

(a) *Identification.* The toynbee diagnostic tube is a listening device intended to determine the degree of openness of the eustachian tube.

(b) *Classification.* Class I.

Subpart C—[Reserved]

Subpart D—Prosthetic Devices

§ 874.3300 Hearing aid.

(a) *Identification.* A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (§ 874.3320), master hearing aid (§ 874.3330), and tinnitus masker (§ 874.3400).

(b) *Classification.* (1) Class I for the air-conduction hearing aid. (2) Class II for the bone-conduction hearing aid.

§ 874.3310 Hearing aid calibrator and analysis system.

(a) *Identification.* A hearing aid calibrator and analysis system is an electronic reference device intended to calibrate and assess the electroacoustic frequency and sound intensity characteristics emanating from a hearing aid, master hearing aid, group hearing aid or group auditory trainer. The device consists of an acoustic complex of known cavity volume, a sound level meter, a microphone, oscillators, frequency counters, microphone amplifiers, a distoration analyzer, a chart recorder, and a hearing aid test box.

(b) *Classification.* Class II.

§ 874.3320 Group hearing aid or group auditory trainer.

(a) *Identification.* A group hearing aid or group auditory trainer is a hearing aid that is intended for use in communicating simultaneously with one or more listeners having hearing impairment. The device is used with an associated transmitter microphone. It may be either monaural or binaural, and it provides coupling to the ear through either earphones or earmolds. The generic type of device includes three types of applications: hardwire systems, inductance loop systems, and wireless systems.

(b) *Classification.* Class II.

§ 874.3330 Master hearing aid.

(a) *Identification.* A master hearing aid is an electronic device intended to simulate a hearing aid during audiometric testing. It has adjustable acoustic output levels, such as those for

gain, output, and frequency response. The device is used to select and adjust a person's wearable hearing aid.

(b) *Classification.* Class II.

§ 874.3375 Battery-powered artificial larynx.

(a) *Identification.* A battery-powered artificial larynx is an externally applied device intended for use in the absence of the larynx to produce sound. When held against the skin in the area of the voicebox, the device generates mechanical vibrations which resonate in the oral and nasal cavities and can be modulated by the tongue and lips in a normal manner, thereby allowing the production of speech.

(b) *Classification.* Class I. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180 with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 874.3400 Tinnitus masker.

(a) *Identification.* A tinnitus masker is an electronic device intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noises. Because the device is able to mask internal noises, it is also used as an aid in hearing external noises and speech.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 874.3.

§ 874.3430 Middle ear mold.

(a) *Identification.* A middle ear mold is a preformed device that is intended to be implanted to reconstruct the middle ear cavity during repair of the tympanic membrane. The device permits an ample air-filled cavity to be maintained in the middle ear and promotes regeneration of the mucous membrane lining of the middle ear cavity. A middle ear mold is made of materials such as polyamide, polytetrafluoroethylene, silicone elastomer, or polyethylene, but does not contain porous polyethylene.

(b) *Classification.* Class II.

§ 874.3450 Partial ossicular replacement prosthesis.

(a) *Identification.* A partial ossicular replacement prosthesis is a device intended to be implanted for the functional reconstruction of segments of the ossicular chain and facilitates the conduction of sound wave from the tympanic membrane to the inner ear. The device is made of materials such as stainless steel, tantalum, polytetrafluoroethylene, polyethylene, polytetrafluoroethylene with carbon fibers composite, absorbable gelatin material, porous polyethylene, or from a combination of these materials.

(b) *Classification.* Class II.

§ 874.3495 Total ossicular replacement prosthesis.

(a) *Identification.* A total ossicular replacement prosthesis is a device intended to be implanted for the total functional reconstruction of the ossicular chain and facilitates the conduction of sound waves from the tympanic membrance to the inner ear. The device is made of materials such as polytetrafluoroethylene, polytetrafluoroethylene with vitreous carbon fibers composite, porous polyethylene, or from a combination of these materials.

(b) *Classification.* Class II.

§ 874.3540 Prosthesis modification instrument for ossicular replacement surgery.

