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Tuesday
January 19, 1982

Highlights

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Highlights

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CHANGED MEETINGS

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

Rules and Regulations

Federal Register
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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 910

[Lemon Reg. 342]

Lemons Grown in California and Arizona; Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market during the period January 17–23, 1982. Such action is needed to provide for orderly marketing of fresh lemons for this period due to the marketing situation confronting the lemon industry.

EFFECTIVE DATE: January 17, 1982.

FOR FURTHER INFORMATION CONTACT: William J. Doyle, Acting Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202–447–5975.

SUPPLEMENTARY INFORMATION: This rule has been reviewed under Secretary's Memorandum 1512–1 and Executive Order 12291 and has been designated a "non-major" rule. This regulation is issued under the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The action is based upon the recommendations and information submitted by the Lemon Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the act.

This action is consistent with the marketing policy for 1981–82. The marketing policy was recommended by the committee following discussion at a public meeting on July 7, 1981. The committee met again publicly on January 12, 1982, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons is easy.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared purposes of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Section 910.642 is added as follows:

§ 910.642 Lemon Regulation 342.

The quantity of lemons grown in California and Arizona which may be handled during the period January 17, 1982, through January 23, 1982, is established at 210,000 cartons.

(Secs. 1–19, 48 Stat. 31, as amended (7 U.S.C. 601–674))

D. S. Kuryloski,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 82-1306 Filed 1-15-82; 11:56 am]
BILLING CODE 3410-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor of three new animal drug applications (NADA's) from D–M Pharmaceuticals, Rockville, MD to Lemmon Co., Sellersville, PA.

EFFECTIVE DATE: January 19, 1982.

FOR FURTHER INFORMATION CONTACT: John R. Markus, Bureau of Veterinary Medicine (HFV–104), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4313.

SUPPLEMENTARY INFORMATION: Lemmon Co., Sellersville, PA 18960, filed supplemental NADA's 48–391, 49–183, and 95–017 providing for the change of sponsor from D–M Pharmaceuticals, Rockville, MD 20850.

The change of sponsor for these NADA's is the result of a corporate merger which does not involve changes in manufacturing facilities, equipment, procedures, or personnel. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), this is a Category I supplemental approval which does not require reevaluation of the safety and effectiveness data in the original applications.

The animal drug regulations are amended in 21 CFR 510.600(c) to reflect this change.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This action is governed by the provisions of 5 U.S.C. 556 and 557 and is therefore excluded from Executive Order 12291 by section 1(a)(1) of the Order.

PART 510—NEW ANIMAL DRUGS

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 21 CFR 5.1; see 46 FR 26052; May 11, 1981)) and redelegated to the

Bureau of Veterinary Medicine (21 CFR 5.83), § 510.600 is amended in paragraph (c)(1) by removing the entry for "D–M Pharmaceuticals, Inc.," and by alphabetically adding a new sponsor entry for "Lemmon Co.", and in paragraph (c)(2) in the entry for "00693" by removing the sponsor name "D–M Pharmaceuticals, Inc.," and inserting alphabetically the name "Lemmon Co.", to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Lemmon Co., Sellersville, PA 18960	000693
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
000693	Lemmon Co., Sellersville, PA 18960
* * * * *	

Effective date. This amendment is effective January 19, 1982.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: January 12, 1982.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 82-1191 Filed 1-18-82; 8:45 am]

BILLING CODE 4160-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA Docket Nos. AH024/025 VA; A-3-FRL-1955-1]

Approval of Revisions of the Virginia State Implementation Plan

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Commonwealth of Virginia has submitted to the Environmental Protection Agency amendments to its air pollution control regulations and requested that they be reviewed and processed as revisions of the Virginia State Implementation Plan (SIP). The amendments consist of changes to Parts I (Definitions), II (General Provisions), III (Air Quality Standards), IV (Existing and Certain Other Sources), VII (Air Pollution Episode), and Appendices C and M.

This notice also approves amendments previously submitted by the Commonwealth between August 14, 1975 and September 6, 1979. This notice will act on the most recent revisions submitted by the Commonwealth and withdraws the earlier revisions which are now obsolete in light of the later submittals.

EFFECTIVE DATE: This action is effective February 18, 1982.

ADDRESSES: Copies of the SIP revisions, as well as accompanying support documentation submitted by Virginia, are available for public inspection during normal business hours at the following locations:

U.S. Environmental Protection Agency, Region III, Air Media & Energy Branch, Curtis Building, 6th & Walnut Streets, Philadelphia, PA 19106, ATTN: Patricia Sheridan

Virginia State Air Pollution Control Board, Room 1106, Ninth Street Office Building, Richmond, VA 23219, ATTN: Mr. John M. Daniel, Jr.

Public Information Reference Unit, EPA Library, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460

The Office of the Federal Register, 1100 L Street, NW., Room 8401, Washington, DC 20408

FOR FURTHER INFORMATION CONTACT: Ms. Eileen Glen, at the EPA, Region III address cited above or by phone at (215) 597–8187.

SUPPLEMENTARY INFORMATION: Between August 14, 1975 and September 21, 1979, the Commonwealth of Virginia submitted to the Environmental Protection Agency amendments to its Regulations for Control and Abatement of Air Pollution and requested that they be reviewed and processed as revisions of the Virginia State Implementation Plan (SIP) for the attainment and maintenance of National Ambient Air Quality Standards. The amendments consist of changes to Parts I (Definitions), II (General Provisions), III (Air Quality Standards), IV (Existing and Certain Other Sources), VII (Air Pollution Episode), and Appendices C and M.

The Commonwealth provided proof that after adequate public notice, public hearings were held with regard to these amendments. The submittal dates of these amendments, as well as the date and locations of the public hearings, are summarized below.

Submittal date	Public hearing date	Location
Aug. 14, 1975	May 12, 1975	Abingdon, Radford, Lynchburg, Fredericksburg, Richmond, Virginia Beach, and Fairfax.
Oct. 20, 1976	July 23, 1976	Richmond, Roanoke, Lynchburg , and Fairfax.
	July 26, 1976	Abingdon, Fredericksburg, and Virginia Beach.
	Sept. 20, 1976	Richmond, Abingdon, Roanoke, Lynchburg, Fredericksburg, Virginia Beach, and Fairfax.
Sept. 20, 1978	July 14, 1978	Richmond.
	July 17, 1978	Abingdon, Roanoke, Lynchburg, Fredericksburg, Virginia Beach, and Fairfax.
Sept. 6, 1979	Feb. 12, 1979	Abingdon, Radford, Lynchburg, Richmond, Virginia Beach, and Falls Church.
	May 14, 1979	Same as above.
Sept. 21, 1979	July 16, 1979	Same as above.
	May 14, 1979	Same as above.
	Some of the submittals have previously been proposed as indicated below:	
Aug. 14, 1975	Nov. 11, 1975	40 FR 53595.
	Mar. 28, 1977	42 FR 16446.
Oct. 20, 1976	Mar. 28, 1977	42 FR 16446.
Sept. 20, 1978	May 21, 1980	45 FR 34018.

As a result of EPA's preliminary review, EPA published a proposed rulemaking in the **Federal Register** on September 29, 1980 (45 FR 64214) proposing approval of and requesting comments on the revisions listed below. Furthermore, because the Commonwealth has submitted amendments to the same regulations at different times over the past years, only the most recent version is being considered by EPA.

The date of the appropriate submission is indicated in parenthesis.

Part I—Definitions

A. Additions

1. Allowable Emissions (9–6–79)
2. Fugitive Emissions (9–6–79)
3. Nonattainment Pollutant (9–6–79)
4. State Implementation Plan (9–21–79)

5. Qualifying Pollutant (9–6–79)
B. Modifications
1. Criteria Pollutant (9–6–79)
2. Combustion Installation (9–20–78)
3. Commence (9–6–79)
4. Emission Standard (9–6–79)
5. Fugitive Dust (9–6–79)
6. Major Stationary Source (9–6–79)
7. Malfunction (8–14–75)
8. Modification (Stationary Source) (9–6–79)
9. Public Comment Period (9–6–79)
10. Standard of Performance (9–6–79)
C. Deletions
1. Beehive Coke Oven (9–6–79)
2. Best Available Control Technology (9–6–79)
3. By-Product Coke Plant (9–6–79)
4. Capital Expenditure (9–6–79)
5. Modification (Major Stationary Source) (9–6–79)
6. Vapor Tight (9–21–79)

Regulation No. and Brief Description

Part II—General Provisions

2.03—*Enforcement of Regulations and Orders*
2.03(c) (9–21–79)—Delayed Compliance Orders are added and are now considered among the administrative means available to the Board.
2.03(e) (9–21–79)—Revisions would delete the Board's ability to assess penalties in an enforcement proceeding.
2.09—*Appeals*
2.09(d) (9–21–79)—Time limit given for filing a petition for appeal of a final decision.
2.09(f) (9–21–79)—"Any petition for a formal hearing or for an appeal by itself shall not constitute a stay of decision on action"—added.
2.33—*Permits—Stationary Sources and Indirect Sources*
2.33(a) (9–6–79)—An exemption, from public comment period and public hearing is added, for sources with allowable emissions of less than one ton per year.
2.33(c) (9–6–79)—Minor administrative changes and additional information requirements for major stationary sources.
2.33(d) (9–6–79)—Several administrative changes, addition of various phrases to protect the ambient air quality standards, deletion of requirements for using best available control technology and complying with lowest achievable emission rate.
2.33(e) (9–6–79)—Several administrative changes, time limit set on completeness determination on an application or additional information submitted, and the availability of public comments received and actions taken by the Board on the permit application.
2.33(h) (9–6–79)—Changes in the length of time allowed for construction or modification to begin or be discontinued before the permit becomes invalid.
2.33(j) (9–6–79)—Relates to Indirect Sources which is not part of the SIP.
2.33(k) (9–6–79)—Several wording changes for clarification purposes.
2.33(l) (9–6–79)—Relates to Indirect Sources and is not part of the SIP.
2.33(m) (9–6–79)—Addition of provisions relative to Interstate Pollution Abatement as required by section 126 of CAA.
2.34—*Facility and Control Equipment Maintenance or Malfunction.* (formally § 2.09)
2.34(a) (10–20–76)—Maintenance of monitoring equipment added to regulation.
2.34(b) (10–20–76)—Minor wording change.
2.34(c) (9–21–79)—Minor wording change.
2.34(d) (9–21–79)—Minor wording change.
2.34(e) (9–21–79)—Changes in length of time that this section shall be applicable.
2.34(f) (9–21–79)—Minor wording change.
2.34(g) (9–21–79)—Addition of phrasing such that the owner would not be in violation if an acceptable application for a variance has been submitted by the owner.

Part III—Ambient Air Quality Standards

2.34(h) (10–20–76)—Wording added to prevent circumvention of monitoring equipment.
3.05—Title change to *Ozone*
3.05(a) (9–6–79)—Change in ambient air quality standard to reflect EPA's relaxation to 0.12 ppm.
3.05(b) (9–6–79)—Wording change—Photochemical oxidants to ozone.
3.05(c) (9–6–79)—Addition that shows what constitutes attainment of the standard.

Part IV—Special Provisions

4.02—*Compliance*—old regulations deleted and new regulations submitted October 20, 1976.
4.02(a) (9–20–78)—Addition of soot blowing exemption to the opacity standard.
4.02(e) (9–20–78)—Regulations added that maintenance and operation of an affected facility will be consistent with good air pollution control practices for minimizing emissions and determination of acceptability of those procedures.
4.02(f) (6) thru (10) (9–21–79)—Addition of regulations for alternate compliance schedules.
4.02(g) (9–6–79)—Addition of regulations for *Stack Heights*

Rule EX–2—Emission Standards for Visible Emissions and Fugitive Dust/Emissions

4.21 (9–20–78)—Deletion of regulations and this section is now reserved.
4.23 (9–6–79)—*Standard and Fugitive Dust*—"Emissions" is added to title.

Rule EX–4—Emission standards for Particulate Emissions from Manufacturing Operations

4.40 (9–6–79)—*General*—Minor word revisions and renumbering of the Section.
4.41 (9–6–79)—*Specific Industries (AQCR 1 thru 6)*—Minor word revisions and renumbering of the section.

Rule EX–5—Emission Standards for Gaseous Pollutants

4.54—*Volatile Organic Compound Emissions—General*
4.54(a) (9–21–79)—*General*—Minor administrative changes were made to (a)(2) and (a)(4).
4.54(b) (9–21–79)—*Reserved*—deletion of former § 4.54(b) (Petition for Alternative Control Methods).
4.54(c)—*Solvent Metal Cleaning*
4.54(f)—*Filling of Storage Tanks*
4.54(g) (9–21–79)—*Volatile Organic Compound Storage—Fixed Roof Tanks*—These sections contain minor administrative changes.
4.54(e) (9–21–79)—*Incinerators/Afterburners*—The months that the exemption is valid have been changed to November thru March.
4.55—*Volatile Organic Compound Emissions—Coating Industry*
4.55(a) (9–21–79)—*General*—Minor administrative changes were made to § 4.55(a)(2) and (a)(4).
4.56—*Volatile Organic Compound Emissions—Petroleum Industry*
4.56(a)—*General*
(c)—*Miscellaneous Petroleum Refinery Sources*
(d) (9–21–79)—*Transfer of Gasoline—Gasoline Dispensing Facilities—Stage I*
(f)—*Tank Trucks*
(g)—*Petroleum Liquid Storage—Fixed Roof Tanks*—Administrative and minor wording changes were made to §§ 4.56(a)(2), (a)(5), (c)(1), (c)(2), (c)(3), (d)(1), (d)(3), (f)(2), and (g)(1).
4.57—*Volatile Organic Compounds Emissions—Miscellaneous Industry*
4.57(a) (9–21–79)—*General*—Administrative changes were made to paragraphs (a)(2) and (a)(4).

4.57(b) (9–21–79)—*Asphalt Paving Operations*—Minor wording changes were made to paragraphs (b)(2)(iii) and (b)(2)(iv).

Rule EX–9—Emission Standards for Coke Ovens

4.90 (9–6–79)—*Applicability and Designation of Affected Facility*—deleted former § 4.90 (Beehive Coke Ovens). New provisions added to designate applicable affected facilities in coke plants.

4.91 (9–6–79)—*Definitions*—deleted former § 4.91 (Other By-Products Coke Ovens). New definitions given to "Charging", "Coking", "Pushing", and "Quenching."

4.92 (9–6–79)—*Standard for Horizontal Slot Sole—Flue Non-Recovery Ovens*—deleted former § 4.92 (Charcoal Kilns). New provisions (§ 4.92(a) (1) thru (4) and (b)) added to regulate emissions from this type of operation.

4.93 (9–6–79)—*Standard for Horizontal Slot Non-Recovery Ovens*—New provisions (§ 4.93(a) (1) thru (4) and (b)) added to regulate emissions from this type of operation.

Part VII—Air Pollution Episodes

7.01(b) (9–6–79)—Deletion of "Health Advisory" stage.

7.02(a) (9–6–79)—Deletion of "Health Advisory" stage.

7.02(b) (9–6–79)—Deletion of "Health Advisory Stage" regulations and renumbering of section.

7.02(d) (9–6–79)—Deletion of "Health Advisory" stage and administrative changes.

Appendices

C (9–6–79)—*Reserved*—deleting former Appendix C (Major Pollutant Sources).

M (9–21–79)—Minor wording and administrative changes.

A summary of the history of each of these revisions and EPA's preliminary findings can be found in the proposed rulemaking published on September 29, 1980 (45 FR 64214). As a result of the above-mentioned **Federal Register** notice, we received comments from the Commonwealth of Virginia, VEPCO, Union Camp Corporation and Philip Morris, Inc.

EPA has reviewed these comments and held further discussions with the Commonwealth. As a result, except for the sections listed below, all of the above-listed revisions are approved. Several revisions are discussed below because EPA believes it is necessary to explain fully why they are being approved even though the revisions were originially proposed for disapproval.

§ 1.02—Malfunction—The Commonwealth has agreed to revise this definition to clearly state that a malfunction cannot be caused by intentional misconduct or negligent conduct on the part of the source. Because this definition will be revised shortly, EPA will take no action on the existing definition at this time.

§ 1.02—Capital Expenditure—EPA had originally proposed to disapprove deletion of this definition because it is necessary for the Commonwealth's NSPS program. The Commonwealth is correct in its comment that EPA should not disapprove a SIP revision because it does not satisfy the requirements of the NSPS program. Therefore, EPA is approving the proposed deletion but will review the NSPS Delegation of Authority to the Commonwealth to determine if such deletion adversely affects the NSPS program thus requiring modification or revocation of the Delegation.

§ 2.03(e)—Because the proposed revision would delete the Board's ability to assess penalties in an enforcement proceeding, EPA had originally proposed disapproval. The Commonwealth has now advised us that the Legislature withdrew the Board's authority to assess penalties and placed said authority with the courts. Because the authority no longer exists, EPA is approving this deletion.

§ 2.33(d)(6)(v)—EPA had originally proposed to disapprove deletion of this requirement relating to compliance with the lowest achievable emission rate by sources constructing in nonattainment areas. The Commonwealth has advised us that the requirement has not been deleted but merely moved to Section 5.43, which is the subject of a separate rulemaking. Therefore, EPA is now approving deletion of this section.

§ 2.34(a)—EPA originally proposed disapproval of this revision in error. Therefore, EPA is now approving the change.

§ 2.34(b)—EPA has reviewed its preliminary findings and, based on comments from the Commonwealth, now agrees that this section can be approved.

§ 2.34(d)—EPA had proposed disapproval of this section. However, on February 19, 1981, the Commonwealth submitted a SIP revision adding § 2.34(i). This revision alleviates EPA's concern and is the subject of a separate rulemaking. Therefore, we are now approving § 2.34(d).

§ 2.34(g)—EPA proposed disapproval of this section because an ambiguity exists in that this section uses the phrase "acceptable application for a variance." A source could submit a completed application for a variance which is subsequently denied. In such a case, a question could arise as to whether such a source is considered to have violated the applicable emission standard or monitoring requirement caused by a malfunction. The Commonwealth has agreed to modify the language to reflect that the variance must have been granted. Because this section is now being revised, EPA will not take any further action at this time.

§ 4.02(a)(3)—EPA originally proposed to disapprove this section because the proposed amendment to Section 4.02(a)(3) does not correct the previously noted deficiencies in this section. Furthermore, this amendment is also unacceptable in that it would exempt "soot blowing" from applicability under the visible emission regulation. This exemption is unacceptable from an enforceability viewpoint. Most large power plants blow soot automatically and semi-continuously. Also, large industrial boilers blow soot quite frequently. The net effect of the proposed change would be to virtually exempt large power plants from visible emission limitations, and make enforcement at industrial boilers so cumbersome as to effectively exempt them from visible emission regulations also. Visible emission observations are the primary means by which we evaluate continuing compliance of particulate sources. The Commonwealth has agreed to delete the soot blowing exemption for major sources. The section will be revised to allow soot blowing by small boilers only. Therefore, pending submittal of these revisions, EPA will not take any further action.

§§ 4.02(f) (6) thru (10)—EPA had originally proposed disapproval of these sections because they allow compliance schedules to differ from those contained in Appendix N. Any such alternative schedule must be Federally enforceable and, therefore, would have to be submitted to EPA as a DCO in accordance with Section 113(d) of the Clean Air Act or as a SIP revision pursuant to Section 110 and would not become effective until EPA had acted upon the request. In light of the Commonwealth's comments and their agreement to delete "economic infeasibility" from § 4.02(f)(6), EPA is now approving §§ 4.02(f) (7) thru (10). We will take no further action on § 4.02(f)(6) until the new revision is submitted.

§ 4.02(g)(1)—This section differs from Section 123 of the Clean Air Act in that the Act relates to the *setting* of an emission limit while the

Commonwealth's regulation deals with *compliance* with the emission limit. Any stack height, not just that in excess of good engineering practices, can have no effect on compliance with an emission standard. The Commonwealth has agreed to revise this section and therefore, EPA will take no further action until the revised SIP is submitted. Furthermore, correction of this section alleviates our concerns regarding § 4.02(g)(4) and, therefore, we are now approving it.

§§ 4.92(a) (1) thru (4) and § 4.93(a) (1) thru (4)—The Commonwealth has agreed to modify these sections as recommended in the proposed rulemaking and to include the appropriate test method as part of the SIP. Therefore, EPA will take no further action until the SIP revision is submitted.

Conclusion

The Administrator's decision to approve the proposed revision was based on the comments received and on a determination that the amendments meet the requirements of Section 110(a)(2) of the Clean Air Act and 40 CFR Part 51, Requirements for Preparation, Adoption and Submittal of State Implementation Plans.

Under Executive Order 12291, EPA must judge whether a regulation is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. This regulation is not major because this action only approves State actions and imposes no new requirements.

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

Pursuant to the provisions of 5 U.S.C. Section 605(b) I certify that SIP approvals under Section 110 and 172 of the Clean Air Act will not have a significant economic impact on a substantial number of small entities. This action only approves State actions. It imposes no new requirements.

Under Section 307(b)(1) of the Clean Air Act, judicial review of this action is available only by the filing of a petition for review in the United States Court of Appeals for the appropriate circuit within 60 days of today. Under Section 307(b)(2) of the Clean Air Act, the requirements which are the subject of today's notice may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

(42 U.S.C. 7401–7642)

Dated: January 7, 1982.

Anne M. Gorsuch,

Administrator.

Note.—Incorporation by reference of the State Implementation Plan for the Commonwealth of Virginia was approved by the Director of the Federal Register on July 1, 1981.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

Subpart VV—Virginia

1. Section 52.2420, Identification of Plan, is amended by adding paragraphs (c)(52), (53), (54), and (55) to read as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

(52) A revision submitted by the Commonwealth of Virginia on October 20, 1976 consisting of amendments to §§ 2.34(a), 2.34(b), and 2.34(h) of the Virginia Air Pollution Control Board Regulations.

(53) A revision submitted by the Commonwealth of Virginia on September 20, 1978 consisting of amendments to Part I, Definitions, modification of "Combustion Installation"; and §§ 4.02(a)(2), 4.02(e), and 4.21 of the Virginia Air Pollution Control Board Regulations.

(54) A revision submitted by the Commonwealth of Virginia on September 6, 1979 consisting of amendments to Part I, Definitions; §§ 2.33(a), 2.33(c), 2.33(d), 2.33(e), 2.33(h), 2.33(k), 2.33(m), 3.05(a), 3.05(b), 3.05(c), 4.02(g) (2), (3), (4), (5), and (6), 4.23, 4.40, 4.41, 4.90, 4.91, 4.92(b), 4.93(b), 7.01(b), 7.02(a), 7.02(b), 7.02(d); and, Appendix C of the Virginia Air Pollution Control Board Regulations.

(55) A revision submitted by the Commonwealth of Virginia on September 21, 1979 consisting of amendments to Part I, Definitions; §§ 2.03(c), 2.03(e), 2.09(d), 2.09(f), 2.34(c), 2.34(d), 2.34(e), 2.34(f), 2.34(g), 4.02(f) (7) thru (10), 4.54(a), 4.54(b), 4.54(c), 4.54(e), 4.54(f), 4.54(g), 4.55(a), 4.56(a), 4.56(c), 4.56(d), 4.56(f), 4.56(g), 4.57(a), 4.57(b); and Appendix M of the Virginia Air Pollution Control Board Regulations.

[FR Doc. 82-1247 Filed 1-18-82; 8:45 am]

BILLING CODE 6560-38-M

40 CFR Part 702

[OPTS-200000A; TSH-FRL 1724-3]

General Practices and Procedures; Prior Notice of Citizen Suit; Procedural Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule promulgates the procedural rule proposed in the Federal Register of June 25, 1980 (45 FR 43148). This rule is promulgated under the authority of section 20 of the Toxic Substances Control Act (TSCA). Section 20 authorizes persons to initiate citizens' suits to restrain certain violations of TSCA or to compel implementation by the EPA of TSCA non-discretionary authorities. Prior to filing suit, persons must give notice both to the Administrator and to the person alleged to have violated the Act. Section 20 requires that this notice be given 60 days prior to beginning a civil suit, except in the case of the alleged failure of the Administrator to file an action under section 7(a)(2) (imminent hazards) in which case the notice must be given 10 days before the action may be commenced. This rule prescribes procedures for giving the notice.

EFFECTIVE DATE: This rule is effective February 18, 1982.

FOR FURTHER INFORMATION CONTACT: Douglas G. Bannerman, Acting Director, Industry Assistant Office (TS-799), Office of Pesticides and Toxic Substances (OPTS), Environmental Protection Agency, Rm. E-511, 401 M St., SW., Washington, D.C. 20460, Toll free: (800-424-9065), Local: (554-1404).

SUPPLEMENTARY INFORMATION: Section 20 of TSCA authorizes any person to file a civil action against (1) any person or persons alleged to be in violation of TSCA or of any rule promulgated under sections 4, 5, or 6, or order issued under section 5 of the Act, or (2) the Administrator, to compel performance of any TSCA non-discretionary acts or duties. The purpose of this section is to provide citizen enforcement of the act and of certain regulations and orders issued under TSCA and enforcement of any act or duty that is not discretionary with the Administrator.

The statute requires that the citizen give notice to the Administrator, and to the person alleged to have violated the Act, 60 days prior to commencing any such action. In the event the citizen alleges that the Administrator has failed to file an action under section 7(a)(2) (imminent hazards), the statute requires

only a 10-day notice period. This required waiting period between the notice and actual filing of the civil action enables the Administrator to take action against the alleged violators, if appropriate, and enables the Administrator to perform any act or duty that is not discretionary, prior to litigation.

Section 20 directs the Administrator to prescribe by rule the manner in which such notices shall be given. This rule describes the procedures to be followed; it is essentially the same as rules promulgated by the EPA under other acts it administers that authorize citizens' suits.

Minor changes in the language of the rule have been made to clarify the provisions. In addition, a new paragraph (a) has been added to § 702.61 to set forth the notice periods in the regulation. This preamble addresses comments received on the proposed rule and discusses other changes made in response to those comments.

Contents of Notice

The notice must specify the location of the alleged violation and the date or dates on which the alleged violation occurred. The notice must also specify the activity alleged to constitute a violation and must include sufficient information to permit the recipient to identify the section of TSCA, or the rule or order alleged to have been violated. In a notice regarding an alleged failure of the Administrator to perform a non-discretionary duty, the notice must identify with reasonable specificity the action taken, or not taken, by the Administrator.

A comment stated concern that the requirement of the proposed rule that the notice must specify "the date or dates of such violation" could not always be met because persons might be unable to exactly specify the date. Moreover, since the notice must also include information relating to the provisions of TSCA being violated, the activity constituting the violation, and the location of the violation, it seemed likely to the commentor that such information would provide sufficient information for later determination of the exact date or dates of any violations. Thus, it should not be necessary for the party giving notice to specifically state the dates on which TSCA was violated. The commentor feared that the date requirement would serve only as a stumbling block in the way of fulfilling the legitimate purpose behind citizens' suits.

The date requirement has been changed to read: "* * * the date or dates of such a violation as closely as the citizen is able to specify them". Identification of the date of the alleged violation, as closely as possible, will constitute compliance.

Another comment on the proposed rule recommended that the citizen be required to specify the harm alleged to have been caused by the violation of TSCA or the failure of the Administrator to perform a non-discretionary act or duty. This recommendation has not been adopted. The purpose of the notice is to apprise the Administrator or potential defendant of the basis of the intended suit and enable him to investigate further. Allegations of harm and other matters that may appear in the plaintiff's complaint can be investigated after the notice is received.

A comment suggested that a recitation of the harm would allow the potential defendant to know whether a justiciable question exists. EPA believes that questions of justiciability, and the question whether proof of harm is necessary in the case, are related more to the development of plaintiff's complaint and defendant's answer in court. These questions would be premature in the notice provided for in this rule.

Manner of Service and Persons to Be Served

If a notice is served by mail, the date on the return receipt card is the effective date of service. If the notice is personally served, the effective date of service is the date it is served. This rule also describes the person or persons to be served, according to the nature of the suit and the defendant.

A recommendation was made by one commentor that, in addition to serving the registered agent of a corporate defendant with a copy of the notice, the citizen should serve a copy of the notice on the head of the corporation at its principal place of business. The language in this section of the final rule has been changed. The rule now requires that a copy of the notice be sent to, not served on, the registered agent of the corporation. If the alleged violator is a private individual or corporation, the rule requires that notice of intent to file suit shall be served on the individual or the owner or managing agent of the plant, facility, or activity alleged to be in violation. EPA has not accepted the recommendation to also serve the head of the corporation at its principal place of business. The citizen can readily identify the individual or the owner or the managing agent of the specific plant or facility alleged to be in violation. It then becomes the responsibility of the organization at that plant or facility to distribute the notice to the appropriate persons within the corporation. Companies can also ensure receipt of such notice by instructing their agents to promptly forward such notices to Headquarters.

Another comment suggested that EPA publish notices in the **Federal Register** of citizens' suits under section 20(a)(2) to compel action by the Administrator and that the publication date of the notice would begin the notice period. The purpose of a **Federal Register** notice would be to allow interested persons to comment. EPA will keep section 20 notices in a file available to the public. However, EPA will not routinely publish such notices in the **Federal Register**. If the result of the citizens' notice or suit is that the Agency begins a regulatory proceeding, then the appropriate time for public comment will be the Agency's publication of a **Federal Register** notice of the proceeding itself. If the action the citizen seeks to compel is not a general Agency proceeding, public comment may not be appropriate. Moreover, the statute states that the notice period under section 20(a)(2) begins upon giving of the notice to the Administrator. The rule reflects this. Delaying the start of the notice period until publication of a **Federal Register** notice would extend the period beyond that specified in section 20.