(a) *Identification.* A prosthesis modification instrument for ossicular replacement surgery is a device intended for use by a surgeon to construct ossicular replacements. This generic type of device includes the ear, nose, and throat cutting block; wire crimper, wire bending die; wire closure forceps; piston cutting jib; gelfoam ™ punch; wire cutting scissors; and ossicular finger vise.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180 with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 874.3620 Ear, nose, and throat synthetic polymer material.

(a) *Identification.* Ear, nose, and throat synthetic polymer material is a device material that is intended to be implanted for use as a space-occupying substance in the reconstructive surgery of the head and neck. The device is used, for example, in augmentation rhinoplasty and in tissue defect closures in the esophagus. The device is shaped and formed by the suregon to conform to the patient's needs. This generic type of device is made of material such as polyamide mesh or foil and porous polyethylene.

(b) *Classification.* Class II.

§ 874.3695 Mandibular implant facial prosthesis.

(a) *Identification.* A mandibular implant facial prosthesis is a device that is intended to be implanted for use in the functional reconstruction of mandibular deficits. The device is made of materials such as stainless steel, tantalum, titanium, cobalt-chromium based alloy, polytetrafluoroethylene, silicone elastomer, polyethylene, polyurethane, or polytetrafluoroethylene with carbon fibers composite.

(b) *Classification.* Class II.

§ 874.3730 Laryngeal prosthesis (Taub design).

(a) *Identification.* A laryngeal prosthesis (Taub design) is a device intended to direct pulmonary air flow to the pharynx in the absence of the larynx, thereby permitting esophageal speech. The device is interposed between openings in the trachea and the esophagus and may be removed and replaced each day by the patient. During phonation, air from the lungs is directed to flow through the device and over the esophageal mucosa to provide a sound source that is articulated as speech.

(b) *Classification.* Class II.

§ 874.3760 Sacculotomy tack (Cody tack)

(a) *Identification.* A sacculotomy tack (Cody tack) is a device that consists of a pointed stainless steel tack intended to be implanted to relieve the symptoms of vertigo. The device repetitively ruptures the utricular membrane as the membrane expands under increased endolymphatic pressure.

(b) *Classification.* Class II.

§ 874.3820 Endolymphatic shunt.

(a) *Identification.* An endolymphatic shunt is a device that consists of a tube or sheet intended to be implanted to relieve the symptons of vertigo. The device permits the unrestricted flow of excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. This device is made of polytetrafluoroethylene or silicone elastomer.

(b) *Classification.* Class II.

§ 874.3850 Endolymphatic shunt tube with valve.

(a) *Identification.* An endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve the symptoms of vertigo. The device directs excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. The function of the pressure-limiting inner ear valve is to impede the flow of endolymph so that a physiologically normal endolymphatic pressure is maintained. The device is made of silicone elastomer and polyamide and contains gold radiopaque

markers within the silicone elastomer sheath.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 874.3.

§ 874.3880 Tympanostomy tube.

(a) *Identification.* A tympanostomy tube is a device that is intended to be implanted for ventilation or drainage of the middle ear. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. A type of tympanostomy tube known as the malleous clip tube attaches to the malleous to provide middle ear ventilation. The device is made of materials such as polytetrafluoroethylene, polyethylene, silicon elastomer, or porous polyethylene.

(b) *Classification.* Class II.

§ 874.3930 Tympanostomy tube with semipermeable membrane.

(a) *Identification.* A tympanostomy tube with a semipermeable membrane is a device intended to be implanted for ventilation or drainage of the middle ear and for preventing fluids from entering the middle ear cavity. The device is inserted through the tympanic membrane to permit a free exchange of air between the outer ear and middle ear. The tube portion of the device is made of silicone elastomer or porous polyethylene, and the membrane portion is made of polytetrafluoroethylene.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 874.3.

Subpart E—Surgical Devices

§ 874.4100 Epistaxis balloon.

(a) *Identification.* An epistaxis balloon is a device consisting of an inflatable balloon intended to control internal nasal bleeding by exerting pressure against the sphenopalatine artery.

(b) *Classification.* Class I.

§ 874.4140 Ear, nose, and throat bur.

(a) *Identification.* An ear, nose, and throat bur is a device consisting of an interchangeable drill bit that is intended for use in an ear, nose, and throat electric or pneumatic surgical drill (§ 874.4250) for incising or removing bone in the ear, nose, or throat area. The bur consists of a carbide cutting tip on a metal shank or a coating of diamond on a metal shank. The device is used in mastoid surgery, frontal sinus surgery, and surgery of the facial nerves.