Public Record

EPA has established a public record for this rulemaking (document number [OPTS–200000A]) which is available for inspection in the OPTS Reading Room E–106, from 8:00 a.m. to 4:00 p.m., Monday through Friday, except holidays, at the address above. This record includes basic information considered by the Agency in developing this rule. The record includes the following categories of information:

1. This final rule.
2. Microfiche of comments on **Federal Register** notices of similar EPA rules.
3. The proposed rule.
4. All comments on the proposed rule.

Under Executive Order 12291, EPA must judge whether a regulation is major and therefore subject to the requirement of a regulatory impact analysis. This regulation is procedural in nature and not major because it simply prescribes the manner in which a citizen must give notice of intent to file suit prior to actually filing as directed by section 20 of TSCA. The regulation has no economic impact and its implementation will not result in any increase in costs or prices. Competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-

based enterprises will not be hindered by this regulation.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments from OMB to EPA, and any EPA response to those comments are available for public inspection in the record for this rulemaking (document number OPTS-200000A) which is located in the OPTS Reading Room, E-106, from 8:00 a.m. to 4:00 p.m., Monday through Friday except holidays.

Therefore, under section 20 of the TSCA (Sec. 20, 90 Stat. 2041, (15 U.S.C. 2619)), Chapter I of Title 40 is amended by adding a new Part 702, consisting at this time of Subpart C, as set out below.

Dated: December 28, 1981.

Anne M. Gorsuch,

Administrator.

Part 702 is added as follows:

PART 702—GENERAL PRACTICES AND PROCEDURES

Subpart A-B—[Reserved]

Subpart C—Citizen Suit

Sec.

Authority: Sec. 20, TSCA, 90 Stat. 2041, (15 U.S.C. 2619).

Subpart A-B—[Reserved]

Subpart C—Citizen Suit

§ 702.60 Purpose.

Section 20 of the Toxic Substances Control Act (TSCA) authorizes any person to begin a civil action to compel performance by the Environmental Protection Agency (EPA) of TSCA non-discretionary acts or duties (section 20(a)(2)) or to restrain any violation of TSCA, or of any rule promulgated under sections 4, 5, or 6, or of any order issued under section 5 of TSCA (section 20(a)(1)). The purpose of this regulation is to prescribe procedures governing the giving of a notice of intent to file suit required by section 20(b) of TSCA as a prerequisite to beginning such civil actions.

§ 702.61 Service of Notice of Intent to File Suit.

(a) *Notice as a prerequisite to suit.* Under section 20 of TSCA, no civil action may be commenced by a citizen to restrain a violation of TSCA, or a rule or order thereunder, unless at least 60 days in advance the citizen has given notice of the intent to file suit to the Administrator and to the person who is alleged to have committed the violation. No civil action may be commenced by a citizen to compel the Administrator to perform any non-discretionary act or duty under TSCA, unless at least 60 days in advance the citizen has given notice of the intent to file suit to the Administrator. However, in the case of an alleged failure by the Administrator to file an action under section 7 of TSCA, the citizen must give notice to the Administrator only 10 days in advance of filing the civil action.

(b) *Method of service.* Notice of intent to file suit can be either personally served or served by certified mail—return receipt requested—to persons identified in paragraph (d) of this section.

(c) *Date of service.* The effective date of service of a notice given in accordance with this rule shall be the date of the return receipt, if served by mail, or the date of receipt if personally served.

(d) *Persons to be served.*—(1) *Violations of TSCA rules or TSCA order.* (i) If the alleged violator is a private individual or a corporation, notice of intent to file suit shall be served on the individual or the owner or managing agent of the plant, facility, or activity alleged to be in violation. If the alleged violator is a corporation, a copy of the notice shall also be sent to the registered agent, if any, of such corporation in the State in which such violation is alleged to have occurred. Notice shall also be served on the Administrator of the EPA.

(ii) If the alleged violator is a State or local government entity, notice of intent to file suit shall be served on the head of the agency. Notice shall also be served on the Administrator of the EPA, and a copy shall be sent to the Attorney General of the United States.

(iii) If the alleged violator is a Federal agency, notice of intent to file suit shall be served on the head of the agency. Notice shall also be served on the Administrator of the EPA, and a copy shall be sent to the Attorney General of the United States.

(2) *Performance of non-discretionary TSCA acts or duties.* Notice of intent to file suit shall be served on the Administrator of the EPA and a copy shall be sent to the Attorney General of the United States.

(3) *Address of persons to be served.* (A) EPA Administrator: 401 M St., SW., Washington, DC 20460. (B) Attorney General of the United States: 10th and Constitution Ave., NW., Washington, DC 20530.

§ 702.62 Contents of notice.

(a) *Violation of TSCA rule or TSCA order.* Notice of intent to file suit regarding an alleged violation of TSCA or any rule promulgated under sections 4, 5, or 6, or an order issued under section 5, shall include sufficient information to permit the recipient to identify:

(1) The specific provision of TSCA or of the rule or order under TSCA alleged to have been violated.

(2) The activity alleged to constitute a violation.

(3) The person or persons responsible for the alleged violation.

(4) The location of the alleged violation.

(5) The date or dates of the alleged violation as closely as the citizen is able to specify them.

(6) The full name, address, and telephone number of the citizen giving notice.

(b) *Failure to act.* Notice regarding an alleged failure of the Administrator to perform any act or duty which is not discretionary shall:

(1) Identify the specific provision of TSCA which requires an act or creates a duty.

(2) Describe with reasonable specificity the action taken or not taken by the Administrator which is alleged to constitute a failure to perform the act or duty.

(3) State the full name, address, and telephone number of the citizen giving the notice.

(c) *Identification of Counsel.* The notice shall state the name, address, and telephone number of the Legal Counsel, if any, representing the citizen giving the notice.

[FR Doc. 82-1246 Filed 1-18-82; 8:45 am]

BILLING CODE 6560-31-M

Proposed Rules

Federal Register
Vol. 47, No. 12
Tuesday, January 19, 1982

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Part 1942

Community Facility Loans and Domestic Water and Waste Disposal System Loans and Grants

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration (FmHA) proposes to revise its regulations to—

(1) Reduce priority for community program assistance to areas or communities outside, but adjacent to or closely associated with, urban areas;

(2) Eliminate community program assistance for recreation facilities that will be used primarily for recreational purposes; and

(3) Make other editorial changes regarding funding priorities.

This is the result of an administrative decision to adjust funding priorities. The intended effects of this action are to help direct FmHA Community Program assistance to areas and communities that are clearly rural in character and to reduce funding for recreation facilities.

DATES: Comments must be received on or before March 22, 1982.

ADDRESSES: Submit written comments in duplicate to the Chief, Directives Management Branch, Farmers Home Administration, Room 6346, South Agriculture Building, 14th and Independence Avenue SW., Washington, DC 20250. All written comments made pursuant to this notice will be available for public inspection at the above address.

FOR FURTHER INFORMATION CONTACT: Jerry W. Cooper, Loan Specialist, Water and Waste Disposal Loan Division, Farmers Home Administration, Room 6328, South Agriculture Building, 14th and Independence Avenue SW,. Washington, DC 20250, Telephone: (202) 382–9589.

SUPPLEMENTARY INFORMATION: This proposed rule has been reviewed under procedures established in Secretary's Memorandum 1512–1 and Executive Order 12291 and has been classified as nonmajor. The proposed rule will not have—

(a) An annual effect on the economy of $100 million or more; or

(b) Any increased costs or prices to consumers, individual industries, Federal, State/or local government agencies, or geographic regions; or

(c) A 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.

Alternatives that would allow the agency to direct its funding priorities to truly rural areas and rural communities and reduce program assistance for recreation facilities have been considered. An alternative considered regarding directing community program assistance to truly rural areas and rural communities is to make no change. Under existing regulations and policy, rural areas and rural communities adjacent to or closely associated with non-rural areas receive the same consideration for FmHA program assistance as truly rural areas. This has resulted in some projects being financed by FmHA in areas that are not clearly rural in character.

Another alternative considered was to delineate eligible areas on a map. This alternative was rejected because it did not allow any flexibility in administering community programs. It would be better to review each loan and grant on its merits rather than be restricted by boundaries on a map. Being locked into boundaries on a map could cause such problems as: higher user costs for rural residents, services not being provided in certain areas, and poorly designed water and sewer systems.

The proposed action will give priority for FmHA community program assistance to truly rural areas and rural communities. This alternative will allow FmHA to establish priorities in funding a project and not totally eliminate any rural area. The proposed action will allow a rural area that is located near a non-rural area to receive program assistance. Some of the benefits of the proposed action will be: improved project feasibility, less conflict with local and State ordinances, and better service to rural areas that are adjacent to or closely associated with a non-rural area.

The establishment of priorities in lieu of mapping would be the most cost-effective method of directing FmHA program assistance to truly rural areas and rural communities. The use of a map to define eligible areas for FmHA program assistance would require a detailed review of each non-rural area to establish a line that would separate rural and non-rural areas. This line would have to be continuously updated as population changes occurred in a non-rural area and this would increase the cost to the public. Rural areas and rural communities that are adjacent to or closely associated with a non-rural area would benefit by establishing priorities rather than mapping. If mapping were used, an area that needs FmHA program assistance could be denied this assistance; however, by using priorities, the area could be provided such assistance.

One alternative regarding recreation loans is to make no change. Under existing regulations and policy, loans for recreation facilities are given lower priority for funding than loans for public safety, health care, or public service facilities. Recreational facility loans are normally approved only to public bodies. FmHA has occasionally received public criticism for financing recreational facilities on the grounds that the facilities are less important and the loans higher risk than other types of community facilities.

Another alternative would be to allow no funds to be used to finance recreational facilities. FmHA desires to further restrict the use of limited program funds to the most necessary types of facilities. There may, however, be situations where the most efficient use of resources would be to develop recreational potential in conjunction with other high priority facilities.

The proposed action makes projects that are primarily for recreational facilities ineligible for community facility loans. This meets the goal of directing limited funds to higher priority facilities and maintains the option to finance multi-purpose facilities where the primary purpose is not recreational but some recreational development is

included. The proposed action will not result in an increased net cost to the public; however, it will maximize benefits to that part of the public the Agency is designated by law to serve.

Charles W. Shuman, Administrator, Farmers Home Administration, has determined that changing priorities to direct FmHA community program assistance to truly rural areas and rural communities and reducing assistance for recreation facilities will not have a significant economic impact on a substantial number of small entities. The proposed rule will direct FmHA community program assistance to rural areas and rural communities that need FmHA's assistance the most. Reducing FmHA program assistance for recreation facilities will result in additional funds being available to small entities in rural areas for other essential community facilities. There is not a significant need for FmHA program assistance in the areas that will be affected by the proposed rule.

The FmHA programs and projects affected by this instruction are subject to State and local clearinghouse review in the manner delineated in FmHA Instruction 1901–H.

CFDA Nos. 10.418 Water and Waste Disposal Systems for Rural Communities and 10.423 Community Facilities Loans.

This document has been reviewed in accordance with 7 CFR Part 1901, Subpart G, "Environmental Impact Statements". It is the determination of FmHA that the proposed action does not constitute a major Federal action significantly affecting the quality of the human environment and in accordance with the National Environmental Policy Act of 1969, Pub. L. 91–190, an Environmental Impact Statement is not required.

Facilities financed by loans and grants for water and waste disposal facilities and loans for essential community facilities must primarily serve rural residents. Under current regulations, water and waste disposal assistance cannot be provided in cities or towns with populations exceeding 10,000; and essential community facility assistance cannot be provided in towns or cities with populations exceeding 20,000. Assistance may be provided in areas outside, but adjacent to or closely associated with these cities or towns. FmHA regulations provide that priority for available program funds should be given to eligible projects and applicants that meet certain conditions. FmHA desires to amend its regulations regarding priorities to clarify the application of priority consideration and to direct program assistance to areas that are clearly rural in character. FmHA also desires to establish a rule that essential community facilities funds will not be used to finance recreation facilities.

PART 1942—ASSOCIATIONS

Accordingly, FmHA proposes to amend § 1942.17 of Subpart A of Part 1942, Chapter XVIII of Title 7, Code of Federal Regulations, by revising the introductory text of paragraph (b), paragraphs (c) and (d)(2), and the introductory text of paragraphs (g)(1)(iii) and (g)(2)(iii) to read as follows:

§ 1942.17 Appendix A—community facilities.

* * * * *

(b) *Applicant eligibility.* Facilities financed by FmHA must primarily serve rural residents. For water or waste disposal facilities the terms "rural" and "rural area" will not include any area in any city or town with a population in excess of 10,000 inhabitants according to the latest decennial census of the United States. For essential community facilities the terms "rural" and "rural area" will not include any area in any city or town with a population in excess of 20,000 inhabitants according to the latest decennial census of the United States. Facilities must be located in rural areas except for utility-type services, such as water, sewer, natural gas, or hydroelectric, serving both rural and non-rural areas. In such cases FmHA funds may be used to finance only that portion serving rural users, regardless of facility location. Loans for water or waste disposal facilities will not be made to any city or town with a population in excess of 10,000. Loans for essential community facilities will not be made to any city or town with a population in excess of 20,000. Assistance to areas or communities adjacent to, or closely associated with, non-rural areas is limited by section 1942.17(c).

* * * * *

(c) *Priorities.* FmHA program assistance will be directed toward truly rural areas and rural communities. Normally, priority will not be given to applications for projects that will serve densly settled areas or communities adjacent to or closely associated with a city or town with a population exceeding 10,000 residents for water or waste disposal assistance or 20,000 residents for essential community facility assistance. When determining whether a rural area or rual community is adjacent to or closely associated with a city or town with a population exceeding 10,000 residents for water and waste disposal or 20,000 residents for essential community facility assistance, minor open spaces such as those created by physical or legal barriers, commercial or industrial development, parks, areas reserved for convenience or appearance, or narrow strips of cultivated land, will be disregarded. An area or community shall be considered adjacent to or closely related with a non-rural area when it constitutes for general, social and economic purposes a single community having a contiguous boundary. Outer boundaries of an incorporated community will extend at least to its legal boundaries. The following paragraphs indicate items and conditions which must be considered in selecting applications for funding. When ranking eligible applications for consideration for limited funds, FmHA officials must consider the priority items met by each application and the degree to which those priorities are met, and apply good judgment.

(1) *Applicant priority.* (i) Priority for available funds will normally be given to public bodies. When this is not practicable:

(A) Loans for facilities providing utility-type service such as water and sewer systems, and natural gas distribution systems may be made to other than public-body-type organizations, when operated on a not-for-profit basis.

(B) Loans for eligible essential community facilities other than utility-type may be made to other than public-body-type organizations when such facilities will be fully available to the public and it is not practicable for a public body to finance them.

(ii) In determining priorities, FmHA officials must keep in mind that applicants which will provide service to communities having a large portion of its population with low income have a greater financial need.

(2) *Project priority.* In determining project priorities, FmHA must give due consideration to State development strategies, projects needing improvements to comply with the Safe Drinking Water Act (See Guide 25, Joint Policy Statement Between the Environmental Protective Agency (EPA) and FmHA), and clearinghouse comments and priority recommendations. FmHA will assign priorities in accordance with the following:

(i) *Utility type.* (A) Water and waste disposal system applications from any municipality or other public agency (including an Indian Tribe on a Federal or State reservation or other Federally recognized Indian tribal group) in a rural community having a population not in

excess of 5,500 having an inadequate water or waste disposal system. Highest priority shall be given to such applications in which:

(*1*) An existing community water supply system requires immediate action as the result of unanticipated diminution or deterioration of its water supply; or

(*2*) An existing waste disposal system is not adequate to meet the needs of the community as a result of unexpected occurrences.

(B) Those projects which will enlarge, extend, or otherwise modify existing facilities to provide service to additional rural residents.

(C) Those projects which involve the merging of ownership, management, and operation of smaller facilities thereby providing for more efficient management and economical service to more rural commnities and residents and more orderly development of the rural area in which the facilities are located.

(ii) *Other essential community facilities.* Each application should be carefully evaluated and full consideration be given to funding those applications having the highest priority and which will serve the largest number of rural residents. The following order of preference should be used in selecting applications for funding:

(A) Public safety facilities—fire, police, rescue, and ambulance services.

(B) Health care facilites—clinics, nursing homes, convalescent facilities, and hospital projects designed to make the facility conform with life/safety codes, medicare and medicaid requirements, and minor expansions needed to meet the immediate requirements of the community.

(C) Public service facilities—courthouse and community buildings.

(D) New hospitals and major expansions of existing hospitals.

(E) Other.

(d) *Eligible loan purposes.* * * *

(2) To construct, enlarge, extend or otherwise improve community facilities providing essential service to rural residents. Such facilities include but are not limited to those providing or supporting overall community development such as fire and rescue services; transportation; traffic control; community, social, and cultural benefits. Funds may not be used to finance projects to be used primarily for recreational purposes. Hydroelectric generating facilities and related connecting systems and appurtenances, and supplemental and supporting structures for other rural electrification or telephone systems (including facilities such as headquarters and office building, storage facilities, and maintenance shops), may be considered when they are not eligible for Rural Electrication Administration financing. Funds may be used for development of industrial park sites, consisting of land and land improvements (e.g. clearing, grading, drainage), necessary access ways and utility extensions to and throughout the site when the park is determined to be an integral part of community development. Funds may not be used in connection with industrial parks to finance on-site utility systems, or business and industrial buildings.

* * * * *

(g) *Security.* * * *

(1) *Public bodies.* * * *

(iii) *Other essential community facilities* other than utility type, such as those for public health and safety, social, and cultural needs and the like will meet the following security requirements.

* * * * *

(2) *Other than public bodies.* * * *

(iii) *Essential community facilities* other than utility type such as those for public health and safety, social, and cultural needs and the like will meet the following security requirements.

* * * * *

(7 U.S.C. 1989; 7 CFR 2.23; 7 CFR 2.70)

Dated: December 28, 1981.

Dwight O. Calhoun,

Acting Administrator, Farmers Home Administration.

[FR Doc. 82-1224 Filed 1-18-82 8:45 am]

BILLING CODE 3410-07-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 210

[Release Nos. 33-6374; 34-18402; IC-12153; File No. S7-918]

Financial Statement Requirements for Registered Investment Companies; Proposed Revision of Rules

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rules.

SUMMARY: The Commission is proposing a revision of Article 6 of Regulation S-X which is appplicable to financial statements filed by registered investment companies. The revisions to Article 6 are being proposed to (1) eliminate rules which are duplicative of generally accepted accounting principles ("GAAP"), (2) effect changes which recognize current industry practices, and (3) integrate and simplify the rules to improve financial reporting. In addition, financial statement requirements for employee stock purchase, savings and similar plans would be similarly amended and transferred to a separate Article 6A. These proposed changes are part of the Commission's comprehensive reexamination of its requirements for financial statements in connection with its efforts to simplify and improve the current disclosure system.

DATE: Comments should be received by the Commission on or before April 30, 1982.

ADDRESSES: Comments should be submitted in triplicate to George A. Fitzsimmons, Secretary, Securities and Exchange Commission, Washington, D.C. 20549. Comment letters should refer to File No. S7-918. All comments will be available for public inspection at the Commission's Public Reference Room, 1100 L Street, N.W., Washington, D.C. 20549.

FOR FURTHER INFORMATION CONTACT: Clarence M. Staubs, or John W. Albert, Office of the Chief Accountant, Securities and Exchange Commission, Washington, D.C. 20549 (202-272-2133).

SUPPLEMENTARY INFORMATION: The Securities and Exchange Commission is proposing a revision of Article 6 of Regulation S-X (17 CFR Part 210) which prescribes the form and content of financial statements filed for registered investment companies and employee stock purchase, savings and similar plans. The revisions to Article 6 are being proposed to (1) eliminate rules which are duplicative of GAAP, (2) effect changes which recognize current industry practices, and (3) integrate and simplify the rules to improve financial reporting. The proposed rules would integrate certain common reporting requirements of management investment companies, unit investment trusts, and face-amount certificate companies (collectively referred to as registered investment companies) in a revised Article 6. Financial statement requirements for employee stock purchase, savings and similar plans would be amended to change valuation requirements for certain assets and transferred to a separate Article 6A.

Under the proposed rules, management investment companies would be required to present a statement of operations rather than the separate statements of income and expense, realized gain or loss on investments, and unrealized appreciation or depreciation of investments currenlty furnished. In addition, the proposed rules would prescribe a reporting format for the

presentation of a statement of net assets and establish criteria for its use. Finally, the proposed rules would amend the requirements regarding the basis used to value certain assets in the balance sheets of closed-end management investment companies.

Background

In January 1980, the Commission issued four separate but related rule proposals[1] which, among other things, initiated a broad project to reexamine its registration and reporting requirements. The project was designed to make major changes in the Commission's disclosure system, and to effect integration of the registration and reporting requirements under the Securities Act of 1933 and the Securities Exchange Act of 1934. A general revision of Articles 3 and 5 of Regulation S–X, included in the January rule proposals, has been accomplished and new uniform requirements governing the periods to be covered by financial statements, including special provisions for management investment companies, have been adopted. In addition, the industry-specific requirements related to property and liability insurance and life insurance companies were recently integrated within a revised Article 7.

In connection with its comprehensive review of Regulations S–X, the Commission has undertaken a review of the requirements for financial statements filed by registered investment companies contained in Article 6 of Regulation S–X. The existing requirements of Article 6 are comprised of a series of special rules applicable to: (1) management investment companies (§§ 210.6–01 to 210.6–10); (2) unit investment trusts (§§ 210.6–10a to 210.6–13); (3) face-amount certificate companies (§§ 210.6–20 to 210.6–24); and (4) employee stock purchase, savings and similar plans (§§ 210.6–30 to 210.6–34), respectively. This segregation of special rules for each type of registered investment company provides preparers of financial statements with a convenient reference; however, it also results in the repetition of many requirements applicable to more than one type of registered investment company. The proposed rules would simplify the requirements under Article 6 by integrating those rules which apply to more than one type of investment company and segregating others which are unique to a specific type of registered investment company.

In this connection, the Commission believes that the operations of unit investment trusts are not sufficiently different from those of management investment companies that separate requirements are necessary. Consequently, requirements for statements of condition and income and distributable funds of unit investment trusts have been integrated within the requirements for balance sheets and statements of operations applicable generally to registered investment companies. Where additional information is relevant to an understanding of the operations of a unit investment trust, it would be provided within the schedules specifically applicable to this type of investment company.

The existing requirements for face-amount certificate companies are set forth in a separate section of Article 6 which includes the special provisions unique to face-amount certificate companies and repeats the general provisions applicable to other types of investment companies. The proposed rules would integrate the requirements applicable to all investment companies, thereby eliminating many repetitious rules. Separate reporting formats for balance sheets and statements of operations would be retained for these companies due to the unique nature of this type of investment company.

In addition to simplifying the rules by integrating common provisions, the proposed rules would revise the existing requirements of Article 6 to eliminate or modify those rules which are duplicative of GAAP, no longer pertinent due to changes in current industry practices, or are made unnecessary by these proposals. A discussion of the more significant of these proposed revisions follows.

Statement of Operations

Under the proposed rules, management investment companies would be required to present a statement of operations rather than the separate statements of income and expense, realized gain or loss on investments, and unrealized appreciation or depreciation of investments furnished pursuant to the existing rules. Since an open-end management investment company continuously trades its shares on the basis of its underlying net assets stated at value,[2] the Commission believes that it would be consistent for such investment companies to report changes in net assets resulting from all investment activities in the determination of operating results. Although a closed-end management investment company does not stand ready to redeem its shares on a continuous basis, the market price at which such shares are traded correlates with the company's net asset value. Furthermore, the proposal to report all changes in net assets resulting from investment activities in a basic statement of operations is consistent with the notion of comprehensive income set forth in Statement of Fianncial Accounting Concepts ("Concepts Statement") No. 3.[3] Under Concepts Statement No. 3, comprehensive income is defined as the change in equity (net assets) of an entity during a period from transactions and other events and circumstances from nonowner sources. It includes all changes in equity during a period except those resulting from investments by owners and distributions to owners.

While the proposed rules would require that the results of all investment activities be combined and reported within a statement of operations, the format prescribed by these rules would clearly distinguish amounts attributable to each of the basic investment activities for which separate statements are currently presented. This reporting format would provide financial statement users with the information necessary to assess the contribution of each element of investment activity. Commentators are requested to specifically address the appropriateness of substituting a statement of operations for the separate statements currently required, as well as the propriety of incuding both realized and unrealized gains and losses in the determination of net income.

Statement of Net Assets

Because of the significance of the investment portfolio and the amount of net assets, both in total and on a pershare basis, to investors and shareholders, management investment

[1] Proposed under Securities Act Release Nos. 6176 (45 FR 5972), 6177 (45 FR 5934), 6178 (45 FR 5943), and 6179 (45 FR 5963), respectively.

[2] Management investment companies are classified as either "open-end" or "closed-end" companies. An open-end management investment company stands ready to redeem its outstanding shares at current net asset value, and generally offers its shares to the public on a continuous basis. A closed-end management investment company, however, does not stand ready to redeem its outstanding shares; its shares are traded in a manner similar to those of other public companies.

[3] Concepts statements, such as Statement No. 3, "Elements of Financial Statements of Business Enterprise", issued in December 1980, do not establish accounting procedures or disclosure practices. Rather, these statements describe concepts and relationships that will underlie future financial accounting standards and practices and in due course serve as a basis for evaluating existing standards and practices.

companies often substitute a statement of net assets for the conventional balance sheet. The proposed rules would prescribe a reporting format for the presentation of a statement of net assets and establish criteria for its use. Since the major asset of any management investment company is its investment portfolio, the statement of net assets is comprised basically of a detailed listing of its securities portfolio similar to the schedule requirements for investment companies prescribed in Regulation S–X (§ 210.12–12). All other assets and total liabilities are netted for presentation in the statement, and a balance captioned as net assets is presented, together with the number of outstanding shares and value per share.

Since the statement of net assets is fully informative only in situations in which an investment company's securities portfolio represents virtually all of its net assets, the proposed rules would establish conditions to restrict the use of this statement to these circumstances. These proposed conditions are (1) that the amount of investment in securities (excluding investments in affiliated issuers) represent at least 95 percent of total assets, (2) that liabilities not be significant (defined as not exceeding 5 percent of total assets), and (3) that only one class of equity securities be outstanding. In addition, investment companies would not be permitted to use a statement of net assets if at the balance sheet date there are outstanding balances with related parties representing other than amounts arising from the conduct of regular investment advisory or management services or they have balances in respect to securities transactions involving short sales, open option contracts, or deposits on securities loaned. Where an investment company has unsettled balances of such nature, the Commission believes that the statement of net assets does not provide adequate disclosure, and that, in such circumstances, diclosure provided by a more conventional balance sheet and related footnotes is appropriate. Commentators are encouraged to specifically address the appropriateness of the criteria proposed by the Commission for the use of the statement of net assets.

Valuation of Assets

Under the existing rules, closed-end management investment companies are permitted to state all assets at either cost or market. In recognition of the significance of asset value to management investment companies, virtually all closed-end companies currently reflect their investment securities at value. The proposed rules would eliminate the option of cost or value and require that closed-end companies state investments in securities at value consistent with current industry practice.

Section 28(b) of the Investment Company Act of 1940 requires investment companies which issue face-amount certificates to value their "qualified assets" in accordance with certain provisions of the Code of the District of Columbia. Unlike management investment companies whose assets are largely comprised of investments in marketable securities, issuers of face-amount certificates often hold more diverse investments, such as real estate. Issuers of face-amount certificates will continue to value all investments pursuant to the statutory requirements.

Other Proposed Changes

The Commission has often been urged to reexamine its existing requirements for the content of the statement of changes in net assets presented by management investment companies. In the view of some, the statement is overly detailed and results in confusion to its users. The proposed rules are intended to simplify the content of this statement by eliminating the presentation of certain information already reported in other statements and by restricting the presentation of other information to supplemental, or footnote, status. For example, net gain or loss on investments as reflected in the statement of operations would be presented in the statement of changes in net assets rather than showing separate captions for the net realized and unrealized components. In addition, changes in net assets resulting from capital share transactions would be presented net on the face of the statement, with details as to sales and redemptions shown in a footnote.

The proposed rules would also eliminate existing requirements for statements of surplus and sources of net assets. Requirements for a statement of surplus would be eliminated since general requirements for its content are already provided in Article 11 of Regulation S–X.[4] The statement of sources of net assets would also be deleted since this statement is not generally presented in practice and much of the information is already provided under other provisions of Article 6.

Under the proposed rules, the nature of the items to be presented as cash on the balance sheets (or statements of assets and liabilities) of registered investment companies would be restricted to cash on hand and demand deposits. This proposed treatment would differ from the reporting practices in other indistries in which time and similar deposits may be included as cash items. The Commission believes that a different presentation is appropriate due to the unique nature of an investment company's operations, in which the investment of discretionary funds in time and similar deposits is considered to be an element of investment activity. Specific comments are encouraged on the distinction afforded to the balance sheet presentation of cash for registered investment companies.

The existing rules include specific instructions as to the appropriate method of accounting for certain transactions, such as those involving dividends and interest on investments. For example, the existing rules specify the conditions under which dividends in arrears on preferred stock or interest received on bonds in default may be recognized as income. Since the method of accounting for these transactions is set forth under GAAP, these specific instructions have been deleted from the proposed rules.

Schedules

In a July 1981 release the Commission eliminated the requirements to disclose cost of individual securities in prospectuses and annual reports of management investment companies.[5] In order to conform to this action, the proposed rules would amend certain schedule requirements to eliminate disclosure of the cost of individual securities. However, much of the schedule information required under the existing rules has been carried forward under the proposed rules for purposes of evoking commentator response. Since a major objective of the Commission's reexamination of its requirements for financial statements is to ease reporting burdens in general while providing for meaningful information where necessary, the Commission solicits the views of both preparers and users of schedule information as to the

[4] Under Securities Act Release No. 6350, "Instructions for the Presentation and Preparation of Pro Forma Financial Information and Financial Statements of Companies Acquired or to be Acquired", the content of existing Article 11 was proposed to be relocated, with certain minor modifications, to a new Rule 3–04 (§ 210.3–04).

[5] Accounting Series Release No. 294, "Standardization of Financial Statement Requirements in Management Investment Company Registration Statements and Reports to Shareholders" (46 FR 36120).

usefulness of the proposed schedule requirements. Commentators are specifically encouraged to address the appropriateness of any of the existing and proposed schedule requirements, evaluating the cost burden of preparing the detailed information in relation to the usefulness of the information presented.

Detailed schedules required to be filed for registered investment companies and for which specific comment is encouraged include the following:

For Management Investment Companies

210.12-12 Investment in Securities of Unaffiliated Issuers
210.12-13 Investment—Other than Securities
210.12-14 Investments in Affiliates

For Unit Investment Trusts, and for Those Unincorporated Management Investment Companies Which Are Issuers of Periodic Payment Plan Certificates

210.12-19 Investments in Securities
210.12-20 Trust Shares

For Face-Amount Certificate Investment Companies

210.12-21 Investments in Securities of Unaffiliated Issuers
210.12-22 Investments in and Advances to Affiliates and Income Thereon
210.12-23 Mortgage Loans on Real Estate and Interest Earned on Mortgages
210.12-24 Real Estate Owned and Rental Income
210.12-25 Supplementary Profit and Loss Information
210.12-26 Certificate Reserves
210.12-27 Qualified Assets on Deposit

FASB Extraction Project

Much of the authoritative literature concerning investment companies is provided in the industry audit guide, "Audits of Investment Companies", issued by the American Institute of Certified Public Accountants ("AICPA"). This audit guide was issued in 1973 and generally has been adhered to in practice. In order to recognize subsequent changes in the industry, however, the investment company guide is scheduled for revision by the AICPA during the early part of 1982.

In 1979, the Financial Accounting Standards Board ("FASB") announced its project to extract the specialized accounting and reporting principles and practices from the AICPA Guides and Statements of Position.[6] The audit guide for investment companies will be included as part of this project. Presently, the principles and practices embodied in the AICPA guides are considered preferable accounting, but are not enforceable standards to be adhered to under Rule 2-03 of the AICPA's Code of Professional Ethics.[7] Should the extraction project be completed prior to the adoption of final Commission rules, duplicative Commission rules will be deleted.

Stock Purchase, Savings and Similar Plans

Plans Affected

A portion of Article 6 of Regulation S-X (§ 210.6-30 through § 210.6-34) applies to employee stock purchase savings and similar plans, interests in which constitute securities which are required to be registered with this Commission.[8] Such plans may include, among others, those referred to as stock purchase, savings, option, bonus, appreciation, profit-sharing, thrift, incentive and certain pension plans.

Valuation of Assets

Under the existing rules, these employee plans are permitted to reflect assets in statements of financial condition at either cost or market. It appears inappropriate to permit assets which are held by these plans to be reported on a basis different from that used to derive amounts which may be realized by the participating employees at a given point in time. The proposed rules would require that these plans reflect their investment assets at a value which (i) with respect to securities for which market quotations are readily available is market value and (ii) with respect to other securities and assets is fair value as determined in good faith by the trustee(s) (or the person or persons who exercise similar responsibilities) for the plan.

Rule 6-31.4 (§ 210.6-31.4) already requires plans which value investments at cost to disclose the market value of each type of investment. Therefore, it appears that there should be little or no incremental cost involved in reporting such investments at market. Since the Commission is concerned with the cost burden associated with its rules, specific comments are invited as to the circumstances, if any, under which the incremental costs of reporting these assets at market or fair value would be other than insubstantial.

Other Matters

Adoption of the amended rules proposed in this release would impact the references to specific provisions of Article 6, including provisions for financial statements, contained in other Articles of Regulation S-X. Appropriate changes to these references will be made in any final rules resulting from this proposal.

Text of Proposed Rules

PART 210—FORM AND CONTENT OF AND REQUIREMENTS FOR FINANCIAL STATEMENTS, SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934, PUBLIC UTILITY HOLDING COMPANY ACT OF 1935, INVESTMENT COMPANY ACT OF 1940, AND ENERGY POLICY AND CONSERVATION ACT OF 1975

Part 210 of 17 CFR Chapter II is proposed to be amended as follows:

§§ 210.6-01 through 210.6-24 [Removed]

1. By removing §§ 210.6-01 to 210.6-24 and adding new §§ 210.6-01 to 210.6-10 as follows:

Registered Investment Companies

§ 210.6-01 Application of §§ 210.6-01 to 210.6-10.

Sections 210.6-01 to 210.6-10 shall be applicable to financial statements filed for registered investment companies.

§ 210.6-02 Definition of certain terms.

The following terms shall have the meaning indicated in this rule unless the context otherwise requires. (Also see § 210.1-02 of this part.)

(a) *Affiliate.* The term "affiliate" means an "affiliated person" as defined in section 2(a)(3) of the Investment Company Act of 1940 unless otherwise indicated. The term "control" has the meaning in section 2(a)(9) of that Act.

(b) *Value.* As used in §§ 210.6-01 to 210.6-10, the term "value" shall have the meaning given in section 2(a)(41)(B) of the Investment Company Act of 1940.

(c) *Balance sheets; statements of net assets.* As used in §§ 210.6-01 to 210.6-10, the term "balance sheets" shall include statements of assets and liabilities as well as statements of net assets unless the context clearly indicates the contrary.

(d) *Qualified assets.* (1) For companies issuing face-amount certificates subsequent to December 31, 1940 under the provisions of section 28 of the Investment Company Act of 1940, the term "qualified assets" means qualified investments as that term is defined in section 28(b) of the Act. A

[6] Statement of Financial Accounting Standards No. 32, "Specialized Accounting and Reporting Principles and Practices in AICPA Statements of Position and Guides on Accounting and Auditing Matters" (September, 1979).

[7] As a result, accountants are not presently required to justify departure from financial accounting and reporting practices sanctioned by an AICPA guide or Statement of Position.

[8] Releases 33-6188 and 33-6281 dated February 1, 1980 and January 15, 1981 discuss application of the Securities Act of 1933 to employee benefit plans.

statement to that effect shall be made in the balance sheet.

(2) For other companies, the term "qualified assets" means cash and investments which such companies do maintain or are required, by applicable governing legal instruments, to maintain in respect of outstanding face-amount certificates.

(3) Loans to security holders may be included as qualified assets in an amount not in excess of certificate reserves carried on the books of account in respect of each individual certificate upon which the loans were made.

§ 210.6-03 Special rules of general application to registered investment companies.

The financial statements filed for persons to which §§ 210.6-01 to 210.6-10 are applicable shall be prepared in accordance with the following special rules in addition to the general rules in §§ 210.1-01 to 210.4-10 (Articles 1, 2, 3, and 4). Where the requirements of a special rule differ from those prescribed in a general rule, the requirements of the special rule shall be met.

(a) *Content of financial statements.* The financial statements shall be prepared in accordance with the requirements of this part (Regulation S-X) notwithstanding any provision of the articles of incorporation, trust indenture or other governing legal instruments specifying certain accounting procedures inconsistent with those required in §§ 210.6-01 to 210.6-10.

(b) *Audited financial statements.* Where, under Article 3 of this part, financial statements are required to be certified, the independent accountant shall have been selected and ratified in accordance with section 32 of the Investment Company Act of 1940, 54 Stat. 838, 15 U.S.C. 1140, and the applicable rules thereunder.

(c) *Consolidated and combined statements.*

(1) Consolidated and combined statements filed for registered investment companies shall be prepared in accordance with §§ 210.3A-01 to 210.3A-05 (Article 3A) except that (i) statements of the registrant may be consolidated only with the statements of subsidiaries which are investment companies; (ii) a consolidated statement of the registrant and any of its investment company subsidiaries shall not be filed unless accompanied by a consolidating statement which sets forth the individual statements of each significant subsidiary included in the consolidated statement: *Provided, however,* That a consolidating statement need not be filed if all included subsidiaries are totally held; and (iii) consolidated or combined statements filed for subsidiaries not consolidated with the registrant shall not include any investment companies unless accompanied by consolidating or combining statements which set forth the individual statements of each included investment company which is a significant subsidiary.

(2) If consolidating or combining statements are filed, the amounts included under each caption in which financial data pertaining to affiliates is required to be furnished shall be subdivided to show separately the amounts (i) eliminated in consolidation and (ii) not eliminated in consolidation.

(d) *Valuation of assets.* The balance sheets of registered investment companies, other than issuers of face-amount certificates, shall reflect all investments at value, with the aggregate cost of each class of investment reported under §§ 210.6-04.1, 6-04.2 and 6-04.3 and of the total investments reported under § 210.6-04.4 or § 210.6-05(b)(1) shown parenthetically. As required by section 28(b) of the Investment Company Act of 1940, "qualified" assets of face-amount certificate companies shall be valued in accordance with certain provisions of the Code of the District of Columbia. For guidance as to valuation of securities, see Accounting Series Release Nos. 113, 116, 118 and 219.

(e) *Qualified assets.* State in a note the nature of any investments and other assets maintained or required to be maintained, by applicable legal instruments, in respect of outstanding face-amount certificates. If the nature of the qualifying assets and amount thereof are not subject to the provisions of section 28 of the Investment Company Act of 1940, a statement to that effect shall be made.

(f) *Restricted securities.* State in a note the following information as to investment securities which cannot be offered for public sale without first being registered under the Securities Act of 1933 (restricted securities):

(1) The policy of the person with regard to acquisition of restricted securities.

(2) The policy of the person with regard to valuation of restricted securities. Specific comments shall be given as to the valuation of an investment in one or more issues of securities of a company or group of affiliated companies if any part of such investment is restricted and the aggregate value of the investment in all issues of such company or affiliated group exceeds five percent of the value of total assets. (As used in this paragraph, the term "affiliated" shall have the meaning given in § 210.6-02(a) of this part.)

(3) A description of the person's rights with regard to demanding registration of any restricted securities held at the date of the latest balance sheet.

(g) *Income recognition.* Dividends shall be included in income on the ex-dividend date; interest shall be accrued on a daily basis. Neither dividends nor interest shall be included unless payment is reasonably assured by past experience, guaranty or otherwise. Dividends declared on short positions existing on the record date shall be recorded on the ex-dividend date and included as an expense of the period.

(h) *Federal income taxes.* Appropriate provision shall be made on the basis of the applicable tax laws, for Federal income taxes that it is reasonably believed are, or will become, payable in respect of (1) investment income, (2) realized gain on investments and (3) unrealized appreciation on investments. The company's status as a "regulated investment company" as defined in Subtitle A, Chapter 1, Subchapter M of the Internal Revenue Code, as amended, shall be stated in a note referred to in the appropriate statements. Such note shall also indicate briefly the principal assumptions on which the company relied in making or not making provisions for income taxes. However, a company which retains realized capital gains and designates such gains as a distribution to shareholders in accordance with section 852(b)(3)(D) of the Internal Revenue Code shall, on the last day of its taxable year (and not earlier), make provision for taxes on such undistributed capital gains realized during such year.

(i) *Issuance and repurchase by a registered investment company of its own securities.* In a footnote or separate statement referred to in the balance sheet, show for each class of the company's securities:

(1) The number of shares, units, or principal amount of bonds sold during the period of report, the amount received therefor, and, in the case of shares sold by closed-end management investment companies, the difference, if any, between the amount received and the net asset value or preference in involuntary liquidation (whichever is appropriate) of securities of the same class prior to such sale; and

(2) The number of shares, units, or principal amount of bonds repurchased during the period of report and the total or average cost thereof. Closed-end management investment companies shall furnish the following additional

information as to securities repurchased during the period of report:

(i) As to bonds and preferred shares, the aggregate difference between cost and the face amount or preference in involuntary liquidation and, if applicable net assets taken at value as of the date of repurchase were less than such face amount or preference, the aggregate difference between cost and such net asset value;

(ii) As to common shares, the weighted average discount per share, expressed as a percentage, between cost of repurchase and the net asset value applicable to such shares at the date of repurchases.

The information required by paragraph (i)(2)(i) and (ii) may be based on reasonable estimates if it is impracticable to determine the exact amounts involved.

(j) *Series companies.* A person which in essence is comprised of more than one separate investment company shall include the information required by this part (Regulation S–X) on a comparative basis, except as to footnotes which need not be comparative.

(k) *Certificate reserves.* (1) For companies issuing face-amount certificates subsequent to December 31, 1940 under the provisions of section 28 of the Investment Company Act of 1940, balance sheets shall reflect reserves for outstanding certificates computed in accordance with the provisions of section 28(a) of the Act.

(2) For other companies, balance sheets shall reflect reserves for outstanding certificates determined as follows:

(i) For certificates of the installment type, such amount which, together with the lesser of future payments by certificate holders as and when accumulated at a rate not to exceed 3½ per centum per annum (or such other rate as may be appropriate under the circumstances of a particular case) compounded annually, shall provide the minimum maturity or face amount of the certificate when due.

(ii) For certificates of the fully-paid type, such amount which, as and when accumulated at a rate not to exceed 3½ per centum per annum (or such other rate as may be appropriate under the circumstances of a particular case) compounded annually, shall provide the amount or amounts payable when due.

(iii) Such amount or accrual therefor, as shall have been credited to the account of any certificate holder in the form of any credit, or any dividend, or any interest in addition to the minimum maturity or face amount specified in the certificate, plus any accumulations on any amount so credited or accrued at rates required under the terms of the certificate.

(iv) An amount equal to all advance payments made by certificate holders, plus any accumulations thereon at rates required under the terms of the certificate.

(v) Amounts for other appropriate contingency reserves, for death and disability benefits or for reinstatment rights on any certificate providing for such benefits or rights.

(l) *Inapplicable captions.* Attention is directed to the provisions of § 210.4–03 which permit the omission of separate captions in financial statements as to which the items and conditions are not present, or the amounts involved not significant. However, amounts involving directors, officers, and affiliates shall nevertheless be separately set forth except as otherwise specifically permitted under a particular caption.

§ 210.6–04 Balance sheets.

This rule is applicable to balance sheets filed by registered investment companies except for persons who substitute a statement of net assets in accordance with the requirements specified in § 210.6–05(a), and issuers of face-amount certificates which are subject to the special provisions of § 210.6–06 of this part. Balance sheets filed under this rule shall comply with the following provisions:

Assets

1. *Investments in securities of unaffiliated issuers.* State in a note to the financial statements the amount of the aggregate gross unrealized appreciation for all securities in which there is an excess of value over cost and the aggregate gross unrealized depreciation for all securities in which there is an excess of cost over value.

2. *Investment in and advances to affiliates.* State separately investments in and advances to (a) controlled companies and (b) other affiliates.

3. *Investments—other than securities.* State separately each major class.

4. *Total investments.*

5. *Cash.* Include under this caption cash on hand and demand deposits. Provide in a note to the financial statements the information required under § 210.5–02.1 regarding restrictions and compensating balances.

6. *Accounts and notes receivable.* State separately amounts receivable from (a) sales of investments; (b) subscriptions to capital shares; (c) dividends and interest; (d) directors and officers; and (e) others, showing any other category of receivables which is in excess of five percent of total assets.

7. *Deposits for securities sold short and open option contracts.* State separately amounts held by brokers and custodians in connection with (a) short sales and (b) open option contracts.

8. *Other assets.* State separately (a) prepaid and deferred expenses; (b) pension and other special funds; (c) organization expenses; and (d) any other item not properly classified in another asset caption the amount of which is in excess of five percent of total assets.

9. *Total assets.*

Liabilities

10. *Accounts payable and accrued liabilities.* State separately amounts payable for (a) securities sold short; (b) open option contracts written; (c) other purchases of securities; (d) capital shares redeemed; (e) dividends or other distributions on capital shares; and (f) others. State separately the amount of any other liabilities which is in excess of five percent of total liabilities. Securities sold short and open option contracts written shall be stated at the market value of the related security.

11. *Deposits for securities loaned.* State the market value of securities loaned and indicate the nature of the collateral held as security for the loan.

12. *Other liabilities.* State separately (a) amounts payable for investment advisory, management and service fees; and (b) the total amount payable to (1) officers and directors; (2) controlled companies; and (3) other affiliates, excluding any amounts owing to noncontrolled affiliates which arose in the ordinary course of business and which are subject to usual trade terms.

13. *Notes payable, bonds and similar debt.* (a) State separately amounts payable to (1) banks or other financial institutions for borrowings; (2) controlled companies; (3) other affiliates; and (4) others, showing for each category amounts payable within one year and amounts payable after one year.

(b) Provide in a note the information required under § 210.5–02.19(b) regarding unused lines of credit for short-term financing and §§ 210.5–02.22(a) and (b) regarding unused commitments for long-term financing arrangements.

14. *Total liabilities.*

15. *Commitments and contingent liabilities.*

Net Assets

16. *Units of capital.* (a) State on the face of the balance sheet, or if voluminous in a note, the title of each class of capital shares or other capital units, the number authorized, the number outstanding, and the dollar amount thereof.

(b) Unit investment trusts, including those which are issuers of periodic payment plan certificates, also shall state in a note to the financial statements (a) the total cost to the investors of each class of units or shares; (b) the adjustment for market depreciation or appreciation; (c) other deductions from the total cost to the investors for fees, loads and other charges, including an explanation of such deductions; and (d) the net amount applicable to the investors.

17. *Accumulated undistributed income (loss).* State on the face of the balance sheet (a) the accumulated undistributed investment income-net, (b) accumulated undistributed net realized gains (losses) on investment transactions, and (c) net unrealized appreciation (depreciation) in value of investments at the balance sheet date.

18. *Other elements of capital.* State separately any other elements of capital or residual interests appropriate to the capital structure of the reporting entity.

19. *Net assets applicable to outstanding units of capital.*

§ 210.6-05 Statements of net assets.

(a) Persons having ony one class of equity securities outstanding may substitute a statement of net assets, as prescribed in § 210.6-05(b) below, for the balance sheet otherwise required by § 210.6-04 of this part: *Provided,* That

(1) There are no amounts due from or to officers, directors, controlled persons, or affiliates other than for regular investment advisory, management, and service fees covering a period of less than 60 days prior to the end of the latest period.

(2) At the close of the latest period, there were no amounts, conditions, or transactions related to (i) securities sold short, (ii) open option contracts written, (iii) deposits for securities loaned, or (iv) agreements to repurchase portfolio securities.

(3) Neither the total of all assets other than investments in securities of unaffiliated issuers nor the total of all liabilities exceeds five percent of the amount of total assets.

(b) Statements of net assets filed for persons meeting the requirements under § 210.6-05(a) shall consist of the following:

(1) A schedule of investments in securities of unaffiliated issuers as prescribed in §§ 210.12-12 or 210.12-19, as appropriate.

(2) The excess (or deficiency) of other assets over (under) total liabilities stated in one amount.

(3) The balance of the amounts captioned as *net assets.* The number of outstanding shares and net asset value per share shall be shown parenthetically.

(4) The information required by (i) § 210.6-04.16, (ii) § 210.6-04.17 and (iii) § 210.6-04.18 shall be furnished in a note to the financial statements.

§ 210.6-06 Special provisions applicable to the balance sheets of issuers of face-amount certificates.

Balance sheets filed by issuers of face-amount certificates shall comply with the following provisions:

Assets

1. *Investments.* State separately each major class: such as, real estate owned, first mortgage loans on real estate, other mortgage loans on real estate, investments in securities of unaffiliated issuers, and investments in and advances to affiliates.

2. *Cash.* Include under this caption cash on hand and demand deposits. Provide in a note to the financial statements the information required under § 210.5-02.1 regarding restrictions and compensating balances.

3. *Accounts and notes receivable.* State separately amounts receivable from (a) sales of investments; (b) dividends and interest; (c) directors and officers; and (d) others, showing any other category of receivables which is in excess of five percent of total assets.

4. *Total qualified assets.* State in a note to the financial statements the amount of qualified assets on deposit classified as to general classes of assets and as to general types of depositories, such as banks and states, together with a statement as to the purpose of the deposits.

5. *Other assets.* State separately (a) investments in securities of unaffiliated issuers not included in qualifying assets in item 1 above; (b) investments in and advances to affiliates not included in qualifying assets in item 1 above; and (c) any other item not properly classified in another asset caption the amount of which is in excess of five percent of total assets.

6. *Total assets.*

Liabilities

7. *Certificate reserves.* Issuers of face-amount certificates shall state separately reserves for (a) certificates of the installment type; (b) certificates of the fully-paid type; (c) advance payments; (d) additional amounts accrued for or credited to the account of certificate holders in the form of any credit, dividend, or interest in addition to the minimum amount specified in the certificate; and (e) other certificate reserves. State in an appropriate manner the basis used in determining the reserves, including the rates of interest of accumulation.

8. *Notes payable, bonds and similar debt.* (a) State separately amounts payable to (1) banks or other financial institutions for borrowings; (2) controlled companies; (3) other affiliates; and (4) others, showing for each category amounts payable within one year and amounts payable after one year.

(b) Provide in a note the information required under §§ 210.5-02.19(b) regarding unused lines of credit for short-term financing and §§ 210.5-02.22 (a) and (b) regarding unused commitments for long-term financing arrangements.

9. *Accounts payable and accrued liabilities.* State separately (a) amounts payable for investment advisory, management and service fees; and (b) the total amount payable to (1) officers and directors; (2) controlled companies; and (3) other affiliates, excluding any amounts owing to noncontrolled affiliates which arose in the ordinary course of business and which are subject to usual trade terms. State separately the amount of any other liabilities which is in excess of five percent of total liabilities.

10. *Total liabilities.*

11. *Commitments and contingent liabilities.*

Stockholders' Equity

12. *Capital shares.* State on the face of the balance sheet, or if voluminous in note, the title of each class of captial shares or other capital units, the number authorized, the number outstanding and the dollar amount thereof. Show also the dollar amount of any capital shares subscribed but unissued, and show the deduction for subscriptions receivable therefrom.

13. *Other elements of capital.* (a) State separately any other elements of capital or residual interests appropriate to the capital structure of the reporting entity.

(b) A summary of each account under this caption setting forth the information prescribed in § 210.11-02 shall be given in a note or separate statement for each period in which a statement of operations is presented.

14. *Total liabilities and stockholders' equity.*

§ 210.6-07 Statements of operations.

Statements of operations filed by registered investment companies, other than issuers of face-amount certificates subject to the special provisions of § 210.6-08 of this part, shall comply with the following provisions:

1. *Investment income.* State separately income from (a) dividends; (b) interest on securities; and (c) other income. If income from investments in or indebtedness of affiliates is included hereunder, such income shall be segregated under an appropriate caption subdivided to show separately income from (1) controlled companies; and (2) other affiliates. If non-cash dividends are included in income, the bases of recognition and measurement used in respect to such amounts shall be disclosed. Any other category of income which exceeds five percent of the total shown under this caption shall be stated separately.

2. *Expenses.* (a) State separately the total amount of investment advisory, management and service fees, and expenses in connection with research, selection, supervision, and custody of investments. Amounts of expenses incurred from transactions with affiliated persons shall be disclosed together with the identity of and related amount applicable to each such person accounting for five percent or more of the total expenses shown under this caption together with a description of the nature of the affiliation. Expenses incurred within the person's own organization in connection with research, selection and supervision of investments shall be stated separately. Reductions or reimbursements of management or service fees shall be shown as a negative amount or as a reduction of total expenses shown under this caption.

(b) State separately any other expense item the amount of which exceeds five percent of the total expenses shown under this caption.

(c) A note to the financial statements shall include information concerning management and service fees, the rate of fee, and the base and method of computation. State separately the amount and a description of any fee reductions or reimbursements representing (1) expense limitation agreements or commitments; and (2) offsets received from broker-dealers showing separately for each amount received or due from (i) unaffiliated persons; and (ii) affiliated persons. If no management or service fees were incurred for a period, state the reason therefor.

(d) A note to the financial statements shall describe the basis and method of

compensating directors and other persons included in the definition in section 2(a)(12) of the Investment Company Act of 1940.

(e) If any expenses were paid otherwise than in cash, state in the details in a note.

(f) State in a note to the financial statements the amount of brokerage commissions (including dealer markups) paid to affiliated broker-dealers in connection with purchase and sale of investment securities. Open-end management companies shall state in a note the gross amount of sales charges deducted from the proceeds of sale of capital shares by the principal underwriter and the net amounts retained by any affiliated principal underwriter or other affiliated broker-dealer.

3. *Interest and amortization of debt discount and expense.*

4. *Investment income before income tax expense.*

5. *Income tax expense.* State separately (a) Federal income taxes and (b) other taxes on income applicable to investment income, distinguishing taxes payable currently from deferred income taxes.

6. *Investment income-net.*

7. *Realized and unrealized gain (loss) on investments.*

(a) State separately the net realized gain or loss on transactions in (1) investment securities of unaffiliated issuers, (2) investment securities of affiliated issuers, and (3) investments other than securities.

(b) Distributions of realized gains by other investment companies shall be shown separately under this caption.

(c) State separately (1) the gain or loss from expiration or closing of option contracts written, (2) the gain or loss on closed short positions in securities, and (3) other realized gain or loss. Disclose in a note to the financial statements the number and associated dollar amounts as to option contracts written: (a) at the beginning of the period; (b) during the period; (c) expired during the period; (d) closed during the period; (e) exercised during the period; (f) balance at end of the period.

(d) State separately the amount of the net increase or decrease during the period in the unrealized appreciation or depreciation in the value of investment securities and other investments held at the end of the period.

(e) State separately any (1) Federal income taxes and (2) other income taxes applicable to realized and unrealized gain (loss) on investments, distinguishing taxes payable currently from deferred income taxes.

8. *Net gain (loss) on investments.*

9. *Net income (loss).*

§ 210.6-08 Special provisions applicable to the statements of operations of issuers of face-amount certificates.

Statements of operations filed by issuers of face-amount certificates shall comply with the following provisions:

1. *Investment income.* State separately income from (a) interest on mortgages; (b) interest on securities; (c) dividends; (d) rental income; and (e) other investment income. If income from investments in or indebtedness of affiliates is included hereunder, such income shall be segregated under an appropriate caption subdivided to show separately income from (1) controlled companies; and (2) other affiliates. If non-cash dividends are included in income, the bases of recognition and measurement used in respect to such amounts shall be disclosed. Any other category of income which exceeds five percent of the total shown under this caption shall be stated separately.

2. *Investment expenses.* (a) State separately the total amount of investment advisory, management and service fees, and expenses in connection with research, selection, supervision, and custody of investments. Amounts of expenses incurred from transactions with affiliated persons shall be disclosed together with the identity of and related amount applicable to each such person accounting for five percent or more of the total expenses shown under this caption together with a description of the nature of the affiliation. Expenses incurred within the person's own organization in connection with research, selection and supervision of investments shall be stated separately. Reductions or reimbursements of management or service fees shall be shown as a negative amount or as a reduction of total expenses shown under this caption.

(b) State separately any other expense item the amount of which exceeds five percent of the total expenses shown under this caption.

(c) A note to the financial statements shall include information concerning management and service fees, the rate of fee, and the base and method of computation. State separately the amount and a description of any fee reductions or reimbursements representing (1) expense limitation agreements or commitments; and (2) offsets received from broker-dealers showing separately for each amount received or due from (i) unaffiliated persons; and (ii) affiliated persons. If no management or service fees were incurred for a period, state the reason therefor.

(d) A note to the financial statements shall describe the basis and method of compensating directors and other persons included in the definition in section 2(a)(12) of the Investment Company Act of 1940.

(e) If any expenses were paid otherwise than in cash, state the details in a note.

(f) State in a note to the financial statements the amount of brokerage commissions (including dealer markups) paid to affiliated broker-dealers in connection with purchase and sale of investment securities.

3. *Interest and amortization of debt discount and expense.*

4. *Investment income before income tax expense.*

5. *Income tax expense.* State separately (a) Federal income taxes and (b) other taxes on income applicable to investment income, distinguishing taxes payable currently from deferred income taxes.

6. *Provision for certificate reserves.* State separately any provision for additional credits, or dividends, or interests, in addition to the minimum maturity or face amount specified in the certificates. State also in an appropriate manner reserve recoveries from surrenders or other causes.