(b) *Classification.* Class I.

§ 874.4175 Nasopharyngeal catheter.

(a) *Identification.* A nasopharyngeal catheter is a device consisting of a bougie or filiform catheter that is intended for use in probing or dilating the eustachian tube. This generic type of device includes eustachian catheters.

(b) *Classification.* Class I.

§ 874.4250 Ear, nose, and throat electric or pneumatic surgical drill.

(a) *Identification.* An ear, nose, and throat electric or pneumatic surgical drill is a rotating drilling device, including the handpiece, that is intended to drive various accessories, such as an ear, nose, and throat bur (§ 874.4140), for the controlled incision or removal of bone in the ear, nose, and throat area.

(b) *Classification.* Class II.

§ 874.4350 Ear, nose, and throat fiberoptic light source and carrier.

(a) *Identification.* An ear, nose, and throat fiberoptic light source and carrier is an AC-powered device that generates and transmits light through glass of plastic fibers and that is intended to provide illumination at the tip of an ear, nose, or throat endoscope. Endoscopic devices which utilize fiberoptic light sources and carriers include the bronchoscope, esophagoscope, laryngoscope, mediastinoscope, laryngeal-bronchial telescope, and nasopharyngoscope.

(b) *Classification.* Class II.

§ 874.4420 Ear, nose, and throat manual surgical instrument.

(a) *Identification.* An ear, nose, and throat manual surgical instrument is one of a variety of devices intended for use in surgical procedures to examine or treat the bronchus, esophagus, trachea, larynx, pharynx, nasal and paranasal sinus, or ear. This generic type of device includes the esophageal dilator; tracheal bistour (a long, narrow surgical knife); tracheal dilator; tracheal hook; laryngeal injection set; laryngeal knife; laryngeal saw; laryngeal trocar; laryngectomy tube; adenoid curette; adenotome; metal tongue depressor; mouth gag; oral screw; salpingeal curette; tonsillectome; tonsil guillotine; tonsil screw; tonsil snare; tonsil suction tub; tonsil suturing hook; antom reforator; ethmoid curette; frontal sinus-rasp; nasal curette; nasal rasp; nasal rongeur; nasal saw; nasal scissors; nasal snare; sinus irrigator; sinus trephine; ear curette; ear excavator; ear rasp; ear scissor, ear snare; ear spoon; ear suction tub; malleous ripper; mastoid gauge; microsurgical ear chisel; myringotomy tube inserter; ossici holding clamp; sacculotomy tack inserter; vein press; wire ear loop; microrule; mirror; mobilizer; ear, nose, and throat punch; ear, nose and throat knife; and ear, nose, and throat trocar.

(b) *Classification.* Class I.

§ 874.4490 Microsurgical argon laser.

(a) *Microsurgical argon laser for use in otology*—(1) *Identification.* A microsurgical argon laser for use in otology is a device intended to cut, destroy, or alter tissue or bone of the ear using laser light energy.

(2) *Classification.* Class II.

(b) *Microsurgical argon laser for all other uses*—(1) *Identification.* A microsurgical argon laser for all other uses, including use in laryngology and general use in otolaryngology, is a device that is intended to cut, destroy, or alter tissue.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before the device identified in paragraph (b) may be commercially distributed. See § 874.3.

§ 874.4500 Ear, nose, and throat microsurgical carbon dioxide laser.

(a) *Identification.* An ear, nose, and throat microsurgical carbon dioxide laser is a device intended for the surgical excision of tissue from the ear, nose, and throat area. The device is used, for example, in microsurgical procedures to excise lesions and tumors of the vocal cords and adjacent areas.

(b) *Classification.* Class II.

§ 874.4680 Bronchoscope (flexible or rigid) and accessories.

(a) *Identification.* A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the bronchoscope and is intended to examine or treat the larynx and tracheobronchial tree. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the rigid ventilating bronchoscope, rigid nonventilating bronchoscope, nonrigid bronchoscope, laryngeal-bronchial telescope, flexible foreign body claw, bronchoscope tubing, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, flexible biopsy curette, and rigid bronchoscope aspirating tube, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

§ 874.4710 Esophagoscope (flexible or rigid) and accessories.