7. *Net investment income or loss.*

8. *Realized gain or loss on investments.*

(a) State separately the net realized gain or loss on transactions in (1) investment securities of unaffiliated issuers, (2) investment securities of affiliated issuers, and (3) other investments.

(b) Distributions of capital gains by other investment companies shall be shown separately under this caption.

(c) State separately any (1) Federal income taxes and (2) other income taxes applicable to realized gain (loss) on investments, distinguishing taxes payable currently from deferred income taxes.

9. *Net income or loss.*

§ 210.6-09 Statements of changes in net assets.

Statements of changes in net assets filed for persons to whom this article is applicable shall comply with the following provisions:

1. *From investment activities.* State separately (a) investment income-net as shown by § 210.6-07.6; (b) distributions from investment income-net; (c) balance; (d) net gain (loss) on investments as shown by § 210.6-07.8; (e) distributions from net gain on investments; and (f) balance.

2. *Net equalization charges and credits.* State the net amount of accured undivided earnings separately identified in the price of capital shares issued and repurchased.

3. *Increase or decrease in accumulated net income.*

4. *From capital share transactions.* (a) State the increase or decrease in net assets derived from the net change in the number of outstanding shares or units. The number of shares or units representing the net change shall be disclosed.

(b) Disclose in a note to the financial statements for each class of the person's shares the value of shares issued in reinvestment of dividends and distributions of net gains on investments.

5. Net assets at the beginning of the period.

6. Net assets at the end of the period.

§ 210.6-10 What schedules are to be filed.

(a) When information is required in schedules for both the person and the person and its subsidiaries consolidated, it may be presented in the form of a single schedule, provided that items pertaining to the registrant are separately shown and that such single schedule affords a properly summarized presentation of the facts. If the information required by any schedule (including the notes thereto) is shown in the related financial statement or in a note thereto without making such statement unclear or confusing, that procedure may be followed and the schedule omitted.

(b) The schedules shall be examined by an independent accountant if the related financial statements are so examined.

(c) *Management investment companies.* Except as otherwise provided in the applicable form:

(1) The schedules specified below in this rule shall be filed for management investment companies as of the dates of the most recent audited balance sheet and any subsequent unaudited statement being filed for each person or group.

Schedule I—Investments in securities of unaffiliated issuers. The schedule prescribed by § 210.12–12 shall be filed in support of caption 1 of each balance sheet.

Schedule II—Investments—other than securities. The schedule prescribed by § 210.12–13 shall be filed in support of caption 3 of each balance sheet. This schedule may be omitted if the investments, other than securities, at both the beginning and end of the period amount to less than one percent of the value of total investments (§ 210.6–04.4).

Schedule III—Investments in and advances to affiliates. The schedule prescribed by § 210.12–14 shall be filed in support of caption 2 of each balance sheet.

Schedule IV—Amounts due from directors and officers. The schedule prescribed by § 210.12–03 shall be filed with respect to each person among the directors and officers from whom any amount was owed at any time during the period for which related statements of changes in net assets are required to be filed.

Schedule V—Investments—securities sold short. The schedule prescribed by § 210.12–12A shall be filed in support of caption 10(a) of each balance sheet.

Schedule VI—Open option contracts written. The schedule prescribed by § 210.12–12B shall be filed in support of caption 10(b) of each balance sheet.

Schedule VII—Short-term borrowings. The schedule prescribed by § 210.12–10 shall be filed in support of any amounts included in caption 13 of each balance sheet, which are payable within one year to banks for borrowings; factors and other financial institutions for borrowings; and holders of any short-term notes.

(d) *Unit investment trusts.* Except as otherwise provided in the applicable form:

(1) Scheduled I, II, and IV, specified below in this section, shall be filed for unit investment trusts as of the dates of the most recent auditied balance sheet and any subsequent unaudited statement being filed for each person or group.

(2) Schedules III and V, specified below in this section, shall be filed for unit investment trusts for each period for which a statement of operations is required to be filed for each person or group.

Schedule I—Investment in securities. The schedule prescribed by § 210.12–19 shall be filed in support of caption 1 of each balance sheet (§ 210.6–04) or caption (b)(1) of each statement of net assets (§ 210.6–05), as appropriate, and of captions 1(a), and 1(b), and 7(b) of each statement of operations.

Schedule II—Trust shares. The schedule prescribed by § 210.12–20 shall be filed in support of caption 16 of each balance sheet (§ 210.6–04) or caption 4(i) of each statement of net assets (210.6–05).

Schedule III—Gain or loss from transactions in trust property. A schedule shall be filed showing for each investment set forth in Schedule I in which there were any sales or redemptions during the period: (a) the aggregate amount received from sale; (b) the aggregate cost of the investment sold; and (c) the realized gain or loss thereon.

Schedule IV—Allocation of trust assets to series of trust shares. If the trust assets are specifically allocated to different series of trust shares, and if such allocation is not shown in the balance sheet in columnar form or by the filing of separate statements for each series of trust shares, a schedule shall be filed showing the amount of trust assets, indicated by each balance sheet condition filed, which is applicable to each series of trust shares.

Schedule V—Allocation of trust income and distributable funds to series of trust shares. If the trust income and distributable funds are specifically allocated to different series of trust shares and if such allocation is not shown in the statement of income and distributable funds in columnar form or by the filing of separate statements for each series of trust shares, a schedule shall be submitted showing the amount of income and distributable funds, indicated by each statement of operations filed, which is applicable to each series of trust shares.

(e) *Face-amount certificate investment companies.* Except as otherwise provided in the applicable form:

(1) Schedules I, V and X, specified below, shall be filed for face-amount certificate investment companies as of the dates of the most recent audited balance sheet and any subsequent unaudited statement being filed for each person or group.

(2) All other schedules specified below in this section shall be filed for face-amount certificate investment companies for each period for which a statement of operations is filed, except as indicated for Schedules III and IV.

Schedule I—Investment in securities of unaffiliated issuers.—The schedule prescribed by § 210.12–21 shall be filed in support of caption 1 and, if applicable, caption 5(a) of each balance sheet. Separate schedules shall be furnished in support of each caption, if applicable.

Schedule II—Investments in and advances to affiliates and income thereon. The schedule prescribed by § 210.12—22 shall be filed in support of captions 1 and 5(b) of each balance sheet and caption 1 of each statement of operations. Separate schedules shall be furnished in support of each caption, if applicable.

Schedule III—Mortgage loans on real estate and interest earned on mortages. The schedule prescribed by § 210.12—23 shall be filed in support of captions 1 and 5(c) of each balance sheet and caption 1 of each statement of operations, except that only the information required by column G and note 8 of the schedule need be furnished in support of statements of operations for years for which related balance sheets are not required.

Schedule IV—Real estate owned and rental income. The schedule prescribed by § 210.12—24 shall be filed in support of captions 1 and 5(a) of each balance sheet and caption 1 of each statement of operations for rental income included therein, except that only the information required by columns H, I and J, and item "Rent from properties sold during the period" and note 4 of the schedule need be furnished in support of statements of operations for years for which related balance sheets are not required.

Schedule V—Qualified assets on deposit. The schedule prescribed by § 210.12—27 shall be filed in support of the information required by caption 4 of § 210.6–06 as to total amount of qualified assets on deposit.

Schedule VI—Amounts due from officers and directors. The schedule prescribed by § 210.12—03 shall be filed with respect to each director, officer, or employee from whom any amount was owned at any time during the period for which related statements of operation are filed. State if an exemption has been granted by the Commission with respect to amounts included in this schedule.

Schedule VII—Short-term borrowings. The schedule prescribed by § 210.12—10 shall be filed in support of any amounts included in caption 8 of each balance sheet which are payable within one year to banks for borrowings; factors and other financial institutions for borrowings; and holders of any short-term notes.

Schedule VIII—Indebtedness to affiliates—not current. The schedule prescribed by § 210.12—05 shall be filed in support of any amounts included in caption 9 of each balance sheet. This schedule and Schedule II may be combined if desired.

Schedule IX—Supplementary profit and loss information. The schedule prescribed by § 210.12—25 shall be filed in support of each statement of operations.

Schedule X—Guarantees of securities of other issuers. The schedule prescribed by § 210.12—08 shall be filed with respect to any guarantees of securities of other issuers by the person for which the statement is filed.

Schedule XI—Certificate reserves. The schedule prescribed by § 210.12—26 shall be filed in support of caption 7 of each balance sheet.

Schedule XII—Valuation and qualifying accounts. The schedule prescribed by § 210.12—09 shall be filed in support of all other reserves included in the balance sheet.

Employee Stock Purchase, Savings and Similar Plans

2. By removing § 210.6–30 and adding a new § 210.6A–01 as follows:

§§ 210.6A–01 Application of §§ 210.6A–01 to 210.6A–05.

(a) Sections §§ 210.6A–01 to 210.6A–05 shall be applicable to financial

statements filed for employee stock purchase, savings and similar plans.

3. By removing § 210.6–31 and adding a new § 210.6A–02 as follows:

§ 210.6–31 [Removed]

§ 210.6A–02 Special rules applicable to employee stock purchase, savings and similar plans.

The financial statements filed for persons to which this article is applicable shall be prepared in accordance with the following special rules in addition to the general rules in §§ 210.1–01 to 210.4–10. Where the requirements of a special rule differ from those prescribed in a general rule, the requirements of the special rule shall be met.

(a) *Investment programs.* If the participating employees have an option as to the manner in which their deposits and contributions may be invested, a description of each investment program shall be given in a footnote or otherwise. The number of employees under each investment program shall be stated.

(b) *Net asset value per unit.* Where appropriate, the number of units and the net asset value per unit shall be given by footnote or otherwise.

(c) *Federal income taxes.* (1) Appropriate provision shall be made, on the basis of the applicable tax laws, for Federal income taxes that it is reasonably believed are, or will become, payable in respect of (i) current net income, (ii) realized net gain on investments, and (iii) unrealized appreciation on investments. If the plan is not subject to Federal income taxes, a note shall so state indicating briefly the principal assumptions on which the plan relied in not making provision for such taxes.

(2) State the Federal income tax status of the employee with respect to the plan.

(d) *Valuation of assets.* The statement of financial condition shall reflect all investments at value, showing cost parenthetically. For purposes of this rule, the term "value" shall mean (1) market value for those securities having readily available market quotations and (2) fair value as determined in good faith by the trustee(s) for the plan (or by the person or persons who exercise similar responsibilities) with respect to other securities and assets.

§§ 210.6–32, 210.6–33, 210.6–34 as §§ 210.6A–03, 210.6A–04 and 210.6A–05 [Redesignated]

4. By redesignating §§ 210.6–32, 210.6–33, and 210.6–34, as §§ 210.6A–03, 210.6A–04, and 210.6A–05, respectively.

5. By revising § 210.12–12 and adding new §§ 210.12–12A and 210.12–12B to read as follows:

§ 210.12–12 Investments in securities of unaffiliated issuers.

[For management investment companies only]

Column A	Column B	Column C
Name of issuer and title of issue [1] and [2].	Balance held at close of period. Number of shares principal amount of bonds and notes.	Value of each item at close of period. [3] [5] [6] [7] [8]

[1] Each issue shall be listed separately: *Provided,* however, that an amount not exceeding five percent of the total of Column C may be listed in one amount as "Miscellaneous securities," provided the securities so listed are not restricted, have been held for not more than one year prior to the date of the related balance sheet, and have not previously been reported by name to the shareholders of the person for which the statement is filed or to any exchange, or set forth in any registration statement, application, or annual report or otherwise made available to the public.

[2] List separately (a) common shares; (b) preferred shares; (c) bonds and notes; (d) time deposits; and (e) put and call options purchased. Within each of these subdivisions, classify in an appropriate manner according to type of business; e.g., aerospace, banking, chemicals, machinery and machine tools, petroleum, utilities, etc.; or according to type of instrument; e.g., commercial paper, bankers' acceptances, certificates of deposit. Restricted securities shall not be combined with unrestricted securities of the same issuer. Repurchase agreements shall be stated separately showing for each the name of bank or broker-dealer from whom purchased, stipulated interest rate, repurchase date and description of collateral securities. The totals for each class of investments, subdivided by business grouping or instrument type, shall be shown together with their percentage value compared to net assets (§§ 210.6–04(19) or 210.6–05(b)(3)).

[3] Column C shall be totaled. The total of column C shall agree with the correlative amounts shown on the related balance sheet.

[4] Indicate by an appropriate symbol each issue of securities which is non-income producing. Evidences of indebtedness and preferred shares may be deemed to be income producing if, on the respective last interest payment date or date for the declaration of dividends prior to the date of the related balance sheet, there was only a partial payment of interest or a declaration of only a partial amount of the dividends payable; in such case, however, each such issue shall be indicated by an appropriate symbol referring to a note to the effect that, on the last interest or dividend date, only partial interest was paid or partial dividends declared. If, on such respective last interest or dividend date, no interest was paid or no cash or in kind dividends declared, the issue shall not be deemed to be income producing. Common shares shall not be deemed to be income producing unless, during the last year preceding the date of the related balance sheet, there was at least one dividend paid upon such common shares.

[5] Indicate by an appropriate symbol each issue of restricted securities. State the followng in a footnote: (a) as to each such issue (1) acquisition date, (2) carrying value per unit of investment at date of related balance sheet, e.g., a percentage of current market value of unrestricted securities of the same issuer, etc., and (3) the cost of such secunties; (b) as to each issue acquired during the year preceding the date of the related balance sheet, the carrying value per unit of investment of unrestricted securities of the same issuer at (1) the day the purchase price was agreed to and (2) the day on which an enforceable right to acquire such securities was obtained; and (c) the aggregate value of all restricted securities and the percentage which the aggregate value bears to net assets.

[6] Indicate by an appropriate symbol each issue of securities subject to option.

[7] Where value is determined on any basis other than closing prices reported on a national securities exchange, explain such other basis in a footnote.

[8] State in a footnote the aggregate cost for Federal tax purposes.

§ 210.12–12A Investments—securities sold short.

[For management investment companies only]

Column A	Column B	Column C
Name of issuer and title issue [1].	Balance short position at close of period. (Number of shares).	Value of each open short position. [2] [3]

[1] Each issue shall be listed separately.

[2] Column C shall be totaled. The total of column C shall agree with the correlative amounts shown on the related balance sheet.

[3] Where value is determined on any basis other than closing prices reported on a national securities exchange, explain such other basis in a footnote.

§ 210.12–12B Open option contracts written.

[For management investment companies only]

Column A	Column B	Column C	Column D	Column E
Name of issuer [2].	Number of contracts [3].	Exercise price.	Expiration date.	Value. [4]

[1] Information as to put options shall be shown separately from information as to call options.

[2] Options of an issuer where exercise prices or expiration dates differ shall be listed separately.

[3] If the number of shares subject to option is substituted for number of contracts, the column name shall reflect that change.

[4] Column E shall be totaled and shall agree with the correlative amount shown on the related balance sheet.

6. By revising § 210.12–13 as follows:

§ 210.12–13 Investments other than securities.

[For management investment companies only]

Column A	Column B	Column C	Column D	Column E	Column F
Description [1]	Value of each item at beginning of period—quantity. [2]	Value of gross purchases and additions made during period—quantity. [3]	Gross sales and reductions during period—quantity. [3]	Balance held at close of period—quantity. [2] [3] [4] [5]	Value of each item at close of period. [6] [7] [8]

[1] The required information is to be given as to all investments which were held at any time during the period. List each major class of investments by descriptive title.

[2] If practicable, indicate the quantity or measure in appropriate units.

[3] Indicate by an appropriate symbol each investment which is non-income producing.

[4] Indicate by an appropriate symbol each investment not readily marketable. The term "investment not readily marketable" shall include investments for which there is no independent publicly quoted market and investments which cannot be sold because of restrictions or conditions applicable to the investment or the company.

[5] Indicate by an appropriate symbol each investment subject to option. State in a footnote (a) the quantity subject to option, (b) nature of option contract, (c) option price, and (d) dates within which options may be exercised.

[6] Column F shall be totaled and shall agree with the correlative amount shown on the related balance sheet.

[7] State the basis of determining value.

[8] State in a footnote the aggregate cost for Federal income tax purposes.

7. By revising § 210.12–14 as follows:

§ 210.12–14 Investments in and advances to affiliates.

[For management investment companies only]

Column A	Column B	Column C	Column D	Column E
Name of issuer and title of issue or nature of indebtedness [1].	Number of shares—principal amount of bonds, notes and other indebtedness held at close of period.	Amount of equity in net profit and loss for the period [2] [6].	Amount of dividends or interest [2] [5]..... (1) Credited to income..... (2) Other.....	Value of each item at close of period [2] [3]

[1] (a) List each issue separately and group (1) investments in majority-owned subsidiaries, segregating subsidiaries consolidated; (2) other controlled companies; and (3) other affiliates. Give totals for each group. If operations of any controlled companies are different in character from those of the company, group such affiliates (1) within divisions and (2) by type of activities.
(b) If during the period there has been any increase or decrease in the amount of investment in and advance to any affiliate, state in a footnote (or if there have been changes to numerous affiliates, in a supplementary schedule) (1) name of each issuer and title of issue or nature of indebtedness; (2) balance at beginning of period; (3) gross additions; (4) gross reductions; (5) balance at close of period as shown in Column E. Include in the footnote or schedule comparable information as to affiliates in which there was an investment at any time during the period even though there was no investment at the close of the period of report.
[2] Columns C, D and E shall be totaled. The totals of Column E shall agree with the correlative amount shown on the related balance sheet.
[3] State the basis of determining the value of each item in Column E.
[4] (a) Indicate by an appropriate symbol each issue of restricted securities. The information required by instruction 5 of § 210.12–12 shall be given in a footnote.
(b) Indicate by an appropriate symbol each issue of securities subject to option. The information required by instruction 5 of § 210.12–13 shall be given in a footnote.
[5] (a) Include in Column d (1) as to each issue held at the close of the period, the dividends or interest included in caption 1 of the statement of operations. In addition, show as the final item in Column D (1) the aggregate of dividends and interest included in the statement of operations in respect of investments in affiliates not held at the close of the period. The total of this column shall agree with the correlative amount shown on the related statement of operations.
(b) Include in Column D (2) all other dividends and interest. Explain in an appropriate footnote the treatment accorded each item.
(c) Indicate by an appropriate symbol all non-cash dividends and explain the circumstances in a footnote.
(d) Indicate by an appropriate symbol each issue of securities which is non-income producing.
[6] The information required by Column C shall be furnished only as to controlled companies.

8. By revising § 210.12–19 as follows:

§ 210.12–19 Investments in securities.[1]

[For issuers of periodic payment plan certificates and unit investment trusts]

Part 1					Part 2			
Column A	Column B	Column C	Column D	Column E	Column F	Column G	Column H	Column I
Name of issuer and title of issue [2].	Market value at beginning of period. Number of shares—principal amount of bonds and notes.	Gross purchases and additions as to each issue during period. Number of shares—principal amount of bonds and notes [3].	Gross sales and reductions as to each issue during period. Number of shares—principal amounts of bonds and notes.	Balance held at close of period. Number of shares—principal amount of bonds and notes.	Market value of each issue at close of period [4] [5] [7].	Distribution received on trust shares.	Dividends on other shares [6].	Interest.

[1] The required information is to be given as to each issue of securities held at any time during the period.
[2] Group separately (a) shares of investment companies, and (b) other securities. As to securities set forth in group (a), list separately (1) trust shares in trusts created or serviced by the depositor or sponsor of this trust; (2) trust shares in other trusts; and (3) securities of other investment companies. As to securities set forth in group (b), list (1) evidences of indebtedness; (2) preferred shares; (3) common shares; and (4) other securities. Within each of these subdivisions classify according to type of business insofar as possible, e.g., railroads, utilities, banks, insurance companies, industrials. Give totals of each group, subdivision, and class.
[3] Describe briefly the nature of any additions otherwise than through cash purchases.
[4] Column F shall be totaled. The total of Column F at the close of the most recent period shall agree with the related caption in the balance sheet.
[5] If market value is determined on any basis other than closing prices reported on any national securities exchange, explain such other basis in a note.
[6] Identify all dividends other than cash taken up in income, and state the basis on which so taken up.
[7] State in a footnote the aggregate cost for purposes of the Federal income tax.

9. By revising § 210.12–20 as follows:

§ 210.12–20 Trust shares.

For all Issuers of Periodic Payment Plan Certificates and unit investment trusts:

1. Amount at which ——— trust shares were carried at beginning of period (Notes 1, 2)..... $
2. Additions during period resulting from:
   (a) Creation of ——— trust shares (Note 1).....
   (b) Allocations of investment income-net and realized gains.....
   (c) Unrealized appreciation (depreciation) in underlying trust property (Note 2).....
   (d) Other additions (Note 3).....
3. Total additions.....
4. Deductions during period resulting from:
   (a) Surrender and cancellation of ——— trust shares (Note 1).....
   (b) Other distributions (or transfers to distributable funds) of amounts credited to trust shares.....
   (c) Other deductions (note 4).....
5. Total deductions.....
6. Amount at which ——— trust shares were carried at end of period (Notes 1, 5)..

NOTES

1. Insert the applicable number of trust shares.
2. State the basis of determining the amount.
3. State separately each significant item.
4. State separately all significant items. If market depreciation of underlying trust property is included, the amount thereof shall be shown separately. Expenses required to be set forth in the statement of operations shall not be set forth here.
5. The balance at the close of the most recent period shall agree with caption 16 of the related balance sheet.

These amendments are proposed to be effective for fiscal periods ending after June 30, 1982.

[Secs. 7, 8, and 19(a) of the Securities Act of 1933 (15 U.S.C. 77g, 77h, and 77s(a)); sections 12, 13, 15(d) and 23(a) of the Securities Exchange Act of 1934 (15 U.S.C. 781, 78m, 78o(d), 78w); and sections 8, 30(d), 31(c), and 38(a) of the Investment Company Act of 1940 (15 U.S.C. 80a–8, 80a–29(d), 80a–30(c), and 80a–37(a))]

In addition, the Commission is mindful of the cost to registrants and others of its proposals and recognizes its responsibilities to weigh with care the costs and benefits which result from its rules. Accordingly, the Commission specifically invites comments on the costs of registrants and others of the adoption of the proposals published herein.

By the Commission.

George A. Fitzsimmons,

Secretary.

January 11, 1982.

Regulatory Flexibility Act Certification

I, John S.R. Shad, Chairman of the Securities and Exchange Commission, hereby certify, pursuant to 5 U.S.C. 605(b) that the proposed amendments contained in Securities Act Release No. 33–6374 which revise the financial statement requirements for registered investment companies will not have a significant economic impact on any entity subject to its provisions and, therefore, will not have a significant economic impact on a substantial number of small entities. The reason for this certification is that it is anticipated that the effects of the proposed amendments will not be significant for any class of registrants because the compliance burden is not being increased and the required information is generally available from existing accounting records or otherwise available to the affected companies.

John S.R. Shad,

Chairman.

January 11, 1982.

[FR Doc. 82-1225 Filed 1-18-82; 8:45 am]

BILLING CODE 8010-01-M

Notices

Federal Register
Vol. 47, No. 12
Tuesday, January 19, 1982

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.

COMMISSION ON CIVIL RIGHTS

Alabama Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Alabama Advisory Committee to the Commission will convene at 1:30 p.m., and will end at 2:30 p.m., on February 25, 1982, at the Holiday Inn-State Capitol, 924 Madison Avenue, in the Banquet A Room, Montgomery, Alabama, 36104. The purpose of this meeting is to conduct a press conference to release a report on the Voting Rights involving the Southern Region of the United States.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Marie Jamison, 3328 Dell Road, Birmingham, Alabama, 35223, (205) 872-0283 or the Southern Regional Office, Citizens Trust Bank Building, 75 Piedmont Avenue, N.E., Room 362, Atlanta, Georgia, 30303, (404) 221-4391.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., January 13, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-1228 Filed 1-18-82; 8:45 am]

BILLING CODE 6335-01-M

Georgia Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Georgia Advisory Committee to the Commission will convene at 2:00 p.m., and will end at 6:00 p.m., on February 25, 1982, at the Peachtree Plaza Hotel, Peachtree and International Boulevard, Tower Meeting Room Number 7, Atlanta, Georgia, 30343. The purpose of this meeting is to have a press conference to release the Voting Rights Report, and to discuss program planning for fiscal year 1982.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Clayton Sinclair, 5095 Dublin Drive, N.W., Atlanta, Georgia 30305, (404) 349-3861 or the Southern Regional Office, Citizens Trust Bank Building, 75 Piedmont Avenue, N.E., Room 362, Atlanta, Georgia 30303.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., January 13, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-1229 Filed 1-18-82; 8:45 am]

BILLING CODE 6335-01-M

Illinois Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Illinois Advisory Committee to the Commission will convene at 10:00 a.m., and will end at 3:00 p.m., on February 8, 1982, at the John C. Kluczynski Federal Building, 230 South Dearborn Street, Room 3280, Chicago, Illinois 60604. The purpose of this meeting is to discuss the draft report on the Housing Consultation, and the impact of budget cuts on civil rights issues.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Thomas Pugh, 500 West Melbourne Avenue, Peoria, Illinois 61604, (309) 686-3121 or the Midwestern Regional Office, 230 South Dearborn Street, 32nd Floor, Chicago, Illinois 60604, (312) 353-7479.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., January 13, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-1230 Filed 1-18-82; 8:45 am]

BILLING CODE 6335-01-M

Maryland Advisory Committee; Amendment to Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights that a meeting of the Maryland Advisory Committee of the Commission originally scheduled for January 19, 1982, at Silver Spring, Maryland, (FR Doc. 81-36078, page 61495) has been changed.

The meeting now will be held on January 27, 1982, beginning at 6:00 p.m., and will end at 10:00 p.m., at the Maryland National Capital Parks and Planning Commission, in the Auditorium, 8787 Georgia Avenue, Silver Spring, Maryland, 20907.

Dated at Washington, D.C., January 13, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-1231 Filed 1-18-82; 8:45 am]

BILLING CODE 6335-01-M

Mississippi Advisory Committee; Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Mississippi Advisory Committee to the Commission will convene at 2:00 p.m., and will end at 6:00 p.m., on February 25, 1982, at the Holiday Inn, Downtown, 200 East Amite, in the Willow Room, Jackson, Mississippi, 39205. The purpose of this meeting is to have a press conference to release the Voting Rights Report from the Southern Region, and to discuss program planning for fiscal year 1982.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Mary Ramberg, 1514 Gay Street, Jackson, Mississippi, 39211, (601) 355-1175 or the Southern Regional Office, Citizens Trust Bank Building, 75 Piedmont Avenue, N.E., Room 362, Atlanta, Georgia, 30303, (404) 221-4391.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., January 13, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82-1232 Filed 1-18-82; 8:45 am]

BILLING CODE 6335-01-M

New Mexico Advisory Committee; The Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the New Mexico Advisory Committee to the Commission will convene at 10:0 a.m., and will end at 4:00 p.m., on February 6, 1982, at the Sheraton Inn, I–25, 750 North Street, Francis Drive, in the Board Room, Santa Fe, New Mexico, 87501. The purpose of this meeting is to conduct orientation for the new members of the Committee, and to discuss program planning for FY'82.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Honorable Roberto A. Mondragon, Lieutenant Governor's Office, State Capitol, Room 425, Santa Fe, New Mexico, 87503, (505) 827–2513 or the Southwestern Regional Office, Heritage Plaza, 418 South Main, San Antonio, Texas, 78204, (512) 229–5570.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., January 13, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82–1233 Filed 1–18–82; 8:45 am]

BILLING CODE 6335–01–M

North Carolina Advisory Committee: Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the North Carolina Advisory Committee to the Commission will convene at 1:00 p.m., and will end at 4:00 p.m., on February 18, 1982, at the Holiday Inn—Four Seasons, in the Board Room, 2131 High Point Road, Greensboro, North Carolina, 27402. The purpose of this meeting is to discuss program planning for FY'82, and to report on the Greensboro Race Relations study.

Persons desiring additional information or planning a presentation to the Committee, should contact the Chairperson, Tommie Young, 4303 King Arthur Place, Greensboro, North Carolina, 27405, (919) 379–7783 or the Southern Regional Office, Citizens Trust Bank Building, 75 Piedmont Avenue, N.W., Room 362, Atlanta, Georgia, 30303, (404) 221–4391.

The meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., January 13, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82–1234 Filed 1–18–82; 8:45 am]

BILLING CODE 6335–01–M

Tennessee Advisory Committee; Amendment to Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights that a meeting of the Tennessee Advisory Committee of the Commission originally scheduled for January 29, 1982, at Knoxville, Tennessee, (FR Doc. 82–743, on page 1316) has been changed.

The meeting now will be held on January 22, 1982, beginning at 2:30 p.m., and will end at 6:30 p.m., at the Hyatt Regency Knoxville, 500 Hill Avenue, in the James Polk Room, Knoxville, Tennessee 37915.

Dated at Washington, D.C., January 13, 1982.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 82–1235 Filed 1–18–82; 8:45 am]

BILLING CODE 6335–01–M

DEPARTMENT OF COMMERCE

International Trade Administration

Prestressed Concrete Steel Wire Strand From South Africa; Postponement of Preliminary Countervailing Duty Determination

AGENCY: International Trade Administration, Commerce.

ACTION: Postponement of preliminary countervailing duty determination.

SUMMARY: The preliminary determination on prestressed concrete steel wire strand (PC strand) from South Africa is being postponed. We intend to issue the determination not later than April 8, 1982.

EFFECTIVE DATE: January 19, 1982.

FOR FURTHER INFORMATION CONTACT: Paul Thran, Office of Investigations, Import Administration, U.S. Department of Commerde, 14th and Constitution Avenue, N.W., Washington, D.C. 20230 (202) 377–1276.

SUPPLEMENTARY INFORMATION: On December 4, 1981, we announced our initiation of a countervailing duty investigation to determine whether the government of South Africa is giving its producers and exporters of PC strand certain benefits that are bounties or grants within the meaning of section 303 of the Tariff Act of 1930, as amended ("the Act"). The notice stated that we would issue a preliminary determination by February 2, 1982.

As detailed in the notice of initiation of the countervailing duty investigation, the petition alleges that numerous subsidy programs are provided by the government of South Africa to producers and exporters of PC strand. The alleged subsidy programs are numerous and raise complex issues. Moreover, it is difficult to determine the extent of utilization of these programs. We have determined that the South African government and the other parties concerned are cooperating and that additional time is necessary to make the preliminary determination. For these reasons we determine that this case is extraordinarily complicated in accordance with section 703(c)(1)(B) of the Act and we intend to issue a preliminary determination not later than April 8, 1982.

This notice is published pursuant to section 703(c)(2) of the Act.

Leonard M. Shambon,

Acting Deputy Assistant Secretary for Import Administration.

[FR Doc. 82–1226 Filed 1–18–82; 8:45 am]

BILLING CODE 3510–25–M

ENVIRONMENTAL PROTECTION AGENCY

[WH–5–FRL–2032–3]

Aquifer System in Eastern Wisconsin: Request for EPA Determination Regarding Aquifer System

AGENCY: Environmental Protection Agency.

ACTION: Notice of comment period extension.

SUMMARY: The Environmental Protection Agency, Region V, announces the extension of the public comment period for the Wisconsin sole or principal drinking water source petition (**Federal Register**; November 13, 1981, page 56039). Comments should be directed toward technical information in support or against the petitioned area.

DATES: Comments will be accepted until January 22, 1982. At least 45 days notice will be given before any public hearing that may be held.

ADDRESS: Written comments, requests for public hearing, and data should be sent to Region 5, Environmental Protection Agency, 230 South Dearborn Street, Chicago, Illinois 60604, ATTN: 5WWS, Wisconsin Aquifer Petition.

FOR FURTHER INFORMATION CONTACT: Karen Theisen, Water Supply Branch, at

the above address or telephone (312) 886-6190. Copies of the petition are available upon request.

Dated: December 31, 1981.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 82-1253 Filed 1-18-82; 8:45 am]

BILLING CODE 6560-38-M

FEDERAL RESERVE SYSTEM

[Docket No. R-0382]

Fee Schedules for Federal Reserve Bank Services

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed 1982 fee schedules for wire transfer and net settlement services.

SUMMARY: The Monetary Control Act of 1980 (Title I of Public Law 96-221) requires that schedules of fees be established for Federal Reserve Bank services. The Board adopted a fee schedule for 1981 for wire transfer and net settlement services effective January 29, 1981. The Board now seeks comment on a new fee structure and new prices for these services to be implemented in 1982.

DATE: Interested parties are invited to submit relevant data, views and other comments by February 10, 1982. Comments should be addressed to: William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, N.W., Washington, D.C., 20551 and should refer to Docket No. R-0382. Comments received may be inspected in Room B-1122 between 8:45 a.m. and 5:15 p.m., except as provided in section 261.6(a) of the Board's Rules Regarding Availability of Information (12 CFR 261.6(a)).

FOR FURTHER INFORMATION CONTACT: Lorin S. Meeder, Associate Director for Federal Reserve Bank Operations (202/452-2738); Earl G. Hamilton, Assistant Director for Federal Reserve Bank Operations (202/452-3879); Elliott C. McEntee, Assistant Director for Federal Reserve Bank Operations (202/452-2231); Paul P. Burik, Economist (202/452-2687); Gilbert T. Schwartz, Associate General Counsel (202/452-3625); Daniel L. Rhoads, Attorney (202/452-3711).

SUPPLEMENTARY INFORMATION: The Monetary Control Act of 1980 requires that fee schedules be developed for Federal Reserve Bank services based on pricing principles established by the Board. The Board, in accordance with the requirements of the Act, published for comment proposed pricing principles and fee schedules for services on August 28, 1980 (45 FR 58689). On December 30, 1980, after considering the comments received from the public, the Board adopted revised pricing principles and fee schedules for wire transfer and net settlement services (46 FR 1338). The wire transfer and net settlement fee schedules were effective January 29, 1981. The 1981 fee schedule for the wire transfer service provided for a basic origination charge of $0.80 per origination plus a $2.70 surcharge for off-line origination and a $1.80 surcharge for telephone advice, when requested. A basic charge of $1.80 for telephone advice to off-line receivers became effective March 26, 1981. The net settlement fee schedule paralleled the fee schedule for wire transfers with a basic settlement charge of $0.80 per settlement and a surcharge of $2.70 when the settlement is originated off-line. A surcharge of $1.80 was established where telephone advice was requested.

The Act requires that "[o]ver the long run fees shall be established on the basis of all direct and indirect costs actually incurred in providing the Federal Reserve services priced . . . except that the pricing principles shall give due regard to competitive factors and the provision of an adequate level of such services nationwide." The Act also requires that fees for Federal Reserve services take into account "the taxes that would have been paid and the return on capital that would have been provided had the services been furnished by a private business firm." This markup is referred to as the private sector adjustment factor (PSAF). In establishing 1981 prices for Federal Reserve Bank services, the Board used a private sector adjustment factor of 16 percent based on methodology explained in the Board's announcement of December 31, 1980. At that time, the Board stated that it would review the PSAF annually and would adjust it as appropriate. Using a methodology substantially similar to that used to device the 1981 PSAF, the Board has adopted a private sector adjustment factor of 16 percent to be used in developing 1982 fee schedules for price Federal Reserve Bank services. This PSAF of 16 percent was used to develop the proposed 1982 fee structure for wire transfer and net settlement services.

The proposed fees for the wire transfer service reflect estimated 1982 costs of providing the service plus a 16 percent PSAF. In general, 1982 wire transfer fees will increase from 1981 fees. Additionally, the proposed fee schedule reflects structural changes from the 1981 fee schedule. The Board proposed to charge both the sender and the receiver for each wire transfer of funds. The Board believes that imposition of a charge on receivers is appropriate since receivers benefit from the Federal Reserve's wire transfer service in the form of immediate availability and irrevocability of funds transferred by wire. Additionally, many receivers request that senders use the Federal Reserve wire to transfer funds. The proposed charge for receivers is based on an even sharing between receivers and senders of the Reserve Banks' costs plus PSAF for basic wire transactions.

The Board also proposes to impose a surcharge for interdistrict wire transfers. Interdistrict wire transfers are generally more costly than intradistrict transfers and imposing the surcharge would permit the System to recover the additional costs (labor, lines, computer, accounting and adjustment costs) generally incurred by such transfers. This price differential would also be more equitable to local users.

The proposed fee structure for the wire transfer service for 1982 is as follows:

(1) Originator pays $0.65 per transfer.

(2) Receiver pays $0.65 per transfer.

(3) Originator pays a $0.15 surcharge per interdistrict transfer.

(4) Surcharges for off-line origination and telephone advice will be increased to $3.50 and $2.25, respectively.

The 1981 fee schedule for the net settlement service paralleled the 1981 fee schedule for the wire transfer service. The Board proposes to separate the fee schedules for these two services in recognition of the different costs involved and the fact that these services create different rights and responsibilities for the System and its customers. Therefore, the Board proposes the following 1982 fee schedule for the net settlement service:

(1) $1.30 per intradistrict settlement entry *or* $1.45 per interdistrict entry, plus

(2) $5.00 per off-line settlement, plus

(3) $2.25 per telephone advice (if requested).

The fee for on-line settlement will be determined by whether the entry is intradistrict or interdistrict with the fee being $1.30 or $1.45, respectively. This fee structure is based on estimated 1982 costs of providing the service plus a 16 percent PSAF. The Board also proposes to permit Reserve Banks to negotiate higher fees for those net settlement arrangements that create unique or unusual expenses, subject to review.

By order of the Board of Governors of the Federal Reserve System, January 7, 1982.

William W. Wiles,

Secretary of the Board.

FR Doc. 82-1227 Filed 1-18-82; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 81F-0387]

Abbott Laboratories: Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Abbott Laboratories has filed a petition proposing that the food additive regulations be amended to provide for the safe use of cyclohexylsulfamic acid in resinous and polymeric coatings.

FOR FURTHER INFORMATION CONTACT: Mary W. Lipien, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B3593) has been filed by Abbott Laboratories, North Chicago, IL 60064, proposing that the food additive regulations be amended to provide for the safe use of cyclohexylsulfamic acid as a catalyst in resinous and polymeric coatings.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c) (proposed December 11, 1979; 44 FR 71742).

Dated: January 8, 1982.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 82-1193 Filed 1-18-82; 8:45 am]

BILLING CODE 4160-01-M

Office of the Secretary

Privacy Act of 1974; Report of New System of Records

AGENCY: Office of the Secretary/ASPER/OPSI and OCAM, HHS.

ACTION: Notification of New System of Records.

SUMMARY: In accordance with 5 U.S.C. 552a(e) (4), we are issuing public notice of our intent to establish a new system of records—the Office of Personnel Systems Integrity Management Information System Efficiency Report, HHS/OS/ASPER/OPSI and OCAM. The system will collect and store caseload information in order to prepare reports which will reflect caseload statistics, staff receipts, production, processing times, case location and status which OPSI and OCAM uses for case management, control, and manpower planning (to identify backlogs, case processing problems, staff utilization, budget estimations, appraise employee performance and productivity, formulate or renegotiate perfermane objectives).

DATES: We invite public comment on the proposed routine use disclosures on or before February 18, 1982. We filed a report of a new system of records with the President of the Senate, The Speaker of the House of Representatives, and the Director, Office of Management and Budget on January 11, 1982. This proposed system will become effective, without further notice, 60 days after the new system filing date, unless we receive comments on the proposed routine use disclosures, which would result in a contrary determination.

ADDRESS: Address comments to: Dr. Howard Harrison, Health and Human Services, Room 2046, Switzer Building, 330 Independence Avenue, S.W., Washington, D.C., 20201.

FOR FURTHER INFORMATION CONTACT: Betty Colton in Room 2054 at the above address.

SUPPLEMENTARY INFORMATION: We are proposing to establish the Management Information System Efficiency Report as an automated and manual case tracking system. We will use the system to develop caseload information as a data base for internal reporting; to provide more detailed information on cases during the examining or investigative process; to increase productivity; to decrease case turnaround time; and, to coordinate OPSI investigative and examining efforts.

We will maintain system security for this system in accordance with the National Bureau of Standards Guidelines and the Department's ADP Systems Manual, Part 6, ADP Systems Security. We will limit access and use of records in the manual and automated system to persons whose official duties require such access.

We will govern terminal access to the system by use of changing passwords. We will secure terminal equipment and manual system files in appropriate locked areas.

The fourth through sixth proposed routine use disclosure provisions are compatible with the purpose for which records are maintained in this system. Disclosures would enable: (1) the Equal Employment Opportunity Commission to refine the complaints processing procedure and to provide technical assistance to Federal Agencies and Departments as it relates to the efficiency and effectiveness of their complaint systems; (2) the Office of Management and Budget to make a detail and accurate assessment of the complaint's program cost effectiveness; or, (3) the Merit System Protection Board (including its Office of the Special Counsel) to investigate alleged violations of merit system principles.

We have prepared this notice in accordance with the principles and requirements of the Privacy Act.

Therefore, we anticipate no untoward effect on the privacy or other personal or property rights of individuals.

Dated: January 5, 1982.

Thomas S. McFee,

Assistant Secretary for Personnel Administration.

System Notice:

09-90-0095

SYSTEM NAME:

Management Information System Efficiency Report (Miser), HHS/ASPER/OPSI and OCAM.

SECURITY CLASSIFICATION:

None

SYSTEM LOCATION:

Office of Personnel Systems Integrity (OPSI), Room 2411, 330 Independence Avenue, S.W., Switzer Building, Washington, D.C. 20201

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for employment, current, or former employees who have a formal grievance, reconsideration, merit systems complaint, or EEO complaint against the agency or agency official. Names of investigator, examiner, contractor, and/or clerical support person, who are involved in case processing.

CATEGORIES OF RECORDS IN THE SYSTEM:

The automated and manual records contain: grievant or complainant's name, grade, series, organizational unit, city, state, race, sex, type of case, issue, basis; action on case/ dates filed,

received, assigned, referred to EEO or contractor, investigated, adjudicated, hearing held, report written and typed, closed; type of finding; weekly monthly, and yearly production and processing times; names of investigator, examiner, contractor, and/or clerical support staff assigned.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Executive Order 11478, 42 USC 2000e, 29 USC 633a, 5 USC 1302, 3301, 3302, Executive Order 10577; Executive Order 11787.

PURPOSE(S):

Information in this system of records is used for case management, control, and manpower planning (to prepare processing time reports, identify backlogs and case processing problems, staff utilization, budget estimations, appraise employee performance and productivity, formulate or renegotiate performance objectives).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Disclosure may be made:

1. To a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. To the Department of Justice for the purposes of obtaining its advice, when desirable or necessary, to determine whether particular records are required to be disclosed under the Freedom of Information Act.

3. In the event of litigation where the defendant is (a) the Department of Health and Human Services (DHHS), any component of DHHS or any employee of DHHS in his or her official capacity; (b) the United States where DHHS determines that the claim, if successful, is likely to directly affect the operations of DHHS of any of its components; or (c) any DHHS employee in his or her individual capacity where the Justice Department has agreed to represent such employee. DHHS may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

4. The Equal Employment Oppurtunity Commission to refine the complaints processing procedure and to provide technical assistance to Federal agencies and Departments as it relates to the efficiency and effectiveness of their complaints systems.

5. The Office of Management and Budget to make a detailed and accurate assessment of the complaint's program cost effectiveness.

6. The Merit System Protection Board (including its Office of the Special Counsel) to investigate alleged violations of merit system principles.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Magnetic tapes, disks, cassette tapes, bond notebooks, paper forms, and index cards in locked file cabinets.

RETRIEVABILITY:

Information is retrieved by names, docket numbers, or any other data elements (e.g., type of case, organizational unit, dates).

SAFEGUARDS:

Access to and use of these records are limited to those persons whose official duties require such access. Records are kept in locked files or a locked room. Data stored in the automated system is accessed through the use of keywords known only to authorized personnel.

RENTENTION AND DISPOSAL:

Manual and automated records are destroyed by shredding or erasing after periods varying from 1 to 5 years after resolution or final disposition of the complaint or grievance.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Personnel Systems Integrity, Room 2046, 330 Independence Avenue, S.W., Switzer Building, Washington, D.C. 20201.

NOTIFICATION PROCEDURE:

An individual can determine if this system contains a record pertaining to him or her by writing to the System Manager and by providing name and information necessary to identify the record being sought.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record being sought.

CONTESTING RECORD PROCEDURES:

Write to the system manager, and specify the information to be contested.

RECORD SOURCE CATEGORIES:

Investigator, examiner, support staff, and contractor completed status reports; records completed by supervisory staff, intake or control personnel; and, from information on incoming complaint, grievance, or reconsideration.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 82-1255 Filed 1-18-82; 8:45 am]
BILLING CODE 4150-04-M

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before January 8, 1982. Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, U.S. Department of the Interior, Washington, DC 20243. Written comments should be submitted by February 1, 1982.

Carol D. Shull,

Acting Keeper of the National Register.

ALABAMA

PLANTERSVILLE MULTIPLE RESOURCE AREA. This area includes: Chilton County, Riderville, vicinity, *Old Stage Coach Inn,* Old Plantersville Rd.; Dallas County, Plantersville, *Antique Shop,* Old Plantersville Rd.; *Christian Church and Parsonage,* Old Plantersville Rd.; *Dallas County High School,* 5th Ave.; *Doctor's Office,* Old Plantersville Rd.; *Driskell-Martin House,* Old Plantersville Rd.; and *Todd-Biscoe House,* Oak St.

Calhoun County

Jacksonville, *First Presbyterian Church,* 200 E. Clinton St.

Oxford, *Snow, Dudley, House,* 704 Snow St.

Colbert County

Tuscumbia, *Christian, John and Archibald, House,* Off U.S. 72

Dallas County

Selma, *Brown Chapel African Methodist Episcopal Church,* 410 Martin Luther King, Jr. St.

Selma vicinity, *Marshall's Grove,* AL 22

Escambia County

Brewton, *Brewton Historic Commercial District,* AL 3 and U.S. 31

Lauderdale County

Florence, *Coffee High School (Appleby School)* 319 Hermitage Dr.

Madison County

Huntsville, *Robinson, Mrs. William, House,* 401 Quietdale Dr.

Mobile County

Mobile, *Common Street District,* 959—1002 Dauphin St. and 7—19 Common St.

Mobile, *Dauphin Street District*, Dauphin St. From Water to Dearborn Ave.

St. Clair County

Ashville, *Bothwell, Dr. James J., House*, Hartford Ave.

CALIFORNIA

Alameda County

Berkeley, *Fox Court*, 1472–1478 University Ave.
Oakland, *Trinity Church*, 525 29th St.

Humboldt County

Ferndale, *Rectory, Catholic Church of the Assumption*, 563 Ocean Ave.

Napa County

Yountville, *Groezinger Wine Cellars*, 6525 Washington St.

Orange County

San Juan Capistrano, *Yorba, Domingo, Adobe, and Casa Manuel Garcia.*

San Francisco County

San Francisco, *St. Joseph's Church and Complex*, 1401—1415 Howard St.

Tehama County

Red Bluff, *St. Mary's Parish*, 515 Main St.

CONNECTICUT

Hartford County

Hartford, *Pomeroy, Arthur G., House*, 490 Ann St.

DELAWARE

New Castle County

New Castle vicinity, *New Castle Ice Piers.*

INDIANA

Bartholomew County

Columbus, *Columbus Historic District*, Roughly bounded by Pennsylvania RR tracks, Chestnut, 3rd, Washington and Franklin Sts.

St. Joseph County

South Bend, *Chapin Park Historic District*, Roughly bounded by St. Joseph River, Main, Madison, Rex, Lindsey and William Sts., Leland and Portage Aves.

IOWA

Iowa County

Millersburg, *Baird, E. J., House*, Jackson and Fremont Sts.

Johnson County

Iowa City, *Billingsley-Hills House*, 629 Melrose Ave.

Lee County

Fort Madison, *Schlapp, George E., House*, 639 Ave. C.

Pottawattamie County

Council Bluffs, *Reverend Little's Young Ladies Seminary*, 541 6th Ave.

Scott County

Davenport, *Hillside*, 1 Prospect Dr.

KENTUCKY

Woodford County

Nonesuch vicinity, *Archeological Site 15–Wd–61.*

MAINE

Hancock County

Bar Harbor, *Sproul's Cafe*, 128 Main St.

Lincoln County

Wiscasset vicinity, *Parsons, Josiah K., Homestead*, Greenleaf Cove Rd.

Oxford County

Paris, *Robinson-Parsons Farm*, Town Farm Brook Rd.

Somerset County

Salon, *Evergreens, The.*

Washington County

Calais, *Hamilton, Thomas, House*, 78 South St.
Cherryfield, *Campbell, Col. Samuel, House*, U.S. 1.

York County

Kennebunk, *Smith, James, Homestead*, ME 35.
Saco, *Deering, J. G., House*, 371 Main St.

MINNESOTA

Freeborn County

Albert Lea, *Chicago, Milwaukee, St. Paul, and Pacific Railroad Depot*, 606 S. Broadway.

Nobles County

Worthington, *Citizens' National Bank*, 326 10th St.

Ramsey County

St. Paul, *Minnesota Boat Club Boathouse on Raspberry Island*, 1 S. Wabasha St.

St. Louis County

Virginia, *Shirt Factory*, 305 S. 1st St.

Sibley County

Henderson, *Poehler, August F., House*, 700 Main St.

Wabasha County

Wabasha, *First Congregational Parsonage*, 305 W. 2nd St.
Wabasha, *Grace Memorial Episcopal Church*, 205 E. 3rd St.

NEVADA

Carson City (independent city).
St. Charles Hotel-Muller's Hotel, 302, 304 and 310 S. Carson St.

NEW MEXICO

Curry County

Clovis, *Clovis Baptist Hospital*, 515 Prince St.

Lincoln County

Ruidoso vicinity, *New Mexico Military Institute Summer Camp, Main Building*, Carrizo Canyon.

TENNESSEE

Montgomery County

New Providence vicinity, *Fort Defiance (CSA) (Fort Bruce (USA)).*

UTAH

Davis County

Bountiful, *Green, James, House*, 206 N. 100 East St.

Millard County

Hinckley, *Millard Academy*, Off U.S. 6/50.
Scipio, *Quarnberg, Peter, House*, Off UT 63.

Salt Lake County

Salt Lake City, *Casto, Santa Anna, House*, 2731 Casto Lane

San Juan County

Bluff, *Adams, Fred, House*, Off UT 47.
Bluff, *Allen, Jane and John, House*, Off UT 47.
Bluff, *Old Fort Cabins*, Off UT 47.

Summit County

Coalville, *Boyden, John, House*, 47 W. Center St.

Utah County

Goshen, *Morgan, David, House*, Off U.S. 6.

Washington County

Toquerville, *Forsyth, Thomas, House*, Off UT 15.

Weber County

Ogden, *Madison Elementary School*, 2418 Madison Ave.
Ogden, *Patton, Augustus B., House*, 1506 24th St.
Ogden, *Smyth, Dennis A., House*, 635 25th St.

[FR Doc. 82–1308 Filed 1–18–82; 8:45 am]
BILLING CODE 4310–70–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Summary of Decisions Granting in Whole or in Part Petitions for Modification

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Notice of affirmative decisions issued by the Administrators for Coal Mine Safety and Health and Metal and Nonmetal Mine Safety and Health on petitions for modification of the application of mandatory safety standards.

SUMMARY: Under section 101(c) of the Federal Mine Safety and Health Act of 1977, the Secretary of Labor may modify the application of a mandatory safety standard to a mine if the Secretary determines either or both of the following: That an alternative method exists at the petitioner's mine that will guarantee no less protection for the miners affected than that provided by

the standard, or that the application of the standard to the petitioner's mine will result in a diminution of safety to the affected miners.

Summaries of petitions received by the Secretary appear periodically in the **Federal Register.** Final decisions on these petitions are based upon the petitioner's statement, comments and information submitted by interested persons and a field investigation of the conditions at the petitioner's mine. The Secretary has granted or partially granted the requests for modification submitted by the petitioners listed below. In some instances the decisions are conditioned upon the petitioner's compliance with stiplations stated in the decision. [2]

FOR FURTHER INFORMATION CONTACT: The petitions and copies of the final decisions are available for examination by the public in the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203

Dated: January 8, 1982.

Patricia W. Silvey,

Acting Director, Office of Standards, Regulations and Variances.

AFFIRMATIVE DECISIONS ON PETITIONS FOR MODIFICATION

Docket No.	FR notice	Petitioner	Regulations affected	Summary of findings
M-79-20-C	44 FR 18294	Carbon County Coal Corp	30 CFR 75.326	Installation of a fire detection system using carbon monoxide and methane monitoring devices considered acceptable alternate method. Granted with conditions.
M-80-67-C	45 FR 35035	National Mines Corp	30 CFR 75.1710	Use of cabs or canopies on the mine's electric face equipment would result in a diminution of safety in specified low mining heights. Granted with conditions.
M-80-78-C	45 FR 42426	Consolidation Coal Co	30 CFR 75.1105	Enclosing rectifier in a fireproof structure with an automatic fire suppression device considered acceptable alternate method. Granted with conditions.
M-80-102-C	45 FR 69060	Mullin Creek Coal Co., Inc	30 CFR 75.1710	Use of cabs or canopies on petitioner's cutting machine in specified low mining heights would result in a diminution of safety. Granted with conditions.
M-80-105-C	45 FR 53612	Eastern Associated Coal Corp	30 CFR 75.305	Due to flooding and roof falls, petitioner's proposal to establish and maintain specified air monitoring stations considered acceptable alternative method. Granted with conditions.
M-80-112-C	45 FR 57794	Everidge and Nease Coal Company, Inc	30 CFR 75.1710	Use of cabs or canopies on the mine's electric face equipment would result in a diminution of safety in specified low mining heights. Granted in part with conditions.
M-80-115-C	45 FR 61397	Consolidated Coal Co	30 CFR 75.1700	Proposed plan to plug and mine through abandoned oil and gas wells considered acceptable alternate method to leaving coal barriers around the wells. Granted with conditions.
M-80-117-C	45 FR 61398	Consolidated Coal Co	30 CFR 75.1403-8(b)	Removing supplemental roof supports and roof materials to gain additional clearance to comply wih standard would result in a diminution of safety for the miners affected. Granted with conditions.
M-80-118-C	45 FR 61396	Little "T" Coal, Inc	30 CFR 77.1605(k)	Proposed maintenance, traffic control system and safeguards considered acceptable alternative to berms or guards for road control. Granted with conditions.
M-80-123-C	45 FR 70601	Regina Fuel Coal Co	30 CFR 75.1710	Use of cabs or canopies on petitioner's scoops in specified low mining heights would result in a diminution of safety. Granted in part with conditions.
M-80-126-C	45 FR 69061	Sewell Coal Co	30 CFR 75.1105	Proposed housing of pump station in a fireproof building equipped with an automatic fire suppression system considered acceptable alternate method of compliance. Granted with conditions.
M-80-136-C	45 FR 69599	Consolidation Coal Co	30 CFR 75.1105	Enclosing rectifier in a fireproof structure with an automatic fire suppression system considered acceptable alternate method of compliance. Granted with conditions.
M-80-149-C	46 FR 31542	G & A Coal Comapny	30 CFR 75.1710	Use of cabs or canopies on the mine's shuttle cars would result in a diminution of safety in current low mining heights. Granted in part with conditions.
M-80-150-C	45 FR 82762	Beckley Lick Run Co	30 CFR 75.1100-2(b)	Proposed use of a dry pipe fire fighting system activated electrically or manually by a valve on the surface considered acceptable alternate method. Granted with conditions.
M-80-151-C	46 FR 10566	Lester & Simpson Coals, Inc	30 CFR 75.1100-2(b)	Petitioner's proposed fire fighting equipment and controls considered acceptable alternative method of compliance. Granted with conditions.
M-80-153-C	46 FR 8802	Emerald Mines Corp	30 CFR 75.1700	Proposed plan to plug and mine through abandoned oil and gas wells considered acceptable alternate method to leaving coal barriers around the wells. Granted with conditions.
M-80-155-C	46 FR 10566	Peabody Coal Company	30 CFR 75.1710	Use of cabs or canopies on the mine's electric face equipment would result in a diminution of safety in specified mining heights. Granted in part with conditions.
M-80-157-C	46 FR 10568	Webster County Coal Corp	30 CFR 75.305	Due to adverse roof conditions, petitioner's proposal to establish and maintain specified air monitoring stations considered acceptable alternative method. Granted with conditions.
M-80-158-C	46 FR 10565	Eastern Associated Coal Corp	30 CFR 75.1700	Proposed plan to plug and mine through abandoned oil and gas wells considered acceptable alternative to leaving coal barriers around the wells. Granted with conditions.
M-80-161-C	46 FR 15610	Peabody Coal Company	30 CFR 77.213	Increasing the diameter of existing escapeways would result in a diminution of safety. Granted with conditions.
M-80-169-C	46 FR 13861	P.S. & R. Coal Co	30 CFR 75.1400	Proposed operation of mancage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope above the main connecting device considered acceptable alternative method. Granted with conditions.
M-80-174-C	46 FR 13859	Mine Hill Coal Co	30 CFR 75.301	Proposed airflow reduction in petitioner's mine, which would maintain a safe and healthful atmosphere, considered acceptable alternative method of compliance. Granted with conditions.
M-80-175-C	46 FR 13861	Peabody Coal Co	30 CFR 75.1403-5(g)	Maintenance of 18-inch clearance on one side of specified belt conveyor with additional safeguards considered acceptable alternative method. Granted with conditions.
M-80-177-C	46 FR 11728	Sheridan Enterprises, Inc	30 CFR 75.1100-2(b)	Proposed use of a dry-type fire fighting system during the months of October through April considered acceptable alternative method of compliance. Granted with conditions.
M-80-178-C	46 FR 11727	Island Creek Coal Co	30 CFR 75.507-1(a)	Use of nonpermissible submergible pump with specified installation instructions and control systems considered acceptable alternative method. Granted with conditions.
M-80-179-C	46 FR 13859	Leeco, Inc	30 CFR 75.805	Petitioner's junction box, cable requirements and location considered acceptable alternative method of compliance. Granted with conditions.
M-80-180-C	46 FR 13424	Peacock Coal Co	30 CFR 75.301	Proposed airflow reduction in petitioner's mine, which would maintain a safe and healthful atmosphere, considered acceptable alternative method of compliance. Granted with conditions.
M-80-182-C	46 FR 10567	Shannopin Mining Co	30 CFR 75.305	Due to poor roof conditions, petitioner's proposal to establish and maintain specified air monitoring stations considered acceptable alternative method of compliance. Granted with conditions.