(a) *Identification.* An esophagoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the esophagoscope and is intended to examine or treat esophageal malfunction symptoms, esophageal or mediastinal disease, or to remove foreign bodies from the esophagus. When inserted, the device extends from the area of the hypopharynx to the stomach. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

§ 874.4720 Mediastinoscope and accessories.

(a) *Identification.* A mediastinoscope and accessories is a tubular tapered electrical endoscopic device with any of a group of accessory devices which attach to the mediastinoscope and is intended to examine or treat tissue in the area separating the lungs. The device is inserted transthoracicly and is used in diagnosis of tumors and lesions and to determine whether excision of certain organs or tissues is indicated. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel. This generic type of device includes the flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

§ 874.4760 Nasopharyngoscope (flexible or rigid) and accessories.

(a) *Identification.* A nasopharyngoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the nasopharyngoscope and is intended to examine or treat the nasal cavity and nasal pharynx. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel and flexible plastic. This generic type of device includes the antroscope, nasopharyngolaryngoscope, nasosinuscope, nasoscope, postrhinoscope, rhinoscope, salpingoscope, flexible foreign body claw, flexible biopsy forceps, rigid biopsy curette, flexible biospy brush, rigid biopsy forceps and flexible biopsy curette, but excludes the fiberoptic light source and carrier.

(b) *Classification.* Class II.

Subpart F—Therapeutic Devices

§ 874.5220 Ear, nose, and throat drug administration device.

(a) *Identification.* An ear, nose, and throat drug administration device is one of a group of ear, nose, and throat devices intended specifically to administer medicinal substances to treat ear, nose, and throat disorders. These instruments include the powder blower, dropper, ear wick, manual nebulizer pump, and nasal inhaler.

(b) *Classification.* Class I. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 874.5350 Suction antichoke device.

(a) *Identification.* A suction antichoke device is a device intended to be used in an emergency situation to remove, by the application of suction, foreign objects that obstruct a patient's airway to prevent asphyxiation to the patient.

(b) *Classification.* Class III.

(c) *Date PMA or notice or completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 874.3.

§ 874.5370 Tongs antichoke device.

(a) *Identification.* A tongs antichoke device is a device that is intended to be used in an emergency situation to grasp and remove foreign objects that obstruct a patient's airway to prevent asphyxiation of the patient. This generic type of device includes a plastic instrument with serrated ends that is inserted into the airway in a blind manner to grasp and extract foreign objects, and a stainless steel forceps with spoon ends that is inserted under tactile guidance to grasp and extract foreign objects from the airway.

(b) *Classification.* Class III.

(c) *Date PMA or notice of completion of a PDP is required.* A No effective date has been established of the requirement for premarket approval. See § 874.3.

§ 874.5800 External nasal splint.

(a) *Identification.* An external nasal splint is a rigid or partially rigid device intended for use externally for immobilization of parts of the nose.

(b) *Classification.* Class I.

§ 874.5840 Antistammering device.

(a) *Identification.* An antistammering device is a device that electronically generates a noise when activated or when it senses the user's speech and that is intended to prevent the user from hearing the sounds of his or her own voice. The device is used to minimize a user's involuntary hesitative or repetitive speech.

(b) *Classification.* Class I.

Dated: October 22, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. 86N-0010]

Ear, Nose, and Throat Devices; Proposed Exemptions From Premarket Notification

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to exempt from the requirement of premarket notification, with limitations, for ear, nose, and throat devices. Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule classifying these and other devices. These actions are being taken under the Medical Device Amendments of 1976 and are a step in implementing one of the goals in FDA's plan for action.

DATES: Comments by January 5, 1987. FDA is proposing that the final rule based on this proposed rule become effective 30 days after its date of publication in the **Federal Register.**

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David A. Segerson, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-8185.

SUPPLEMENTARY INFORMATION: 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: class I, general controls; class II, performance standards; and class III, premarket approval.

Section 513(d)(2)(A) of the act (21 U.S.C. 360c(d)(2)(A)) authorizes FDA to exempt, by regulation, a generic type of class I device from the requirement of, among other things, premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR Part 807, Subpart E. Such an exemption allows manufacturers to introduce into commercial distribution devices of the generic type exempted without first submitting to FDA a premarket notification. When FDA was publishing its proposed classification regulations for preamendment devices, the agency did not routinely evaluate whether it should grant to manufacturers of such devices placed in class I an exemption from the requirement of premarket notification in section 510(k) of the act and 21 CFR Part 807, Subpart E. Generally, FDA considered such exemptions only when the advisory panels recommended the exemptions.