AFFIRMATIVE DECISIONS ON PETITIONS FOR MODIFICATION—Continued

Docket No.	FR notice	Petitioner	Regulations affected	Summary of findings
M-81-1-C	46 FR 11727	Consolidation Coal Company	30 CFR 75.305	Due to poor roof conditions, petitioner's proposal to establish and maintain specified air monitoring stations considered acceptable alternative method of compliance. Granted with conditions.
M-81-3-C	46 FR 11728	United States Steel Corporation	30 CFR 75.305	Due to poor roof conditions, petitioner's proposal to establish and maintain specified air monitoring stations considered acceptable alternative method of compliance. Granted with conditions.
M-81-7-C	46 FR 11487	Olga Coal Co	30 CFR 75.305	Due to poor roof conditions, petitioner's proposal to establish and maintain specified air monitoring stations considered acceptable alternative method of compliance. Granted with conditions.
M-81-9-C	46 FR 20320	Black Creek Coal Co	30 CFR 75.1400	Proposed operation of mancage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope above the main connecting device considered acceptable alternative method. Granted with conditions.
M-81-13-C	46 FR 14488	Peacock Coal Co	30 CFR 75.1400	Proposed operation of mancage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope above the main connecting device considered acceptable alternative method. Granted with conditions.
M-81-14-C	46 FR 16005	Cress Coal Co	30 CFR 75.1400	Proposed operation of mancage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope above the main connecting device considered acceptable alternative method. Granted with conditions.
M-81-17-C	46 FR 17165	Fraily Coal Co	30 CFR 75.1400	Proposed operation of mancage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope above the main connecting device considered acceptable alternative method. Granted with conditions.
M-81-53-C	46 FR 20321	Jewell Smokeless Coal Corporation	30 CFR 77.214(a)	Petitioner's proposal to construct bulkheads and backfill each opening with a minimum of four feet of relatively impermeable noncombustible and compacted soil with a six-inch diameter water drainage pipe installed considered acceptable alternative method. Granted with conditions.
M-81-54-C	46 FR 21494	Potter & Dotson Coal Company, Inc	30 CFR 75.1710	Use of cabs or canopies on the mine's electric face equipment would result in a diminution of safety in specified mining heights. Granted in part with conditions.
M-81-69-C	46 FR 23339	Saginaw Mining Co	30 CFR 75.305	Due to poor roof conditions, petitioner's proposal to establish and maintain specified air monitoring stations considered acceptable alternative method of compliance. Granted with conditions.
M-81-74-C	46 FR 31099	Mine Hill Coal Co	30 CFR 75.1400	Proposed operation of mancage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope above the main connecting device considered acceptable alternatie method of compliance. Granted with conditions.
M-81-78-C	46 FR 21494	Jones & Laughlin Steel Corp	30 CFR 75.1700	Proposed plan to plug and mine through abandoned oil and gas well considered acceptable alternative method to leaving coal barriers around the wells. Granted with conditions.
M-81-100-C	46 FR 23339	United States Steel Corporation	30 CFR 75.1700	Proposed plan to plug and mine through abandoned oil and gas well considered acceptable alternative to leaving coal barriers around the wells. Granted with conditions.
M-81-102-C	46 FR 25726	Peabody Coal Company	30 CFR 75.305	Due to poor roof conditions, petitioner's proposal to establish and maintain specified air monitoring stations considered acceptable alternative method of compliance. Granted with conditions.
M-81-103-C	46 FR 25162	Dominion Coal Corporation	30 CFR 75.326	Petitioner's proposal to install audio and visual alarm carbon monoxide devices at specific locations along longwall belt conveyor entries considered acceptable alternative method. Granted with conditions.
M-81-104-C	46 FR 25726	Permac, Inc	30 CFR 77.214(a)	Covering abandoned mine opening with refuse with rock drains and gas vents installed before refuse is placed considered acceptable alternative method of compliance. Granted with conditions.
M-81-110-C	46 FR 31099	Metzinger Coal Company	30 CFR 75.1400	Proposed operation of mancage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope above the main connecting device considered acceptable alternative method. Granted with conditions.
M-81-111-C	46 FR 30216	Jeddo-Highland Coal Co	30 CFR 77.216-4	No changes or modifications to existing physical conditions coupled with new inspection and maintenance procedures considered acceptable alternative method. Granted with conditions.
M-81-118-C	46 FR 31542	Mary Lou Coal Corp	30 CFR 75.305	Due to poor roof conditions, petitioner's proposal to establish and maintain specified air monitoring stations considered acceptable alternative method of compliance. Granted with conditions.
M-81-120-C	46 FR 38168	Ray Lucas and Partner's Coal Company	30 CFR 75.1400	Proposed operation of mancage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope above the main connecting device considered acceptable alternative method of compliance. Granted with conditions.
M-81-122-C	46 FR 33679	M.S.W. Coal Company	30 CFR 75.1400	Proposed operation of mancage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope above the main connecting device considered acceptable alternative method of compliance. Granted with conditions.
M-81-127-C	46 FR 35816	K. & L. Coal Company	30 CFR 75.1400	Proposed operation of mancage or steel gunboat with secondary safety connections securely fastened around the gunboat and to the hoisting rope above the main connecting device considered acceptable alternative method of compliance. Granted with conditions.
M-81-130-C	46 FR 38612	Energy Resources, Inc	30 CFR 75.805	Petitioner's junction box, capable requirements and location considered acceptable alternative method of compliance. Granted with conditions.
M-81-168-C	46 FR 43911	Neumeister Coal Co	30 CFR 75.301	Proposed airflow reduction in petitioner's mine, which would maintain a safe and healthful atmosphere considered acceptable alternative method of compliance. Granted with conditions.
M-79-16-M	44 FR 49801	Cotter Corporation	30 CFR 57.11-55	Petitioner's proposal to maintain a portable, truck-mounted emergency hoisting unit considered acceptable alternative method. Granted with conditions.
M-79-38-M	45 FR 8756	Morton Salt Division of Morton-Norwich Products, Inc.	30 CFR 57.21-24(a)	Allowing persons to remain underground and not deenergize the power until methane concentrations exceed one percent considered acceptable alternate method. Granted upon full compliance with conditions.
M-79-39-M	45 FR 8753	Morton Salt Division of Morton-Norwich Products, Inc.	30 CFR 57.21-25	Allowing persons to remain underground and not deenergize the power until methane concentrations exceed one percent considered acceptable alternate method. Granted upon full compliance with conditions.
M-79-45-M	45 FR 8758	Morton-Norwich Products, Inc	30 CFR 57.21-46	Petitioner's proposal to drive crosscuts on centerline distances of 170 feet and with crosscut widths of 70 feet and with specified safety precautions considered acceptable alternate method of compliance. Granted with conditions.

AFFIRMATIVE DECISIONS ON PETITIONS FOR MODIFICATION—Continued

Docket No.	FR notice	Petitioner	Regulations affected	Summary of findings
M-80-30-M	45 FR 32441	Rio Blanco Oil Shale Co	30 CFR 57.21-97	Proposed blasting machine and applicable procedures considered acceptable alternate method of compliance. Granted in part with conditions.
M-80-31-M	45 FR 18513	Potash Company of America	30 CFR 57.11-52(d)	Petitioner's proposal to equip refuge chambers with specified safeguards and equipment considered acceptable alternative method. Granted with conditions.
M-80-42-M	45 FR 32441	Kennecott Minerals Company	30 CFR 55.16-2	Proposal to allow the discharge roller in the primary screen surge bin to operate during cleaning process considered acceptable alternate method of compliance. Granted with conditions.
M-80-73-M	45 FR 54477	Homestake Mining Co	30 CFR 57.11-4	Use of special steel hook ladders considered acceptable alternative method of compliance. Granted with conditions.
M-80-97-M	45 FR 66533	Amax Chemical Corp	30 CFR 57.11-50	Use of refuge area near No. 1 shaft in lieu of second escapeway considered acceptable alternate method. Granted with conditions.
M-80-104-M	46 FR 1372	Tenneco Oil	30 CFR 57.21-46	Petitioner's proposal to drive two decline entries in shaft areas for access to the lower bed and shaft bottom for cleanup and maintenance and to develop the new mine by having crosscuts at up to 200 foot intervals on the main entries and shaft pillar areas considered acceptable alternative method of compliance. Granted with conditions.
M-80-108-M	46 FR 13424	Multi Mineral Corp	30 CFR 57.21-46	Petitioner's proposal to develop single entry access drifts with two crosscuts at specified levels at various distances from the shaft considered acceptable alternate method. Granted with conditions.
M-81-10-M	46 FR 18402	Multi Mineral Corp	30 CFR 57.21-22	Proposal to exhaust return air by means of vent tubing located in the shaft with specified safety precautions considered acceptable alternative method. Granted with conditions.
M-81-24-M	46 FR 29010	Occidental Oil Shale Company	30 CFR 57.4-58	Petitioner's proposed safeguards associated with building fires underground considered acceptable alternative method of compliance. Granted with conditions.

[FR Doc. 82-1117 Filed 1-18-82; 8:45 am]
BILLING CODE 4510-43-M

Occupational Safety And Health Administration

[Docket No. P-100]

Voluntary Programs to Supplement Enforcement and to Provide Safe and Healthful Working Conditions; Request for Comment and Information

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for comment and information.

SUMMARY: OSHA seeks comment on several possible initiatives designed to encourage improvements in the safety and health of American workers. These initiatives would provide incentives for voluntary protection efforts by employers and employees, based upon the belief that labor and management can improve workplace safety and health in ways simply not available to OSHA. Under these initiatives, OSHA would take steps to identify and accord formal recognition to new or existing systems for safety and health protection in establishments which can demonstrate that they are effectively addressing employee safety and health. This will permit OSHA to focus its enforcement resources more effectively on establishments where the most serious hazards exist. Comments are requested at this early stage in order to assure maximum input from all interested parties and the public at large.

DATES: Comments must be submitted by March 15, 1982.

ADDRESSES: Materials should be submitted in quadruplicate to: docket Officer, Room S6212, Docket #P-100, U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Avenue, NW., Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT: Frank Frodyma, Office of Policy Analysis, Integration and Evaluation, Occupational Safety and Health Administration, 200 Constitution Avenue, NW., Washington, D.C. 20210 (202) 523-8021.

SUPPLEMENTARY INFORMATION:

I. Background

OSHA has long recognized that workplace compliance with OSHA standards cannot by itself accomplish the goals spelled out in the Act. The standards, no matter how carefully conceived and properly developed, will probably never cover all unsafe conditions. Furthermore, because of limited resources, the agency will never be able to inspect all of the Nation's workplaces regularly or exhaustively. In addition, employers and employees, because of their day-to-day experience in the workplace, acquire a thorough knowledge of the processes, materials and hazards involved with the job. This knowledge, combined with the ability to set rules and regulations quickly and to provide rewards for positive action, can be used by employers to improve workplace safety and health in ways simply not available to OSHA.

This notice suggests three overall approaches that OSHA hopes to use to encourage voluntary protection efforts in establishments which effectively address employee safety and health, thereby allowing the agency to focus its limited enforcement resources on establishments where the most serious hazards exist. The agency has drafted and included in the docket several program examples that could be used to implement these approaches.

A. *Employee Participation Programs* are designed to encourage employers to comply voluntarily with OSHA standards and to involve employees intimately in their own safety and health protection.

1. *The STAR (Sharing the Accountability for Regulation) Workplace Program* would be aimed at general industry firms with experienced labor-management committees, complete safety and health programs, good safety records, and good OSHA inspection history (if previously inspected).

2. *Project Build,* based on concepts similar to STAR, would be geared to the construction industry, and focused on individual worksites.

3. *Operation Try* would be a cooperative experiments program designed to explore other ways, besides the employee-management committee, of utilizing employee participation to create and maintain safe workplaces and to provide an opportunity for closely monitored experiments with employers who do not meet the more rigorous requirements of STAR or "Build" but have demonstrated good faith efforts to improve safety and health conditions and reduce injuries and illnesses.

B. *Management Initiative Programs* would be designed to recognize employers who have demonstrated success in their efforts to provide improved safety and health protection and to stimulate interest in achieving

such positive results through management initiative and action.

1. *The PRIME (Positive Results through Intensive Management Efforts) Initiative* would be useful for employers with sophisticated health and safety systems who have low injury incidence rates compared to their industry, but do not utilize labor-management committees.

2. *The PRAISE (Positive Results Achieved in Safe Employment) Program* would recognize small to mid-sized employers in low-hazard industries who have good safety records and active safety programs. PRAISE would cover only safety.

C. *Private Sector Support for Small Businesses* would be explored to provide a comprehensive approach to safety and health protection. Trade or professional associations appear to be likely sources of private sector support, but little is known about the availability of resources in this area. The agency asks questions about the feasibility of this approach.

The availability of a variety of tools, such as these six programs, would enable OSHA, along with employers and employees, to select the most effective approach for each particular situation.

PARTICIPATION IN ANY OF THESE PROGRAMS WOULD NOT IN ANY WAY DIMINISH EXISTING EMPLOYER AND EMPLOYEE RIGHTS AND RESPONSIBILITIES UNDER THE OCCUPATIONAL SAFETY AND HEALTH ACT.

Although conceptually each of these approaches could constitute a large program with extensive industry participation, OSHA expects to conduct a number of pilot projects to verify the validity of each design for a period of one first year. In addition, any new project, after the pilot phase, would undergo a probationary period before final authorization would be granted for unrestricted participation. In addition, OSHA would use a staff person to advise, facilitate, and monitor each project's operations.

Examples of how these programs could be developed are available for inspection and copying at the Docket Office in Docket #P–100. In areas where OSHA is flexible, details will be added after the public has had an opportunity to comment. Requests for copies of these examples should be submitted in writing to the Docket Office, Room S–6212, U.S. Department of Labor, 200 Constitution Ave., N.W., Washington, D.C. 20210. The requestor will be billed for any copying charges associated with the request.

OSHA is particularly interested in information and comment from business, labor and the professional safety and health community concerning these approaches and suggestions for additional alternatives which would achieve the objective of encouraging comprehensive private sector efforts to provide worker safety and health protection. Based on the responses received, OSHA may flesh out those programs that appear feasible and announce the implementation of program(s) on an experimental basis or advance new proposals.

II. Approaches on Which Comment Is Requested

We request comment and supporting documentation, wherever available, addressing each of the following three major approaches. We are particularly interested in your response to the group of questions that follows each topic of discussion. We have numbered the questions consecutively through the text. Responses which are keyed to the question numbers will facilitate our review. Since the questions concerning the involvement of States that operate their own occupational safety and health programs pursuant to Section 18 of the Act are applicable to all of these voluntary programs, they follow the program discussions.

A. Employee Participation Programs

OSHA is considering three experimental programs which could serve to obviate the need for scheduled OSHA inspections at participating workplaces: these are the STAR Workplace Program, Project Build, and Operation Try.

The keystone of these three proposed programs is employee participation in helping make the workplace safe. Employee-management committees with safety and health responsibility have, in some circumstances, been shown to be an effective mechanism for encouraging employees to become more active in their own safety and health protection in the workplace, particularly if the committee has equal representation, has regular and documented meetings, conducts periodic inspections and is well-established at the worksite. When coupled with senior management commitment to safety and health, workplace safety and health is enhanced. To confirm mutual interest, an agreement between the employer and the employees which details agreed-upon procedures and mechanisms for accomplishing the goals of the program would be necessary to apply for participation in any of these programs.

OSHA's effort is designed to encourage the development of workplace mechanisms that improve safety and health conditions through cooperative means, or build on already existing structures which achieve this goal. Additionally, we would insist that these programs maintain or achieve a high level of safety and health protection; to encourage participation of employees in safety and health decisions; and to provide safe and healthful workplaces through voluntary means. "Try" also seeks detailed answers about the ability of cooperative efforts, other than joint committees, to provide worker safety and health protection.

1. *OSHA Inspection and Authorization Responsibilities*

As currently envisioned, OSHA may choose not to conduct general schedule inspections in firms which are authorized to participate in one of these pilot projects. At least during the first year, OSHA would, however, assign a Resource Liaison to support each project. At a minimum, this individual would be available as needed to answer questions, attend and facilitiate joint committee meetings, and perhaps accompany walk-arounds. The Resource Liaison would be present during the walkaround to asssit in hazard recognition and abatement planning. It is anticipated that the Resource Liaison likely would be required on-site more often at the initiation of a project. Comment is specifically requested on the appropriate scope of responsibility and authority of the Resource Liaison in each of the proposed programs.

OSHA would, of course, retain the responsibility for handling complaints alleging imminent danger, but OSHA would encourage other safety and health complaints be handled through some type of internal complaint system by the worksite committee. For example, when complaints of unsafe or unhealthful workplace conditions are addressed to OSHA, the agency would inform the worker of the approved program and encourage use of the internal complaint system. If the worker still wished to file a formal complaint, OSHA would revert to routine procedures. If the worker wished to have the complaint referred to the firm, he or she would be given the right to remain anonymous pursuant to Section 8(f)(1) of the Act and receive notification of the disposition of the complaint. Also, a complainant dissatisfied with the disposition of a referred complaint could use the OSHA appeal procedures currently in effect.

In addition to complaints, fatalities and serious accidents would continue to be subject to OSHA inspection and OSHA would retain the discretiionary

right of citation whenever inspections were made. If hazards were cited, OSHA would give consideration to the "good faith" demonstrated by participation in these programs when calculating penalties. Detailed field staff procedures will be developed for handling any program that is undertaken.

Participation in any of these suggested programs would be authorized by the Assistant Secretary. Detailed qualifications, including an establishment's safety record, would be specified, and OSHA would audit the firm's qualifications prior to acceptance.

Your comments regarding OSHA's role in these programs to encourage voluntary protection efforts are requested, particularly in response to the following questions:

(1) What should OSHA require of a firm prior to considering the possibility of eliminating the firm from OSHA's general schedule inspection list? Should participation only be authorized for individual plant sites, or should multi-site companies be allowed to qualify as one applicant?

(2) Should the qualifications for an individual firm's or plant's injury/illness record be based on the last recorded year or an average over several years? Should it be based on lost workday cases or a combination of lost workday cases and incidence rates?

(3) Should individual firms or plants be audited against the national average for specific industries, the national average for large industry groupings, or the state average for the industry?

(4) In certain high-hazard industries, there are employers who have worked hard to make their workplaces safer and to reduce the injury/illness rate. When the high-hazard nature of the industry is considered, some have been relatively successful; however, they still have higher rates than the average for general industry. What injury/illness rate, if any, would justify participation of such a firm which met the other qualifications of one of these programs?

(5) Should the Resource Liaison (RL) have responsibilities other than those mentioned? Should there be minimum requirements for the RL's presence during the first year (such as, attend four committee meetings, accompany two walk-arounds)?

(6) What time period, if any, should be required for response to complaints referred to the committee?

(7) Should the starting time and duration of a construction project be relevant to whether a company is accepted into Project Build?

(8) Should approval or acceptance in these programs be conditional on performance during a probationary period? If so, how long should the probation be?

2. *Projected Approval Criteria*

a. *Employee Participation*

As previously stated, some degree of employee participation is a prerequisite for all three of these suggested programs. OSHA would expect, but not necessarily require, the participation to be on employer-paid time. The agency would, however, require participation to be free from disciplinary actions related to appropriate committee activities.

Both the STAR Workplace Program and Project Build would require the use of an employee-management committee based on the previously stated concepts of equal representation, regular and documented meetings, and periodic inspections.

For purposes of participation in either STAR or "Build", as currently envisioned, the committee would need authority to oversee the disposition of any complaints brought to its attention, initiate independent accident investigations (if the committee so desires), oversee abatement of hazards, review relevant firm records or surveys (if applicable), and have access to all relevant information.

Your comments are requested concerning employee participation, particularly in response to the following questions:

(9) Should there be committee requirements or responsibilities for STAR and "Build" other than those listed?

(10) Are the committee responsibilities realistic?

(11) Should committees be granted the right to consult outside experts? If so, who should bear the cost?

(12) It has been suggested that a committee might be liable for failure to assure abatement, whether or not they were aware of the hazard, if employees were hurt. Some have recommended that the addition of a "hold harmless" clause to the agreement would absolve the committee of legal responsibility. Would a "hold harmless" clause be useful in protecting committee members from liability?

(13) How often should employee-management committees meet? Should the frequency of meetings depend on the severity of the hazards faced? What should the determining factor(s) be? Should a general range of acceptable periods for meetings be set or a minimum frequency such as "at least monthly"?

(14) How ofter should committee inspections occur at the worksite? Should the number and frequency of inspections be tied to the number and frequency of meetings in any way?

(15) Construction worksites typically have a large number of subcontractors. How can they best be integrated into the mechanics of Project Build?

b. *Management Commitment*

Since management commitment to such a program is crucial to its success, a firm would need a written administrative policy that would include a statement of support for the specific program, identify resource commitments, specify the program's authority and identify the scope of the program.

Employee participation and management commitment would be the two basic requirements for "Try". Beyond these basic requirements, each "Try" experiment would be tailored to meet the needs of the employees and management of the participating firm, and OSHA would gear the evaluation of each project to the specific needs of that experiment. The remaining criteria for STAR and "Build" which follow in c, d, and e are virtually the same.

c. *Requirements for Safety and Health Program*

A firm wishing to participate in either program would need a written safety program which covers all aspects of the workplace, addresses hazards specific to the workplace, and includes personal protective equipment requirements and an employee training program in safe work practices. The safety program should clearly assign responsibility for workplace safety and be actively pursued at the worksite. The health program (which may be a part of the written safety program) should include company procedures for industrial hygiene sampling and surveying, personal protective equipment rules, employee training program for utilizinng personal protective devices and handling hazardous substances, and retention of medical records. A complete health program requires both medical and industrial hygiene services which might be provided in a variety of ways, depending on the company's resources and the hazards involved. While a large company with ample resources might have complete in-plant medical and industrial hygiene services, other firms could provide the same services by contracting for assistance. In all cases, OSHA would expect testing, sampling, or surveys to be conducted in accord with standardized procedures as established by the National Institute for

Occupational Safety and Health, OSHA, or by a national consensus organization.

An applicant for the STAR Workplace Program would be generally expected to cover both safety and health, although a small firm with few potential health hazards could apply for a partial STAR program covering only safety. Project Build would be structured along similar lines.

Your comments concerning the requirements for a safety and health program are requested.

(16) Are there items which should be required in the health or safety program in addition to those listed?

(17) Should the OSHA-supported consultation service be used as a resource for businesses that wish to set up health programs? If so, what should that role be? Should there be limitations on the activities of the consultation service?

d. *Training in Support of Employee Participation Programs*

Some type of formal training program for all employees (including new hires) on the existence, purpose, and use of the employee-management committee would be necessary to ensure that the program and committee would be utilized effectively. Committee members likely would need other kinds of training to function effectively. OSHA would, where feasible and appropriate, either assist in such training, or assist the committee in identifying alternatives.

Your comments concerning training conducted in support of the employee participation programs are requested, particularly in response to the following questions:

(18) What is a reasonable amount of time to allow for training new hires in the use of the committee, e.g., before starting work; up to two weeks?

(19) Should there be minimum training requirements for committee members? Should this training take place before acceptance?

(20) Is special continuing training for committee members necessary? If so, what kind would be needed? Is this a role for the Resource Liaison?

(21) What mechanisms should be used to provide training? Should employers be held accountable for funding committee training? Should participants be permitted to negotiate a mutually-acceptable means of funding the training?

e. *Data Requirements*

OSHA would expect a firm participating in either STAR of "Build" to retain and make available to OSHA copies of the injuries and illnesses log and/or workers' compensation injury reports, and committee records. Because it would be difficult to base approval and evaluation of a program solely on a firm's written records, consideration is being given to having recordkeepers certify the validity of records.

Your comments concerning recordkeeping requirements are requested.

(22) Should both the log and workers' compensation reports be kept for OSHA review?

(23) Should other records be required? If so, what?

(24) How can records be verified?

3. *Evaluation*

During a program's pilot project phase, OSHA would evaluate each project periodically to ensure that the project was functioning as agreed and to identify problem and/or success areas that could be dealt with on a program-wide basis. Since the Resource Liaison would have first-hand knowledge of each project's operations, his/her preliminary assessment would be an invaluable first step in the evaluation of each project.

As now projected, measures of program effectiveness would include at least the following indicators:

(a) A comparison of injury incidence rates and lost workday cases to a specific rate;

(b) The effectiveness of the committee based on reliability and timeliness in carrying out responsibilities, the nature of the problems addressed and actions taken, and the accessibility of the committee to employees;

(c) The satisfaction of the signatories; and

(d) The satisfaction of non-committee employees based on random interviews.

As previously stated, OSHA would evaluate each cooperative experiment based on the objectives of the project and measures of achievement which would be agreed to in advance by all parties.

Should there be more than on project in an employee participation program, the program would be evaluated as a whole to ensure that the objectives were met and that necessary adjustments were made in the overall program for improvement. After the pilot project phase, program evaluation would be required periodically.

OSHA requests you comments regarding evaluation requirements, particularly in response to the following questions:

(25) Are the proposed evaluation requirements realistic? What other effectiveness measures should be used? Are there other evaluation indicators that should be considered for any of the programs? In construction projects, incidence rates may be misleading because of the changes in employment levels and phases of construction. How can use of these rates be reconciled with need for valid data?

(26) Should participants be required to meet the acceptance qualifications for experience rates at all times during the acceptance period? If not, what range of performance should be allowed? Should participation be terminated if participating employers exceed the limit?

(27) Should requirements for participants to provide evaluation data be specified?

(28) Are there trade secret or privacy questions that would arise from OSHA's public use of collected information?

4. *Termination*

With advance notice, any party would be able to terminate participation in any of these programs.

Your comments concerning termination are invited.

(29) What advantages or disadvantages would there be to allow immediate termination for any of the parties? Should there be a minimum time period for advance notice of termination? If so, how much?

B. *Management Initiative Programs*

OSHA is considering two experimental programs, PRIME and PRAISE, to recognize employers who do not use labor-management committees, but have demonstrated success in their efforts to provide voluntary safety and health protection. The distinguishing features of these programs are management initiative and action to provide that voluntary protection. PRIME would have much in common with STAR. The probation period, the firm's general qualifications and recordkeeping requirements, and OSHA's responsibilities for auditing, liaison, inspection, citation, and evaluation would be virtually the same. The requirements for the safety and health system would be more detailed and include on-site safety and health staff, on-going training for all employees, an internal audit system, and a performance evaluation system for managers that includes health and safety factors.

There would be no requirements for direct employee participation like STAR or "Build" so that management could involve employees in a variety of ways to fit the needs of different health and safety systems. To counterbalance the lack of "active" employee participation, OSHA would require a feedback system

for reporting results to employees, would pool employees during audit and evaluation, and could conduct an inspection during the pre-approval audit. In addition, if an employer wished to have OSHA complaints referred to it for informal resolution, the firm would have to have a suitable mechanism for handling and responding to such complaints. As with the STAR program, an employee would retain the right to file a formal complaint under Section 8(f) of the Act.

In order to develop a program that would increase the utilization of comprehensive employer protection systems, OSHA is seeking answers to the following questions:

(30) Should OSHA remove participating companies or plants under this program from general schedule inspection lists? If so, are there additional qualifications that should be required? Should participation be conditional on performance during a probationary period?

(31) Should participation be authorized for individual plant sites, or should multi-site companies and/or multi-subsidiary corporations be allowed to qualify together? Why?

(32) Should the requirement concerning the firm's safety record be based on the last recorded year or an average over several years? On lost workday cases or combination of lost workday cases and incidence rates? The national average for the specific industry, the national average for large industry groupings or the state average for the industry?

(33) Should employee complaints made about participating companies or plants be handled in the same way as those envisioned for qualified companies with employee-management committees for safety and health (i.e., complainants would be encouraged to use internal systems with the right to have OSHA refer complaints anonymously, would receive notification of the disposition of the complaint and OSHA would have the discretion to inspect if the complaint disposition is appealed by the complainant)?

(34) What should be involved in the pre-approval audit for OSHA to make the determination that the qualifications for such a program exist within the applicant organization, e.g., inspections, employee interviews or questionnaires?

(35) Should there be minimum requirements for the Resource Liaison's presence during the first year?

(36) Should both the injuries/illnesses log and worker's compensation reports be kept for OSHA review? Should other records be required? How can records be verified?

(37) Should the measures of effectiveness be different from those in STAR? Should random interviews of workers be a part of an evaluation? Should requirements for participants to provide evaluation data be specified? Should a requirement for the participant to conduct an annual self-evaluation be included?

(38) Should participants be required to meet the acceptance qualifications for experience rates at all times during the acceptance period or be allowed a range of performance? Should participation be terminated if the limit is exceeded?

(39) Are there trade secret or privacy questions that would arise from OSHA's public use of collected information?

(40) Should there be a minimum time period required for advance notice of termination? What advantages or disadvantages would there be to allowing immediate termination by either party?

PRAISE would be primarily an effort to recognize past achievement in the field of workplace safety. It would be aimed at the small to mid-sized employer in a low-hazard industry who likely would not be a top priority for OSHA inspection.