Recently, FDA developed criteria for exempting certain class I devices from the requirement of premarket notification, to reduce the number of premarket notifications on relatively innocuous devices while freeing agency resources for the review of more complex notifications.

The development of these criteria and the issuance of proposed and final rules exempting appropriate devices from the requirement of premarket notification in section 510(k) of the act will help implement a goal in FDA's July 1985 "A Plan for Action" (Ref. 1).

Criteria for 510(K) Exemptions

FDA is proposing to exempt a generic type of class I device from the requirement of premarket notification with the limitations described below, if FDA determines that premarket notification is not necessary for the protection of the public health. FDA may propose to grant an exemption if both of the following criteria are met:

1. FDA has determined that the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device such as device design or materials. When making these determinations, FDA may consider the frequency, persistence, cause, or seriousness of such claims or risks, or other factors.

2. FDA has determined that: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that are of the type that could affect safety and effectiveness will (1) be readily detectable by users by visual examination or other means, such as routine testing, e.g., testing of a clinical laboratory reagent with positive and negative controls, before causing harm; or (2) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (c) that any changes in the device will not be likely to result in a change in the device's classification.

FDA will make the determination above based on its knowledge of the device, including past experience with premarket notification and publicly available reports or studies on device performance. Based on the above criteria, FDA will place the exempted device into the same class as the class I device to which it would be substantially equivalent.

FDA may, if it has concerns only about certain types of changes in a class I device, grant a limited exemption from premarket notification for the generic type of device. A limited exemption will specify what types of changes manufacturers must continue to report to FDA. For example, FDA may exempt a device except when a manufacturer intends to use a different material.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic of a device that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Application of the Criteria to Class I; Ear, Nose, and Throat Devices

In the proposed rule of January 22, 1982 (47 FR 3280), FDA proposed to classify preamendments ear, nose, and throat devices in accordance with the amendments. When FDA proposed to classify the four devices below, the agency did not propose exemptions from the requirement of premarket notification for these devices and the Panel did not recommend exemptions from the requirement of premarket notification for certain of the devices. FDA agrees that full exemption from premarket notification is unjustified for these devices; however, the agency, for the efficient enforcement of the act and consistent with its policy regarding exemptions from premarket notification, now is proposing to exempt from the requirement of premarket notification, with limitations, the four devices below.

Section	Device
874.1100	Earphone cushion for audiometric testing
874.3540	Prosthesis modification instrument for ossicular replacement surgery
874.4420	Ear, nose, and throat manual surgical instrument
874.5800	External nasal splint

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the devices above in class I. FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices above. However, the proposed exemptions for the earphone cushion for audiometric testing (§ 874.1100); prosthesis modification instrument for ossicular replacement surgery (§ 874.3540); ear, nose, and throat manual surgical instrument (§ 874.4420); and the external nasal splint (§ 874.5800) are limited and would apply only to those devices made of the same materials that were used in the devices before May 28, 1976.

Reference

The following information has been placed in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Food and Drug Administration—A Plan for Action," Public Health Service, Department of Health and Human Services, July 1985, p. 18.

Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) (April 26, 1985; 50 FR 16636) 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.

Economic Impact

FDA has carefully analyzed the economic effects of this proposed rule and has determined that the proposed rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this proposed rule has been carefully analyzed, and it has been determined that the proposed rule does not constitute a major rule as defined in section 1(b) of the Executive Order.

The devices subject to this proposed rule are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j), with certain exemptions. Under any final rule based on this proposal, the devices would remain subject to such controls, other than premarket notification.

Interested persons may, on or before January 5, 1987, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two 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.

List of Subjects in 21 CFR Part 874

Ear, nose, and throat devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Part 874 be amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR Part 874 continues to read as follows:

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)); 21 CFR 5.10.

2. Part 874 is amended by adding new § 874.9 to read as follows:

§ 874.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufactures of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

3. In § 874.1100 by revising paragraph (b) to read as follows:

§ 874.1100 Earphone cushion for audiometric testing.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807.

4. In § 874.3540 by revising paragraph (b) to read as follows:

§ 874.3540 Prosthesis modification instrument for ossicular replacement surgery.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180,

with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

5. In § 874.4420 by revising paragraph (b) to read as follows:

§ 874.4420 Ear, nose, and throat manual surgical instrument.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807.

6. In § 874.5800 by revising paragraph (b) to read as follows:

§ 874.5800 External nasal splint.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807.

Dated: October 22, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86-25093 Filed 11-5-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 874, 878, and 886

[Docket Nos. 78N-1566 et al.]

Medical Devices; Withdrawal of Certain Proposed Rules for Device Classification

AGENCY: Food and Drug Administration.

ACTION: Withdrawal of proposed rules.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the proposed rules classifying 15 ear, nose, and throat devices, a general and plastic surgery device, and an ophthalmic device to eliminate unnecessary regulations. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying ear, nose, and throat devices.

FOR FURTHER INFORMATION CONTACT: David A. Segerson, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-8185.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 22, 1982 (47 FR 3280), January 19, 1982 (47 FR 2810), and January 26, 1982 (47 FR 3694), FDA proposed to classify ear, nose, and throat, general and plastic surgery, and ophthalmic devices, respectively. These actions were taken as part of the agency's overall implementation of the Medical Device Amendments of 1976 (the amendments) that established a system for the regulation of medical devices 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: class I (general controls), class II (performance standards), and class III (premarket approval). The amendments also established a procedure for the agency to promulgate regulations classifying each generic type of device into one of these three classes. Persons who disagree with a final classification of a device may petition for reclassification of the device under Subpart C of 21 CFR Part 860. Because the same generic type of device may be used in different medical specialty area (cardiovascular, general and plastic surgery, anesthesiology, etc.) under different names and because FDA is attempting to reduce unnecessary regulations, the agency continues to consolidate its list of generic types of devices.

FDA proposes that the transdermal stimulator (§ 874.5850) be classified into class III (47 FR 3280). After publishing the proposed regulation as part of the ear, nose, and throat device classification proceeding (Docket No. 78N-1636), the agency determined that the device is an investigational device not in commercial distribution before May 28, 1976, the enactment date of the amendments. Because the device was not in commercial distribution and is not substantially equivalent to a device that was in commercial distribution, the transdermal stimulator is classified into class III under section 513(f) of the act (21 U.S.C. 360c), without the agency's publication of a classification regulation for the device. No comments were received by FDA on this proposed regulation.

To eliminate unnecessary regulations, FDA is withdrawing 14 of the 67 ear, nose, and throat proposed regulations that were published in the **Federal Register** of January 22, 1982. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying ear, nose, and throat devices. In that final rule, FDA is grouping 23 proposed ear, nose, and throat devices into nine generic types of ear, nose, and throat devices. The term "generic type of device" is defined in 21 CFR 860.3(i). Therefore, in that final rule each of the 14 devices listed below in the column on the left is being grouped into the generic type of device opposite in the column on the right. FDA is withdrawing each of the proposed regulations listed in the column on the left. Further, FDA is postponing classification of six generic types of ear, nose, and throat devices pending review of additional data, including two devices being grouped. FDA advises that, for the proposed regulations for the ear, nose, and throat devices being withdrawn, summaries of any comments submitted and FDA's responses are discussed in the preamble to the appropriate final rule.

Proposed rugulations being withdrawn	Final regulations published elsewhere in this issue of the FEDERAL REGISTER
78N-1584—Ear, nose, and throat porous polyethylene synthetic polymer material.	78N-1583—Ear, nose, and throat synthetic polymer material.
78N-1637—Porous polyethylene partial ossicular replacement prosthesis.	78N-1577—Partial ossicular replacement prosthesis.
78N-1639—Porous polyethylene total ossicular replacement prosthesis.	78N-1578—Total ossicular replacement prosthesis.
78N-1641—Porous polyethylene tympanostomy tube.	78N-1595—Tympanostomy tube.
78N-1607—Bronchial, tracheal, or esophageal surgical instrument.	78N-1609—Ear, nose, and throat manual surgical instrument.
78N-1608—Surgical instrument for the ear.	Do.
78N-1610—Laryngeal surgical instrument.	Do.
78N-1611—Pharyngeal surgical instrument.	Do.
78N-1612—Nasal and paranasal sinus surgical instrument.	Do.
78N-1617—Ear, nose, and throat endoscopic accessory.	78N-1616—Bronchoscope (flexible or rigid) and accessories.
78N-1625—Laryngeal-bronchial telescope.	Do.
78N-1628—Tracheostomy tube cuff.	78N-1626—Tracheostomy tube and tube cuff.