OSHA would also identify a local Resource Liaison for each of these projects to answer questions, provide assistance and assure abatement of any complaint-identified hazard and notify complainants of the disposition. A complainant who was dissatified with the disposition could use OSHA's appeal procedures currently in effect. There would be no change in the handling of health problems, complaints alleging imminent danger, and fatality or catastrophe investigations.

OSHA would reserve the right to audit the applicant's qualifications prior to acceptance into PRAISE. Such an audit could include an on-site visit to review records and conduct a general assessment of safety conditions and facilities. This type of audit could be used for evaluation, as well.

Before initiating a recognition program of this nature OSHA would like your comments, particularly in response to the following questions:

(41) Since these firms would not likely be inspected in any case, are there other qualifications that OSHA should require for participation in PRAISE?

(42) Should some type of employee involvement be demonstrable before acceptance?

(43) Could a recognition program of this nature apply to firms in more hazardous industries?

(44) Should health coverage be included in PRAISE? If so, what additional qualifications should be added, if any?

C. *Support for Small Businesses*

Most of the programs that have been described are primarily suited to relatively large employers. Small businesses are not likely to have the resources to provide for safety and health professionals either through hiring or contract assistance. The use of employee-management committees may not be practical for the smaller employers because of the difficulty in sparing workers to spend time on safety and health matters. While PRAISE is geared to the smaller employer who has been successful in making the workplace safe, OSHA recognizes that there are other small employers who need and want help. At this time OSHA offers assistance to small employers through the consultation program, but we are interested in expanding upon that assistance through private sector support which could provide a more comprehensive approach to safety and health protection.

Trade association and/or professional associations are possible sources that could provide safety and health support systems similar to those utilized by large corporations and even some medium-sized businesses. Professional safety and health staffs, either working directly for trade associations, professional associations or under contract, could draw up safety and health practices for an entire industry, provide constructive audits of individual businesses and serve as a resource to help address new safety and health problems as they arise.

We would like your comments, particlarly in response to the following questions:

(45) Do trade associations or professional associations have the resources to provide such services? If not, what mechanism might be used to provide such resources? Would large corporations of the same or related industries or the larger corporate suppliers of the industry be willing to donate expertise or other resources on a short or long-term basis?

(46) Do trade associations and professional associations consider that such a role is consistent with their charters and with their members' expectations?

(47) Have any trade or professional associations attempted to provide intensive safety and health systems to small businesses? If so, with what results? Have any trade or professional associations been requested to provide extensive services for small businesses?

(48) Should unions involved in the industry accept part of the responsibility for such programs—decision-making, resources, expertise, audit assistance? Have any trade associations, professional associations or unions attempted to supply safety and health protection systems to small businesses in any specific industry? If so, with what results?

(49) If such systems are established in an industry either by trade or professional associations alone or with the relevant unions, what should OSHA's role be? Should OSHA give some sort of approval or certification to the program? If so, what criteria should be used? Should OSHA discontinue general schedule inspections under certain circumstances? If so, what should the criteria be? Should OSHA encourage internal resolution of workplace complaints? If so, how should it be done? Who would oversee the resolution of complaints internally?

(50) Should such a system include occupational health support for toxic substances? What resources would be required to do so? Should OSHA play a stronger role in oversight if occupational health is to be covered? If so, what should that role be, given the shortage of OSHA resources?

(51) Should individual businesses be given the right to join such a program? Should they meet specific qualifications to join the program? Should they apply for membership? What role would the trade or professional association play in the approval? What role would OSHA play? Under what conditions, if any, would a company lose the right to participate?

(52) Are there other types of programs that would support small employers' safety and health efforts?

(53) What criteria should be used to define small business, e.g., employment, gross sales, or some combination of criteria?

D. *Alternative Approaches*

In addition to commenting on these specified approaches, OSHA would be interested in any suggestions for alternative programs to encourage voluntary protection in the workplace.

E. *Participation of States with 18(b) Plans*

As provided by Section 18 of the Occupational Safety and Health Act, 23 States, including Puerto Rico and the Virgin Islands, operate their own occupational safety and health programs which must be at least as effective as the Federal program. These States are required in 29 CFR Part 1953 to submit a plan change supplement for administrative policy changes which would impact on the effectiveness of the State program. Since participation in these voluntary protection efforts would necessitate policy changes, States would be required to submit plan changes for approval by the Assistant Secretary. Your comments regarding 18(b) State participation in voluntary protection programs are requested, particularly in response to the following questions:

(54) Should States with OSHA 18(b) plans be encouraged to participate in all or part of the Federal voluntary protection programs? If not all, which, if any, parts are more appropriate for State participation?

(55) Should the 18(b) States be permitted or required to develop completely separate voluntary protection programs? If not, why not? Should this action be dependent on the outcome of OSHA's pilot projects?

(56) Are there changes that need to be made in the overall voluntary protection approach or in any specific program to facilitate State involvement?

(57) Are there other alternatives for State involvement which should be considered?

Respondents are asked to submit comments by March 15, 1982 in quadruplicate, to: Docket Officer, Room S6212, Docket #P–100, U.S. Department of Labor—OSHA, 200 Constitution Avenue, NW., Washington, D.C. 20210.

This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

(Sec., 8(g), Pub. L. 91–596, 84 Stat. 1600 (29 U.S.C. 657(g)))

Signed at Washington, D.C. this 12th day of January, 1982.

Thorne G. Auchter,

Assistant Secretary.

[FR Doc. 82–1286 Filed 1–18–82; 8:45 am]

BILLING CODE 4510–26–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Subcommittee on Clinch River Breeder Reactor; Meeting

The ACRS Subcommittee on Clinch River Breeder Reactor will hold a meeting on February 2 and 3, 1982, Room 1046, 1717 H Street, N.W., Washington, DC. The Subcommittee will discuss with the NRC Staff and the applicant, Project Management Corporation, the Clinch River Breeder Reactor program status including matters concerning licensing, siting and schedules. Notice of this meeting was published December 22.

In accordance with the procedures outlined in the **Federal Register** on September 30, 1981 (46 FR 47903), oral or written statements may be presented by members of the public, 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 Cognizant Federal Employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The entire meeting will be open to public attendance except for those sessions during which the Subcommittee finds it necessary to discuss proprietary and Industrial Security information. One or more closed sessions may be necessary to discuss such information. (Sunshine Act Exemption 4). To the extent practicable, these closed sessions will be held so as to minimize inconvenience to members of the public in attendance.

The agenda for subject meeting shall be as follows:

Tuesday, February 2, 1982—1:00 p.m. until the conclusion of business.

Wednesday, February 3, 1982—8:30 a.m. until the conclusion of business.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, will 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 Project Management Corporation, NRC Staff, their 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 Designated Federal Employee, Mr. Elpidio Igne (telephone 202/634–1413) between 8:15 a.m. and 5:00 p.m., EST.

I have determined, in accordance with Subsection 10(d) of the Federal Advisory Committee Act, that it may be necessary to close some portions of this meeting to protect proprietary and Industrial Security information. The authority for such closure is Exemption

(4) to the Sunshine Act, 5 U.S.C. 552b(c)(4).

Dated: January 12, 1982.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 82-1245 Filed 1-18-82; 8:45 am]

BILLING CODE 7590-01-M

Advisory Committee on Reactor Safeguards; Subcommittee on Waste Management; Changed Meeting

The ACRS Subcommittee on Waste Management will hold a meeting on January 18, 1982, Room 1046, 1717 H Street, NW, Washington, DC. The Subcommittee will review the technical assistance program in waste management research and will discuss the NRC Safety Research Program budget for FY 1983. Disregard the notice published December 29, 1981 (FR 46 62987).

The entire meeting will be closed to discuss the NRC FY 1983 Safety Research Program Budget as required (Sunshine Act Exemptions (2), (6), and (9)b.) For the reason just stated, such a discussion would not be possible if held in public session.

I have determined, in accordance with Subsection 10(d) Pub. L. 92-463 that it may be necessary to close sessions of the meeting as noted above to discuss matters which relate solely to the internal personnel rules and practices of the agency (Exemption (2)), to discuss information of a personal nature, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy (Exemption (6)), and to discuss preliminary information the release of which would be likely to significantly frustrate the Committee in the performance of its statutory function (Exemption (9)b). The authorities for such closure are Exemptions (2), (6) and (9)b to the Sunshine Act, 5 U.S.C. 552b(c)(2)(6)(9)b.

Dated: January 12, 1982.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 82-1244 Filed 1-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-99]

Babcock & Wilcox Co.; Order Authorizing Dismantling of Facility and Disposition of Component Parts

By application dated July 23, 1981, as revised by letters dated September 23, October 16 and November 23, 1981, Babcock and Wilcox Company (the licensee) requested authorization to dismantle the Lynchburg Pool Reactor (the facility), a pool-type nuclear reactor located in Lynchburg, Virginia, and to dispose of the component parts, in accordance with the plan submitted as part of the application. A "Notice of Proposed Issuance of Orders Authorizing Dismantling of Facility" Disposition of Components Parts, and Termination of Facility License" was published in the **Federal Register** on October 30, 1981 (46 FR 53821). No request for a hearing or petition for leave to intervene was filed following notice of the proposed action.

The Nuclear Regulatory Commission (NRC) has reviewed the application in accordance with the provisions of the NRC's Rules and Regulations and has found that the dismantling and disposal of component parts under the licensee's dismantling plan will be in accordance with the regulations in 10 CFR Chapter I, and will not be inimical to the common defense and security or to the health and safety of the public. The basis for the findings is set forth in the concurrently issued Safety Evaluation by the Office of Nuclear Reactor Regulation.

The NRC staff has prepared an environmental impact appraisal for this action. Based on that appraisal, the staff has determined that this action will not result in any significant environmental impact and that an environmental impact statement need not be prepared.

Accordingly, Babcock and Wilcox Company is hereby authorized to dismantle the facility covered by Facility Operating License No. R-47, and dispose of the component parts in accordance with their dismantling plan and the NRC's Rules and Regulations.

After completion of the dismantling and decontamination and the submission of a report on the radiation survey to confirm that radiation levels in the facility area meet the values defined in the dismantling plan and an inspection by representatives of NRC, consideration will be given to whether a further order should be issued terminating Facility Operating License No. R-47. Alternatively, after dismantling the facility the licensee may apply to the NRC for inclusion of the residual activity in Special Nuclear Materials License No. SNM-778. Following an inspection by representatives of the NRC and authorization to include this residual activity under SNM-778, consideration will be given to whether a further order should be issued terminating Facility Operating License No. R-47.

For further details with respect to this action see (1) the application for authorization to dismantle facility and dispose of components parts dated July 23, 1981, as revised by letters dated September 23, October 16, and November 23, 1981, (2) the related Safety Evaluation, (3) the Environmental Impact Appraisal, and (4) the Negative Declaration dated January 11, 1982 (which is also being published in the **Federal Register**). All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 11th day of January 1982.

For the Nuclear Regulatory Commission.

Robert L. Tedesco,

Assistant Director for Licensing, Division of Licensing.

[FR Doc. 82-1236 Filed 1-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-99]

Babcock & Wilcox Co., Lynchburg Pool Reactor

The U.S. Nuclear Regulatory Commission (the Commission) has considered the order authorizing dismantling of facility and disposition of component parts for the Babcock and Wilcox Company (the Licensee) Lynchburg Pool Reactor which operated under Facility Operating License No. R-47. The order authorizes the licensee to dissasemble the reactor, which operated at power levels up to 1.0 MW (thermal), and to dispose of its component parts.

The Commission's Office of Nuclear Reactor Regulation has prepared an environmental impact appraisal for this pool-type nuclear reactor. On the basis of this appraisal, the Commission has concluded that an environmental impact statement for this particular action is not warranted because there will be no significant environmental impact attributable to the proposed action. The environmental impact appraisal is available for public inspection at the Commission's Public Document Room at 1717 H Street N.W., Washington, D.C.

Dated at Bethesda, Md., this 11th day of January 1982.

For the Nuclear Regulatory Commission.

James R. Miller,

Chief, Standardization and Special Projects Branch, Division of Licensing.

[FR Doc. 82-1237 Filed 1-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-247]

Consolidated Edison Co. of New York, Inc.; Issuance of Amendment and Negative Declaration to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 75 to Facility Operating License No. DPR-26, issued to the Consolidated Edison Company of New York, Inc. (the licensee), which revised Technical Specifications for operation of the Indian Point Nuclear Generating Unit No. 2 (the facility) located in Buchanan, Westchester County, New York. The amendment is effective as of the date of issuance.

The amendment revises the Technical Specifications to authorize an increase in the capacity of the spent fuel storage pool at the facility. It also places restrictions on load handling in the spent fuel building.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Notice of Proposed Issuance of Amendment to Facility Operating License in connection with this action was published in the **Federal Register** on May 28, 1980 (45 FR 35948). No request for a hearing or petition for leave to intervene was filed within the prescribed limit following notice of the proposed action.

The Commission has prepared an Environmental Impact Appraisal for this action and has concluded that an environmental impact statement for this particular action is not warranted because there will be no significant environmental impact attributable to the action other than that which has already been predicted and described in the Commission's Final Environmental Statement for the facility dated September 1972.

For further details with respect to this action, see (1) the application for amendment dated September 7, 1979, as supplemented May 6, 1980, (2) Amendment No. 75 to License No. DPR-26, (3) the Commission's related Safety Evaluation and (4) the Commission's Environmental Impact Appraisal. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the White Plains Public Library, 100 Martine Avenue, White Plains, New York. A copy of items (2), (3) and (4) may be obtained upon request addressed to the U.S. Nuclear Regualtory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 11th day of January 1982.

For the Nuclear Regulatory Commission.

Steven A. Varga,

Chief, Operating Reactors Branch No. 1, Division of Licensing.

[FR Doc. 82-1238 Filed 1-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-155-OLA]

Consumers Power Co., (Big Rock Point, Unit 1); Reconstitution of Board

Pursuant to the authority contained in 10 CFR § 2.721 (1980), the Atomic Safety and Licensing Board for *Consumers Power Company*, Big Rock Point, Unit 1, Docket No. 50-155-OLA, is hereby reconstituted by appointing the following Administrative Judge to the Board: Peter B. Bloch. Herbert Grossman was chairman of this Board, but, because of a schedule conflict, is unable to continue to serve.

As reconstituted, the Board is comprised of the following Administrative Judges: Peter B. Bloch, Chairman, Dr. Oscar H. Paris, Frederick J. Shon.

All correspondence, documents and other materials shall be filed with the Board in accordance with 10 CFR § 2.701 (1980). The address of the new Board Chairman is: Judge Peter B. Bloch, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Issued at Bethesda, Maryland this 11th day of January 1982.

B. Paul Cotter, Jr.,

Chief Administrative Judge, Atomic Safety and Licensing Board Panel.

[FR Doc. 82-1239 Filed 1-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-369]

Duke Power Co.; Issuance of Amendment to Facility Operating License No. NPF-9

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 11 to Facility Operating License No. NPF-9, issued to Duke Power Company (licensee) for the McGuire Nuclear Station, Unit 1 (the facility) located in Mechlenburg County, North Carolina. The amendment is effective as of its date of issuance.

This amendment permits operation above 90% rated thermal power for no more than 48 hours in order to verify the full power capability of the unit and the performance of the model D steam generator.

Issuance of this amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations. The Commission has made appropriate findings as required by the Act and the Commission's regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) Duke Power Company letter dated January 4, 1982, (2) Amendment No. 11 to Facility Operating License No. NPF-9 and (3) the Commission's related Safety Evaluation.

These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and the Atkins Library, University of North Carolina, Charlotte (UNCC Station), North Carolina 28223. A copy of these items may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 8th day of January 1982.

For the Nuclear Regulatory Commission.

Elinor G. Adensam,

Chief, Licensing Branch No. 4, Division of Licensing, NRR.

FR Doc. 82-1240 Filed 1-18-82; 8:45 am]

BILLING CODE 7590-01-M

Evaluation Criteria for Detailed Control Room Design Review; Extension of Comment Period

January 12, 1982.

Notice is given that the Commission's Office of Nuclear Reactor Regulation is extending the period for comments on NUREG-0801, Evaluation Criteria for Detailed Control Room Design Review.

This draft report contains guidance to the user (licensee/applicant and NRC staff) to assist: in assessing the significance of identified human

engineering discrepancies; in determining the acceptability of the Detailed Control Room Design Review, and the resulting control room design improvements. These criteria were developed in response to Item I.D.1 "Control Room Design Review," of NUREG–0660, NRC Action Plan developed as a result of the TMI accident.

This draft report was issued for public and industry comment. Notice of issuance was announced on page 560870 of the November 13, 1981 **Federal Register**, Vol. 46, No. 219. Comments were due by December 28, 1981. Because of numerous public and industry requests the due date for comments has been extended to February 12, 1982. All comments should be forwarded to: Mr. Mark Greenberg, Human Factors Engineering Branch, Division of Human Factors Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

For further information, contact Mark Greenberg, Division of Human Factors Safety, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone (301) 492–8344.

Dated at Bethesda, Maryland, this 12th day of January, 1982.

Joel J. Kramer,

Acting Director, Division of Human Factors Safety, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1242 Filed 1-18-82; 8:45 am]

BILLING CODE 7590-01-M

Human Factors Acceptance Criteria for the Safety Parameter Display System; Extension of Comment Period

January 12, 1982.

Notice is given that the Commission's Office of Nuclear Reactor Regulation is extending the period for comments on NUREG–0835, Human Factors Acceptance Criteria for the Safety Parameter Display System (SPDS).

This draft report contains guidance to the user (licensee/applicant and NRC staff) to assist: in assessing conformance of SPDS designs to the functional criteria stated in NUREG–0696. These functional criteria and acceptance criteria were developed in response to Item I.D.2 "Plant Safety Parameter Display Console" of NUREG–0660, NRC Action Plan developed as a result of the TMI accident.

This draft report was issued for public and industry comment. Notice of issuance was announced on page 55024 of the November 5, 1981 **Federal Register**, Vol. 46, No. 214. Comments were due by December 21, 1981. Because of numerous public and industry requests the due date for comments has been extended to February 12, 1982. All comments should be forwarded to: Mr. Leo Beltracchi, Human Factors Engineering Branch, Division of Human Factors Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

For further information, contact Leo Beltracchi, Division of Human Factors Safety, Office of Nuclear Regulation, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Telephone (301) 492–8355.

Dated at Bethesda, Maryland, this 12th day of January, 1982.

Joel J. Kramer,

Acting Director, Division of Human Factors Safety, Office of Nuclear Reactor Regulation.

[FR Doc. 82-1243 Filed 1-18-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50–266 and 50–301]

Wisconsin Electric Power Co.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 58 to Facility Operating License No. DPR–24, and Amendment No. 62 to Facility Operating License No. DPR–27 issued to Wisconsin Electric Power Company (the licensee), which revised Technical Specifications for operation of Point Beach Nuclear Plant, Unit Nos. 1 and 2 (the facilities) located in the Town of Two Creeks, Manitowoc County, Wisconsin. The amendments are effective five days from the date of issuance for Unit 1 and upon return to power from the Spring 1982 refueling outage for Unit 2.

The amendments revised the degraded grid undervoltage relay setpoint and associated time delay.

The application for the amendments complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendments. Prior public notice of these amendments was not required since the amendments do not involve a significant hazards consideration.

The Commission has determined that the issuance of these amendments will not result in any signficiant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of these amendments.

For further details with respect to this action, see (1) the application for amendments dated December 3, 1981 as modified by letter dated December 30, 1981, (2) Amendment Nos. 58 and 62 to License Nos. DPR–24 and DPR–27, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555, and at the Joseph Mann Library, 1516 16th Street, Two Rivers, Wisconsin 54241. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 6th day of January 1982.

For the Nuclear Regulatory Commission.

Robert A. Clark,

Chief, Operating Reactors Branch #3, Division of Licensing.

[FR Doc. 82-1241 Filed 1-18-82; 8:45 am]

BILLING CODE 7590-01-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 12
Tuesday, January 19, 1982

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

CIVIL AERONAUTICS BOARD

[M-340 Amdt. 3, January 8, 1982]

Notice of Deletion of item from the January 7, 1982 Board meeting

TIME AND DATE: 10 a.m. (closed meeting), 2 p.m. (open meeting), January 7, 1982.

PLACE: Room 1012 (closed meeting), room 1027 (open meeting), 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUBJECT:

6. Dockets 20051 and 20700, Petition for Reconsideration of Order 81-10-152 to the extent that it disapproves the Washington National Commuter Airline Association scheduling committee agreement and withdraws antitrust immunity. (Memo 100-D, BDA, OGC, OEA)

STATUS: 1-4c (closed), 5-24 (open).

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673-5068.

[S-73-82 Filed 1-15-82; 3:55 pm]

BILLING CODE 6320-01-M

2

FEDERAL COMMUNICATIONS COMMISSION

Rescheduling of an item considered at the January 5th, 6th and 7th briefings

The Federal Communications Commission will hold a closed briefing on the matter listed below on Tuesday, January 12, 1982 to commence following the scheduled closed meeting in Room 856, at 1919 M Street, N.W., Washington, D.C.

Agenda and Subject

General: Continuation of FY 83 Budget Proposals.

This briefing is closed to the public because it concerns internal personnel rules (See 47 CFR 0.603(b)).

The prompt and orderly conduct of Commission business requires that less than 7-days notice be given consideration of this additional item.

Additional information concerning this briefing may be obtained from Maureen Peratino, FCC Public Affairs Office, telephone number (202) 254-7674.

Issued: January 11, 1982.

William J. Tricarico,

Secretary, Federal Communications Commission.

[S-66-82 Filed 1-15-82; 10:53 am]

BILLING CODE 6712-01-M

3

FEDERAL COMMUNICATIONS COMMISSION

Deletion of Agenda Item From January 13th Open Meeting

The following item has been deleted from the list of agenda items scheduled for consideration at the January 13, 1982, Open Meeting and previously listed in the Commission's Notice of January 6, 1982.

Agenda, Item No., and Subject

Broadcast—2—*Title:* Reregulation and Rules Oversight of Radio and TV Broadcasting. Summary: Modification and clarification of rules pertaining to:

—Classes of AM broadcast channels.
—Designation of new class of AM broadcast station as Class II-C.

Issued: January 12, 1982.

William J. Tricarico,

Secretary, Federal Communications Commission.

[S-68-82 Filed 1-15-82; 10:53 am]

BILLING CODE 6712-01-M

4

FEDERAL COMMUNICATIONS COMMISSION

Rescheduling of an Item Considered at the January 5th, 6th, and 7th Briefings

The Federal Communications Commission announced on January 11, 1982 its intention to hold a Closed Briefing on Tuesday, January 12, 1982 to consider the item listed below. This briefing has been rescheduled to follow the Closed Meeting scheduled for January 13, 1982 in Room 856, at 1919 M Street, NW., Washington, D.C.

Agenda, and Subject

General: Continuation of FY 83 Budget Proposals.

This briefing is closed to the public because it concerns internal personnel rules (See 47 CFR 0.603(b)).

The prompt and orderly conduct of Commission business requires that less than 7-days notice be given consideration of this additional item.

This briefing may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this briefing may be obtained from Maureen Peratino, FCC Public Affairs Office, telephone number (202) 254-7674.

Issued: January 12, 1982.

William J. Tricarico,

Secretary, Federal Communications Commission.

[S-67-82 Filed 1-15-82; 10:53 am]

BILLING CODE 6712-01-M

5

FEDERAL HOME LOAN BANK BOARD

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 47 FR 1238, Monday, January 11, 1982.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m. January 14, 1982.

PLACE: 1700 G. Street, NW., sixth floor, Washington, D.C.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATIOIN: Mr. Marshall (202-377-6679).

CHANGES IN THE MEETING:
The meeting previously scheduled for 10 a.m. has been rescheduled for 5 p.m., January 14, 1982.

[No. 82-5, January 14, 1982]

[S-65-82 Filed 1-15-82; 8:59 am]

BILLING CODE 6720-01-M

6

INTERNATIONAL TRADE COMMISSION

[USITC SE-82-1A/2A]

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 47 FR 721, January 6, 1982, and 47 FR 1238, January 11, 1982.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 a.m., Thursday, January 14, 1982.

CHANGES IN THE MEETING: Emergency notice rescheduling item No. 4(a) (Certain multipurpose power woodworking tools (Docket No. 783)) from the meeting of Thursday, January 14, 1982, to item No. 6 (Any items left over from previous agenda) on Tuesday, January 19, 1982.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 523–0161.

[S–69–82 Filed 1–15–82; 10:55 am]

BILLING CODE 7020–02–M

7

NATIONAL COUNCIL ON EDUCATIONAL RESEARCH (NIE)

DATE AND TIME: February 2, 1982, 9 a.m.–2:30 p.m.

PLACE: Room 823, National Institute of Education, 1200 19th Street, N.W., Washington, D.C.

STATUS: Certification is being sought from the Department of Education Office of General Counsel, that in the opinion of that office, the NCER "would be authorized to close portions of its meeting on February 2, 1982, under 5 U.S.C. 522b(c)(9)(B) and 34 CFR 705.2(a)(9) for the purposes of reviewing and discussing with the Director of NIE options for the NIE fiscal year 1983 budget and procurement planning and budget for fiscal year 1982." Agenda item *#5* will be closed, the rest of the agenda will be open to the public. The public should call to verify the *closing* of this portion of the meeting.

MATTERS TO BE CONSIDERED:

1. Report of the Director (9:10–10:15 a.m.).
2. Educational Technology (10:15 a.m.–10:45 a.m.).
3. Atlanta Meeting Review: Research and School District Improvement (10:45–11:30 a.m.)
4. National Commission on Excellence in Education (11:30 a.m.–12 noon) lunch (12 noon–1 p.m.)
5. Closed session—Report on FY '82 Procurement Plans and FY '83 Budget and Program Planning (1 p.m.–2:30 p.m.).

Adjournment.

CONTACT PERSON FOR MORE INFORMATION: Martha H. Catto, Telephone: (202) 254–7900.

Peter H. Gerber,

Chief, Policy and Administrative Coordination, National Council on Educational Research.

[S–72–82 Filed 1–15–82; 3:10 pm]

BILLING CODE 4000–05–M

8

NATIONAL RAILROAD PASSENGER CORPORATION

In Accordance with Rule 4(a) of Appendix A of the Bylaws of the National Railroad Passenger Corporation, notice is given that the Board of Directors will meet on January 27, 1982.

A. The meeting will be held on Wednesday, January 27, 1982, in the Pierre Suite, 11th Floor, at Loews L'Enfant Plazza Hotel, Washington, D.C., at 9:30 a.m.

B. The meeting will be open to the public at 10:30 a.m. beginning with agenda item No. 3, as described below.

C. The agenda items to be discussed at the meeting follow.

Agenda—National Railroad Passenger Corporation—Meeting of the Board of Directors—January 27, 1982

(9:30 a.m.) *Closed Session:*

1. Internal Personnel Matters
2. Litigation Matters

(10:30 a.m.) *Open Session:*

3. Approval of Minutes of Regular Meeting of December 9, 1982
4. Approval of Amendment to Retirement Income Plan
5. Approval of a Consulting Contract for an Analysis of the Reservation System
6. Resolution Authorizing the Execution of a Cooperative Agreement—Providence, Rhode Island
7. Resolution Authorizing General Partnership Agreement for Development of 30th Street Station, Philadelphia, PA
8. Designation of Representatives to the Amtrak Commuter Services Corporation Board of Directors
9. Commitment Approval Requests

82–13 Phase II of FY 82 Northeast Corridor Track Program—Harrisburg Main Line

82–21 Northeast Corridor Track Program—Springfield Main Line

82–22 Sunnyside Yard Turnout Rehabilitation Northeast Corridor Spine

82–23 New York State Track Improvements

82–25 Disk Storage Equipment Replacement

78–76–S4 Phase IV Funding for Grade Crossing Improvements—State of Florida

10. Approval of Fiscal Year 1982 Capital Plan
11. Fiscal Year 1982 Operating Plan to Satisfy Loan Guarantee Requirement
12. President's Report
13. Date and Place of Next Meeting
14. New Business
15. Adjournment

D. Inquiries regarding the information required to be made available pursuant to Appendix A of the Corporation's Bylaws should be directed to the Corporate Secretary at (202) 383–3754.

January 15, 1982.

Sandra Spence,

Corporate Secretary.

[S–70–82 Filed 1–15–82; 2:08 pm]

9

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 46 FR 1238, January 11, 1982.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING 10 a.m., January 14, 1982.

CHANGES IN THE MEETING: This meeting has been rescheduled for 9:30 a.m. on January 18, 1982.

Dated: January 15, 1982.

[S–71–82 Filed 1–15–82; 2:12 pm]

BILLING CODE 7600–05–M

10

CONSUMER PRODUCT SAFETY COMMISSION.

LOCATION: Third Floor Hearing Room, 1111–18th St., NW., Washington, D.C.

DATE AND TIME: Wednesday, January 20, 1982, 9:30 a.m.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. NEISS Report to Congress

The Staff will brief the Commission, and

the Commissioners will then consider a drafter report to the House Appropriation Committee concerning the National Electronic Inury Surveillance System (NEISS).

2. Prednisone Exemption

The Commission will consider a request to exempt Prednisone from the packaging requirements of the Poison Prevention Packaging Act.

3. Briefing on Amendment to Regulation Implementing Flammability Standards for Clothing Textiles and Vinyl Plastic Film

The staff will brief the Commission on: a) Exemption for Outer Layer Testing of Disposable Diapers. b) Extention of Comment Period on Other Provisions.