Proposed regulations being withdrawn	At this time, FDA is not publishing in the FEDERAL REGISTER final regulations on these devices
78N-1566—Water caloric stimulator.	78N-1565—Air or water caloric stimulator.
78N-1643—Laryngostroboscope (patient-contacting).	78N-1622—Laryngostroboscope.

After publication of the proposal (47 FR 2835; January 19, 1982) to classify the aorto-saphenous vein ostia marker (Docket No. 78N-2688) into class II as part of the general and plastic surgery device classification proceeding, the agency determined that the aorto-saphenous vein ostia marker is included as an accessory in a generic type of device that the agency already has classified into class II as part of the classification proceeding for cardiovascular devices, § 870.3460 *Vascular graft prosthesis of 6 millimeters and greater diameter.* The final regulation to classify the vascular graft prosthesis of 6 millimeters and greater diameter was published in the **Federal Register** of February 5, 1980 (45 FR 7938), following opportunity for

comment. In the **Federal Register** of January 6, 1986 (51 FR 564—Docket No. 83N–0190), the agency issued an invitation for offers to submit or develop a performance standard for the vascular graft prosthesis of 6 millimeters and greater diameter as a step in establishing a performance standard for the device.

A comment received on the January 19, 1982 proposal regarding the aorto-saphenous vein ostia marker stated that the proposed identification excluded certain types of the device that are currently being marketed.

FDA agrees with the comment. However, because FDA now believes that the devices subject to the proposal already have been classified into class II, FDA is withdrawing the proposed regulation.

FDA proposed that the fluorescein strip (§ 886.1310) be classified into class I (47 FR 3694) as part of the ophthalmic device classification proceeding. A comment on that proposed regulation noted that FDA regulates fluorescein solution as a drug, but the agency proposed to classify a strip of filter paper impregnated with fluorescein solution as a device. The comment suggested that FDA regulate the fluorescein solution and the fluorescein strip using the same regulatory controls.

FDA has determined that it will regulate the fluorescein strip as a drug rather than as a device. Accordingly, FDA is withdrawing its proposed regulation classifying the fluorescein strip (Docket No. 78N–3150).

The administrative record for each of the ear, nose, and throat proposals of January 22, 1982, that are being grouped will be included in the administrative record for the docket number that is opposite in the column on the right, and the administrative record for the January 19, 1982, proposal for the aorto-saphenous vein ostia marker will be included in the administrative record (Docket No. 78N–1484) for the proceeding to classify the vascular graft prosthesis of 6 millimeters and greater diameter into class II.

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 the Commissioner of Food and Drugs (21 CFR 5.10), the proposals to classify the 15 ear, nose, and throat devices described above that were published in the **Federal Register** of January 22, 1980, the proposal to classify the aorto-saphenous vein ostia marker that was published in the **Federal Register** of January 19, 1982, and the proposal to classify the fluorescein strip that was published in the **Federal Register** of January 26, 1982, under docket numbers 78N–1566, 78N–1584, 78N–1607, 78N–1608, 78N–1610, 78N–1611, 78N–1612, 78N–1617, 78N–1625, 78N–1628, 78N–1636, 78N–1637, 78N–1639, 78N–1641, 78N–1643, 78N–2688, and 78N–3150 are withdrawn.

Dated: October 22, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 86–25092 Filed 11–5–86; 8:45 am]

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H.R. 3415/Pub. L. 99-582

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H.R. 4037/Pub. L. 99-583

Relating to the Indiana Dunes National Lakeshore, and for other purposes. (Oct. 29, 1986; 4 pages) Price: $1.00

H.R. 4685/Pub. L. 99-584

Texas Wilderness Act Amendments of 1986. (Oct. 29, 1986; 2 pages) Price: $1.00

H.R. 5181/Pub. L. 99-585

To designate the United States Courthouse at 68 Court Street, Buffalo, New York, as the "Michael J. Dillon Memorial United States Courthouse." (Oct. 29, 1986; 1 page) Price: $1.00

H.R. 5218/Pub. L. 99-586

To amend title 5, United States Code, to provide that certain individuals be accorded competitive status for purposes of transferring to the competitive service. (Oct. 29, 1986; 1 page) Price: $1.00

H.R. 5459/Pub. L. 99-587

To direct the release, on behalf of the United States, of certain conditions and reservations contained in a conveyance of land to the State of Utah, and for other purposes. (Oct. 29, 1986; 2 pages) Price: $1.00

H.R. 5470/Pub. L. 99-588

To designate the United States Courthouse for the Eastern District of Virginia in Alexandria, Virginia, as the "Albert V. Bryan United States Courthouse." (Oct. 29, 1986; 1 page) Price: $1.00

H.J. Res. 620/Pub. L. 99-589

Designating the week beginning January 4, 1987, as "National Bowling Week." (Oct. 29, 1986; 1 page) Price: $1.00

H.R. 4350/Pub. L. 99-590

To amend the Wild and Scenic Rivers Act, and for other purposes. (Oct. 30, 1986; 11 pages) Price: $1.00

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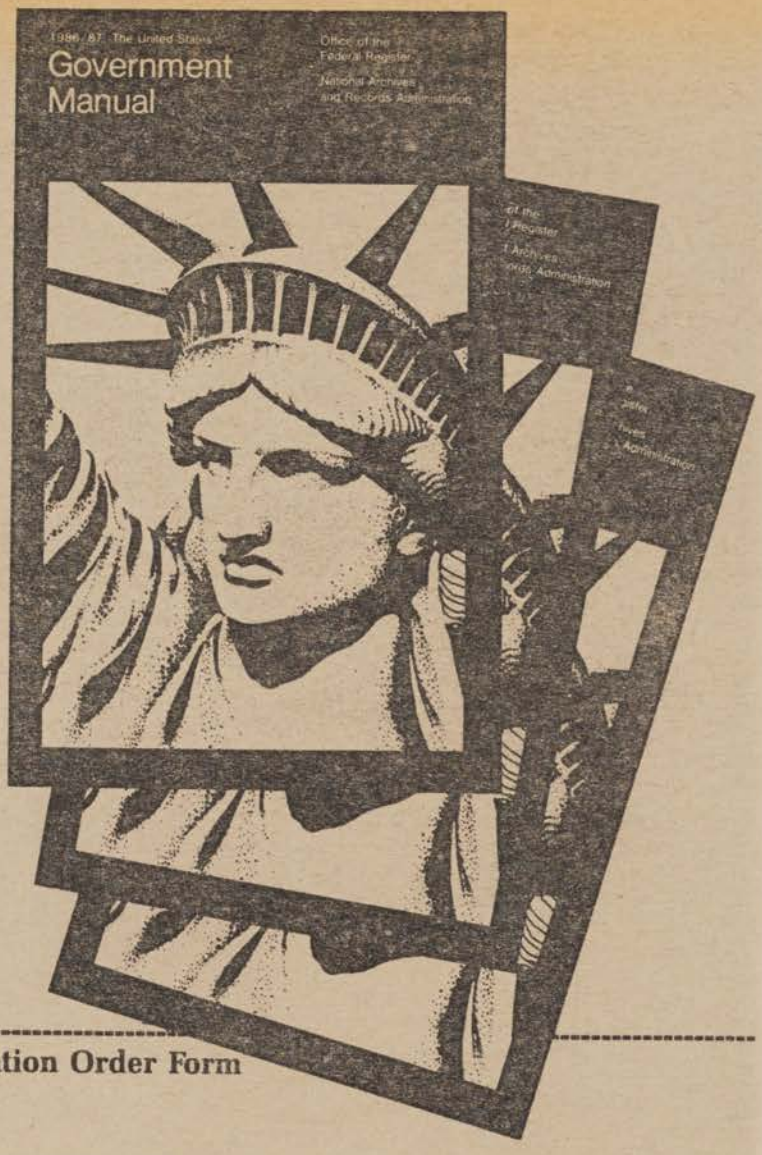

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