4. Request to Convene Advisory Panel on Asbestos

The staff will brief the Commission on a request to convene an Advisory Panel on asbestos.

STATUS: Partially open to the public/ partially closed.

MATTERS TO BE CONSIDERED:

5. General Order on Asbestos

The staff will brief the Commission on activities relating to the Asbestos General Order

Agenda approved January 15, 1982.

FOR ADDITIONAL INFORMATION CONTACT:

Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, Md. 20207, Telephone (301) 492–6800.

[S–74–82 Filed 1–18–82; 9:13 am]

BILLING CODE 6355–01–M

federal register

Tuesday
January 19, 1982

Part II

Department of Health and Human Services

Food and Drug Administration

General and Plastic Surgery Devices: General Provisions and Classification of 54 Devices; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 78N-2646]

General and Plastic Surgery Devices; General Provisions and Classification of 54 Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general rules applicable to the classification of all general and plastic surgery devices. In addition, the agency is proposing general rules applicable to the classification of several medical devices used in dermatology, including dermatological ultraviolet lamps. The Medical Device Amendments of 1976 require the agency to classify all medical devices intended for human use into three categories: Class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulation classifying 55 general and plastic surgery devices. The preamble also describes the activities of the General and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel (formerly the General and Plastic Surgery Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of general and plastic surgery devices. Because there is no dermatology device panel, the agency assigned several dermatological devices to the Genaral and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel for review.

DATES: Comments by March 22, 1982. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mark F. Parrish, Bureau of Medical Devices (HFK-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7156.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: Class I, general controls; class II, performance standards; and class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. (A later section in this preamble discusses general and plastic surgery devices formerly considered new drugs.) These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), FDA issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848).

Activities of Panel

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The General and Plastic Surgery Device Classification Panel (the Panel) was originally chartered on October 15, 1973, as the Panel on Review of General and Plastic Surgery Devices. FDA placed a report of the Panel's tentative classification recommendations on file with the Dockets Management Branch (HFA-305), Food and Drug Administration, and announced the availability of the report to the public by notice published in the **Federal Register** of July 30, 1976 (41 FR 31925). On August 9, 1976, the Panel and other preamendments device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA had referred to it to make certain that its recommendations were in accord with the amendments.

Throughout the Panel's deliberations, interested persons were given an opportuinty to present their views, data, and other information concerning the classification of general and plastic surgery devices. The Panel also invited experts to testify and sought information on many devices from the published literature.

On November 1, 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and former Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the Dockets Management Branch (HFA-305), Food and Drug Administration, and announced its availability to the public by notice published in the **Federal Register** of November 29, 1977 (42 FR 60792). The Panel changed its previous recommendations concerning the classification of several devices after completion of the "General and Plastic Surgery Device Classification Panel Report." These recommendations are contained in Summary Minutes of the July 21, 1977, October 6, 1977, and

following meetings. Summary minutes of these meetings have been placed in the Dockets Management Branch, Food and Drug Administration. Also available in the Dockets Management Branch are summary minutes from all other Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in this proposal.

On April 28, 1978, the agency terminated all of the device classification panels and reestablished them with the same functions, but with new names and a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The General and Plastic Surgery Device Classification Panel was terminated, and its functions are now conducted by the General and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel.

Relationship Between the Device Names in the Device Registration and Listing Codes and the Device Names in Classification Regulations

Some manufacturers have become accustomed to identifying a device by its registration and listing name and three letter code used for purposes of device listing under section 510 of the act (21 U.S.C. 360). However, FDA is still making changes in the names and identifications of generic types of devices in the classification regulations for all devices for which final regulations have not been published. Because FDA has not used the present device registration and listing names in the proposed and final classification regulations, FDA has prepared an index of names of generic types of medical devices used in classification regulations to aid a manufacturer in matching its device with the proper classification regulation. The index shows the device registration and listing product code for each device reviewed by a classification panel and the corresponding name of the generic type of device and classification panel in which the device classification will be published in the **Federal Register**. The agency announced the availability of this index in the **Federal Register** of March 6, 1979 (44 FR 12269). If necessary, this index will be updated and the availability of the revised index will be re-announced in the **Federal Register**. FDA believes that, because that index is available, it is unnecessary to include or cross-reference the present device registration and listing name and product code in the classification regulations. In the future, following publication of most of the device classification regulations, the agency will revise and re-issue the device registration and listing product code, so the device names to be used for registration and listing correspond to the device names in the final device classification regulations.

List of General and Plastic Surgery Devices

In 1972, FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of general and plastic surgery devices. The Panel supplemented the list using its members' knowledge of general and plastic surgery devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included. Additional general and plastic surgery devices, which are not included in this list and which were commercially available before May 28, 1976, will be added to the list as necessary.

FDA is proposing to establish a new Part 878 in Title 21 of the Code of Federal Regulations. Part 878 will consist of sections identifying each general and plastic surgery device with a brief narrative description and stating the classification of that device. A list of the general and plastic surgery devices appears elsewhere in this preamble.

General and Plastic Surgery Device Classifications

The agency is proposing to classify 54 general and plastic surgery devices. The agency is proposing to classify 23 general and plastic surgery devices into class I (general controls), 25 general and plastic surgery devices into class II (performance standards), and 5 general and plastic surgery devices into class III (premarket approval). One proposed section, concerning the cryosurgical unit and accessories, would classify certain devices into class II others into class III. The agency also is publishing the recommendations of the Panel regarding these devices, as required by section 513 (c)(2) and (d)(1) of the act (21 U.S.C. 360c (c)(2) and (d)(1)).

Panel Recommendations

The Panel recommendation concerning a general and plastic surgery device includes the information described below.

1. *Identification.* Both the Panel recommendation and the proposed FDA classification include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 878.1 (21 CFR 878.1), any manufacturer of a newly offered device who files a premarket notification submission under section 510(k) of the act and Part 807 of the regulations (21 CFR Part 807) cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a new device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendments device (or to a postamendments device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The agency believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

Some products have both medical and nonmedical uses. FDA will regulate a multipurpose product as a medical device if it is intended for a medical purpose, i.e., for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." (Section 201(h) of the act (21 U.S.C. 321(h)).) FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general

controls), class II (performance standards), or class III (premarket approval).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). The agency's policy on these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority ("high," "medium," or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and Class III Devices," the agency is not, however, proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's proposed classification differs from the Panel's recommendation, FDA is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulation, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

In the "Panel Recommendations and FDA's Proposed Classifications" section, the summary of the Panel's reasons for a recommendation identifies any device that is an implant or a life-supporting or life-sustaining device. The summary of reasons for any implant or life-supporting or life-sustaining device that is not recommended for classification into class III also explains why the Panel determined that classification of the device into class III is not necessary to provide reasonable assurance of its safety and effectiveness. Also, FDA's proposed classifications provide a similar explanation for an implant or a life-supporting or life-sustaining device that is proposed to be classified into a class other than class III.

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on Panel members' personal knowledge of, and clinical experience with, the devices under review. The Panel particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. R. Rept. No. 94853, 94th Congress, 2d Session 40 (1976)). The agency has determined that clinical experience and judgment constitute valid scientific evidence for classifying certain devices.

In several cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the section for each general and plastic surgery device under the heading "Panel Recommendations and FDA's Proposed Classifications." The agency is adopting as its statement of the basis for issuing the regulation under section 517(f) of the act the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by general and plastic surgery devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to an individual device. The Panel listed infection, allergic reaction, foreign body reaction, migration of implant, tissue necrosis, and discomfort for implanted devices. All surgical devices that come into direct or indirect contact with tissue have the potential of causing infection and foreign body reactions due to contamination of wounds. All surgical devices that come in direct contact with the blood have the potential of causing embolisms, hemolysis, obstruction, or occlusion of a blood vessel by an air bubble (gas embolism), detached blood clot (thromboembolism) or other foreign body (particulate embolism). Many electrically powered devices may cause electrical shock and burns to both patients and operators. The Panel has indicated that some radiation emitting devices, such as electrosurgical devices, may heat the lens of the eye and lead to cataract formation. In some cases, FDA has identified risks to health presented by a device in addition to those listed by the Panel. These additional risks are set out in the preamble under the heading "Panel Recommendations and FDA's Proposed Classifications."

Because the classification recommendation and the FDA regulation may not identify all risks to health presented by a general and plastic surgery device, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each section for a general and plastic surgery device under the heading "Panel Recommendations and FDA's Proposed Classifications" states whether FDA agrees with the Panel's recommendation and describes the agency's proposed classification of the device.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Priorities for Class II and Class III Devices

For a device that the Panel recommends classification into class II or class III, section 513(c)(2)(A) of the act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of performance standards or premarket approval requirements. In developing its advice concerning priorities ("high," "medium," or "low") of devices recommended for classification into class II or class III, the Panel compared the device with other general and plastic surgery devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panel recommended assignment of a "high priority" only to those class II or class III devices that the

Panel believed should receive the agency's immediate attention.

FDA is not proposing at this time to establish priorities for development of performance standards for all class II devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. In the **Federal Register** of February 1, 1980 (45 FR 7489 and 45 FR 7493), FDA published notices identifying which class II devices the agency found to warrant a high priority for the development of performance standards. At a later date, the agency will establish priorities for the development of standards for the remaining class II devices. All priorities established by the agency are based on the classification panels' recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

The agency intends to proceed as quickly as the agency and panel resources permit to require premarket approval of devices classified into class III. There are two factors affecting the length of time necessary before FDA requires submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III—the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a classification panel. For example, where FDA classifies into class III only a few devices within a Panel's specialty area, FDA may at the same time also publish regulations under section 515(b) of the act requiring premarket approval for many of the class III devices considered by the Panel, regardless of whether they are a high, medium, or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification during which a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided in section 501(f) of the act (21 U.S.C. 351(f)).

Exemptions for Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: section 510 (21 U.S.C. 360), registration; section 519 (21 U.S.C. 360i), records and reports; and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice.

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding, or processing of * * * a device or devices" must register with FDA (section 510(b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See Part 807 (21 CFR Part 807).) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510 of the act. Several device classification panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufactuers and their products and conduct necessary inspections.

The agency has determined, however, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions for certain devices. Thus, the agency has proposed to exempt manufacturers of certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k) of the act. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) of the act will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation under Part 820 (21 CFR Part 820), published in the **Federal Register** of July 21, 1978 (43 FR 31508). In the future, FDA may publish other regulations in accordance with section 519 of the act, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. Whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will issue exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below, the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the **Federal Register** of July 21, 1978 (43 FR 31508). At the time of the Panel's recommendations, the GMP regulation had not yet been promulgated, and the agency had not yet developed criteria for exempting manufactuers of a class I device from GMP requirements. The agency has now decided that, if any one of the following criteria is met, FDA will consider exempting from the GMP regulation manufacturers of a class I device that is not labeled or otherwise represented as sterile. The agency will not, however, exempt manufacturers of a device from general requirements concerning records or complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of the GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or routine testing before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the

device GMP regulation. A sterile device must be subject to the entire GMP regulation to ensure that manufacturers adequately reduce the bioburden (number of microorganisms) on the device and its components during the manufacturing process. This reduction is accomplished through adherence to a comprehensive quality assurance program as is required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all manufacturers are required to comply with the complaint file requirements. All device manufacturers also are required to comply with the general requirements concerning records to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of devices from requirements under sections 510 or 520(f) of the act, but has acted on the basis of exemption recommendations of the device classification panels. However, FDA has proposed occasionally to exempt manufacturers of certain devices classified into class I or class II from the requirements of certain sections of the GMP regulation, according to the above exemption criteria. Manufacturers and other interested persons may submit comments on the appropriateness of the proposed exemptions of manufacturers of devices, whether the exemptions are proposed in response to recommendations of the panels or on the agency's initiative. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation is consistent with the criteria discussed above.

The agency is proposing that one general and plastic surgery device, the external aesthetic restoration prosthesis (Docket No. 78N-2661), be exempt from the GMP regulation, except for the requirements concerning records and complaint files.

Guidelines for Preparing Petitions Requesting Exemption or Variance from the Device GMP Regulation for Devices Classified into Class I or Class II

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device GMP regulation. These petitions may be submitted in accordance with provisions of section 520(f)(2) of the act (21 U.S.C. 360j(f)(2)). The agency announced the availability of the guidelines in a notice published in the Federal Register of January 18, 1980 (45 FR 3671).

List of General and Plastic Surgery Devices

The following is a list of the general and plastic surgery devices that FDA is proposing to classify, the section and the Subpart of Part 878 in Title 21 of the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section	Device	Docket No.	Class
	Subpart B—General and Plastic Surgery Diagnostic Devices		
878.1800	Speculum and accessories	78N-2647	I.
	Subpart C—[Reserved]		
	Subpart D—General and Plastic Surgery Prosthetic Devices		
878.3250	External facial fracture fixation appliance	78N-2649	I.
878.3300	Surgical mesh	78N-2650	II.
878.3500	Polytetrafluoroethylene with carbon fibers composite implant material	78N-2651	II.
878.3530	Inflatable breast prosthesis	78N-2653	III.
878.3540	Silicone gel-filled breast prosthesis	78N-2654	III.
878.3550	Chin prosthesis	78N-2655	II.
878.3590	Ear prosthesis	78N-2656	II.
878.3610	Esophageal prosthesis	78N-2657	III.
878.3680	Nose prosthesis	78N-2658	II.
878.3720	Tracheal prosthesis	78N-2659	III.
878.3750	External prosthesis adhesive	78N-2660	I.
878.3800	External aesthetic restoration prosthesis	78N-2661	I.
878.3900	Inflatable extremity splint	78N-2662	I.
878.3910	Noninflatable extremity splint	78N-2663	I.
878.3925	Plastic surgery kit and accessories	78N-2664	I.
	Subpart E—General and Plastic Surgery Surgical Devices		
878.4040	Surgical apparel	78N-2665	II.
878.4060	Nonabsorbable gauze, surgical sponge, and wound dressing for extrenal use	78N-2666	I.
878.4100	Intestine bag	78N-2667	I.
878.4120	Hydrophilic beads for wound exudate absorption	78N-2669	I.
878.4140	Porcine burn dressing	78N-2670	I.
878.4160	Surgical camera and accessories	78N-2671	I.
878.4200	Introduction/drainage catheter and accessories	78N-2672	II.
878.4300	Implantable clip	78N-2674	II.
878.4320	Removable skin clip	78N-2675	I.
878.4350	Cryosurgical unit and accessories	78N-2676	II, III.
878.4370	Surgical drape and drape accessories	78N-2677	II.
878.4380	Aerosol drape adhesive	78N-2678	I.
878.4400	Electrosurgical cutting and coagulation device and accessories	78N-2679	II.
878.4450	Nonabsorbable gauze for internal use	78N-2681	II.

Section	Device	Docket No.	Class
878.4460	Surgeon's gloves	78N-2682	II.
878.4470	Surgeon's gloving cream	78N-2683	I.
878.4580	Surgical lamp	78N-2686	II.
878.4630	Dermatologic ultraviolet lamp	78N-2687	II.
878.4650	Aorto-saphenous vein ostia marker	78N-2688	II.
878.4660	Skin marker	78N-2689	I.
878.4680	Nonpowered, single patient, portable suction apparatus	78N-2690	I.
878.4700	Surgical microscope and accessories	78N-2691	II.
878.4730	Surgical skin degreaser or adhesive tape solvent	78N-2692	I.
878.4750	Implantable staple	78N-2693	II.
878.4760	Removable skin staple	78N-2694	I.
878.4780	Powered suction pump	78N-2695	II.
878.4800	Manual surgical instrument for general use	78N-2696	I.
878.4810	Laser surgical instrument for use in general and plastic surgery and in dermatology	78N-2697	II.
878.4820	AC-powered, battery-powered, and pneumatically powered surgical instrument motors and accessories/attachments	78N-2698	II.
878.4930	Suture retention device	78N-2703	I.
878.4950	Manual operating table and accessories and manual operating chair and accessories	78N-2704	I.
878.4960	Air or AC-powered operating table and accessories and air or AC-powered operating chair and accessories	78N-2705	II.
	Subpart F—General and Plastic Surgery Therapeutic Devices		
878.5070	Air-handling apparatus for a surgical operating room	78N-2709	II.
878.5350	High-frequency needle-type epilator	78N-2711	II.
878.5360	High-frequency tweezer-type epilator	78N-2712	III.
878.5650	Topical oxygen chamber for extremities	78N-2714	II.
878.5900	Nonpneumatic tourniquet	78N-2716	I.
878.5910	Pneumatic tourniquet	78N-2717	II.

The General and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel has recently recommended classification of additional preamendments marketed devices for which classification regulations have not yet been written.

The devices listed below thus are not included in the list of general and plastic surgery devices that are the subject of this proposal rulemaking. The devices listed below will be the subject of proposed regulations codifying their statutory classification to be published at a later date. These devices are:

1. Subcutaneous tissue expander (inflatable implant with attached implanted reservoir).

2. Implanted mammary prostheses of composite saline and gel-filled design.

3. Silicone rubber and gel-type implanted augmentation and reconstruction materials:

Silicone elastomer block.
Silicone gel block.
Small encapsulated silicone gel implant ("gel pillow").
Pectoralis muscle implant.

4. Sunlamp tanning enclosures (beds, couches, booths, etc.).

5. Cargile membrane.

6. Silicone adhesives (for fixation of prostheses components before implantation).

General and Plastic Surgery Devices Formerly Considered New Drugs

Before the passage of the Medical Device Amendments of 1976, certain general and plastic surgery devices were considered by FDA to be new drugs subject to 21 U.S.C. 355. Section 520(1) of the 1976 amendments (21 U.S.C. 360j(1)), contains transitional provisions to ensure that articles previously considered as new drugs continue to be subject to regulatory control until the amendments are implemented. The transitional provisions are applicable to any product that is a device (under a revised definition in 21 U.S.C. 321(h)) anf that satisfies one or more of six criteria. These criteria are that the device is a product (1) for which an approved New Drug Application (NDA) was in effect on May 28, 1976 (the enactment date of the amendments); (2) for which an NDA was filed and no order of approval or refusal to approve had been issued by May 28, 1976; (3) for which a notice of claimed investigational exemption for a new drug (IND) was in effect on May 28, 1976; (4) which is substantially equivalent to a product described in item (1), (2), or (3), above; (5) which had been declared to be a new drug by a **Federal Register** notice before May 28, 1976; or (6) which was the subject of a legal action pending on May 28, 1976, for alleged violation of new drug requirements. Under section 520(1), these devices are classified into class III.

Several generic types of general and plastic surgery devices were regarded by FDA as new drugs before enactment of the amendments and are subject to the transitional provisions under one or more of the criteria listed above. In a notice published in the **Federal Register** of December 16, 1977 (42 FR 63472), FDA identified these devices as:

1. Surgical cones and dressings, other than absorbable hemostatic devices and dressings.

2. Silicone, injectable (including tissue adhesives for use in general surgery).

3. Absorbable surgical sutures.

4. Nonabsorbable surgical sutures.

5. Absorbable hemostatic devices and dressings.

6. Absorbable powders for lubricating surgical gloves.

7. Polytetrafluoroethylene (Teflon™), injectable.

The statute has classified these devices into class III without need for regulations or other action on the part of the agency. See 21 U.S.C. 360j(1). In this proposed regulation, FDA has divided item 1, above, into three generic types of devices and is proposing to reclassify these three transitional devices from class III into either class I or class II. See the discussion under the heading "Panel Recommendations and FDA's Proposed Classifications" for the following three devices: § 878.4060, Docket No. 78N-2666, Nonabsorbable gauze, surgical sponge, and wound dressing for external use; § 878.4140, Docket No. 78N-2670, Porcine burn dressing; and § 878.4450, Docket No. 78N-2681, Nonabsorbable gauze for internal use.

The remaining six categories of devices listed above are not being proposed for reclassification. These devices will, however, be the subject of final regulations codifying their statutory classification into class III. These final regulations will be published on the same date as the final regulations on general and plastic surgery devices that are based on this proposal.

Devices Considered by Two or More Panels

Many devices were reviewed by two or more device panels. For these devices, FDA has been publishing the panel's recommendations in a single proposed classification regulation for each generic device.

The Surgical and Rehabilitation Devices Panel and other panels listed below made classification recommendations concerning the following devices:

Device	Other panels
Balloon-type cardiovascular catheter.	Circulatory systems.
Blood pressure measuring apparatus and monitor.	Circulatory systems. General medical. Respiratory and nervous system.
Cardiac output monitor	Circulatory systems. Respiratory and nervous system.
Cardiovascular catheter	Circulatory systems. Respiratory and nervous system.
Electrocardiograph	Circulatory systems. Respiratory and nervous system.
Stethoscope (direct-acoustic and electronic.	Circulatory systems. General medical.
Adhesive tape and bandage.	General medical.
Autoclave sterilizer	General medical. Ophthalmic; ear, nose, and throat; and dental.
Cotton/dye applicator	General medical. Ophthalmic; ear, nose, and throat; and dental.
Ethylene oxide sterilizer	General medical.
Fluid column thermometer	Do.
Liquid crystal thermometer	Do.
Portable single patient use suction apparatus.	Do.
Temperature monitor	General medical. Respiratory and nervous system.
Tongue blade	General medical.
Wall vacuum O.R. suction apparatus.	General medical. Respiratory and nervous system.
AC-powered endoscope and accessories.	General medical.
Billiary catheter	Do.
Colonic irrigation system	Do.
Incandescent endoscope lamp.	Do.
Inflatable penile prosthesis	Do.
Irrigation and aspiration catheter.	Do.
Rectal catheter	Do.
Rigid rod penile prosthesis	Do.
Stomal bag	Do.
Testicle prosthesis	Do.
Ureteral catheter	Do.
Urethral catheter	Do.
Artificial eye	Opthalmic; ear, nose, and throat; and dental.
Internal eye prosthesis	Do.
Magnetic locator	Do.
Surgical headband light	Do.
Battery powered headlamp	Ophthalmic; ear, nose, and throat; and dental. General medical.
External nasal splint prosthesis.	Ophthalmic; ear, nose, and throat; and dental.
Mandible prosthesis	Do.
Maxilla prosthesis	Do.
Nerve stimulator	Do.
Vascular graft cardiovascular.	Do.
Respiratory monitor	Respiratory and nervous system.
Electroencephalograph	Do.
Continuous PO_2 monitor	Respiratory and nervous system. General medical.
Stretcher	Surgical and rehabilitation. Respiratory and nervous system.
Tendon prosthesis	Surgical and rehabilitation.

The agency is not at this time publishing the recommendations of the General and Plastic Surgery Device Section of the Surgical and Rehabilitation Devices Panel to classify the devices listed above. The agency has published, or will publish, these recommendations and proposed classification regulations along with the recommendations of the other Panels or Sections that reviewed the devices. Some of these other Panels' or Sections' recommendations have already been published in the **Federal Register.** The following table shows the current structure of the advisory committees involved with classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel/Section Name and Publication Date in Federal Register

Circulatory Systems Devices Panel: March 9, 1979, 44 FR 13284–13434 (proposals); February 5, 1980, 45 FR 7904–7971 (final regulations).

Clinical Chemistry and Hematology Devices Panel

Clinical Chemistry Device Section
Clinical Toxicology Device Section
Hematology and Pathology Device Section—September 11, 1979, 44 FR 52950–53063 (proposals); September 12, 1980, 45 FR 60576–60651 (final regulations).

General Medical Devices Panel

General Hospital and Personal Use Device Section—August 24, 1979, 44 FR 49844–49954 (proposals); October 21, 1980, 45 FR 69678–69737 (final regulations).
Gastroenterology-Urology Device Section—January 23, 1981, 46 FR 7562–7641 (proposals).

Immunology and Microbiology Devices Panel

Immunology Device Section—April 22, 1980, 45 FR 27204–27359 (proposals).
Microbiology Device Section—April 22, 1980, 45 FR 27204–27359 (proposals).

Obstetrics-Gynecology and Radiologic Devices Panel

Obstetrics-Gynecology Device Section; Radiology Device Section—April 3, 1979, 44 FR 19894–19971 (proposals); February 26, 1980, 45 FR 12682–12720 (final regulations).

Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel

Ophthalmic Device Section
Ear, Nose, and Throat Device Section
Dental Device Section—December 30, 1980, 45 FR 85962–86168 (proposals).

Respiratory and Nervous System Devices Panel

Anesthesiology Device Section—November 2, 1979, 44 FR 63292–63426 (proposals).
Neurological Device Section—November 28, 1978, 43 FR 54640–55732 (proposals); September 4, 1979, 44 FR 51726–51778 (final regulations).

Surgical and Rehabilitation Devices Panel

Physical Medicine Device Section—August 28, 1979, 44 FR 50458–50537 (proposals).
Orthopedic Device Section
General and Plastic Surgery Device Section—(Insert date of publication in the **Federal Register**) (proposals).

Panel Recommendations and FDA's Proposed Classifications

Section 878.1800; Docket No. 78N–2647; Speculum and accessories.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of specula and accessories:

1. Identification: A speculum is a device that is intended for insertion into a body cavity to facilitate observation. It is either non-illuminated or illuminated and may have various accessories.
2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Costmetic Act (21 U.S.C. 360i).
3. Summary of reasons for recommendation: The Panel recommends that specula and accessories be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls. The Panel believes that records and reports are not necessary for the device because specula and accessories have been used in clinical practice for many years with no apparent problems.
4. Summary of data on which the recommendation is based: The panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.
5. Risks to health: None identified.

FDA agrees with the Panel's recommendation and is proposing that specula and accessories be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA disagrees with the Panel's recommendation that manufacturers of specula and accessories be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 878.3250; Docket No. 78N–2649; External facial fracture fixation appliance.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the

classification of external facial fracture fixation appliances:

1. Identification: An external facial fracture fixation appliance is a metal apparatus used during surgery to immobolize maxillofacial bone fragments in their proper facial relationship for surgical reconstruction and repair.

2. Recommended classification: Class I (general controls): The Panel recommends that the device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 369i).

3. Summary of reasons for recommendation: The Panel recommends that external facial fracture fixation appliances be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health. The materials used in the device are generally acceptable and need be subject only to general controls. The Panel believes that records and reports requirements are not necessary for the device because external facial fracture fixation devices have been used in clinical practice for many years with no apparent problems.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result.

FDA agrees with the Panel's recommendation and is proposing that external facial fracture fixation appliances be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA disagrees with the Panel's recommendation that manufacturers of external facial fracture fixation appliances be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 878.3300; Docket No. 78N–2650; Surgical mesh.

The General and Plastic Surgery Device Classification Panel, the Orthopedic Device Classification Panel, and the Gastroenterology and Urology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of surgical meshes:

1. Identification: A surgical mesh is an implanted metallic or polymeric screen intended for use in reinforcing soft tissue or bone where weakness exists. Examples of surgical mesh are metallic and polymeric mesh for hernia repair, and acetabular and cement restrictor mesh used in orthopedic surgery.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that surgical meshes be classified into class II (performance standards) because the Panels beleive that the device has an established history of safe and effective use. The Panels believe that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Orthopedic Device Classification Panel also recommends that labeling for acetabular mesh used in hip joint repair and femoral cement restictor mesh used in thigh bone repair be required to contain information in the dimensions and strength of the mesh. The Panels believe that general controls alone would not provide sufficient control over these characteristics. Although this device is an implant, the Panels believe that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information available to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the literature. The Orthopedic Device Classification Panel cited the work of Harris and Jones (Ref. *1*) who evaluated acetabular mesh, femoral cement restrictor mesh, and metallic wire mesh in total hip replacement surgery. According to Harris and Jones, the device was implanted in 13 patients with satisfactory results from 6 months to 2 years after implantation. The Gastroenterology and Urology Device Classification Panel reviewed a publication by Mitchell-Heggs (Ref. *2*) which described 41 cases of mesh implantations with a very low rate of complications. The General and Plastic Surgery Device Classification Panel frequently cited the established use of metallic and polymeric mesh in hernia repair.

5. Risks to health: (a) Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result. (b) Implant rejection: The mesh may induce a foreigh body reaction which may result in rejection.

FDA agrees with the Panels' recommendations and is proposing that surgical meshes be classified into class II (performance standards). Although the device is an implant, the agency believes that premarket approval is not necessary because of the extensive clinical usage of surgical mesh over a long period of time and because there is sufficient information available to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device.

FDA has reviewed pertinent clincial literature on surgical meshes (Refs. *1* through *8*). The agency notes that the recurrence rate for the repair of incisional hernias before using meshes was approximately 30 percent and operations were long and had a mortality rate of 2 to 3 percent (Ref. *5*). In addition, a number of patients were considered inoperable because of the severity of associated medical conditions. Subsequently, a number of surgical meshes have been used for the last 20 years: Tantalum (Ref. *2*), chrome cobalt (Ref. *1*), stainless steel (Ref. *3*), polypropylene (Refs. *4, 5,* and *6*), and polyester (Refs. *6, 7,* and *8*). Mitchell-Heggs (Ref. *2*) reported a good clincial result was obtained in 30 (73 percent) of 41 cases for tantalum herniaplasty during a period of 9 years. Recurrence was observed in three cases (7 percent) and sinus formation in four cases (10 percent). There were no postoperative deaths due to tantalum mesh. Harris et al. (Ref. *1*) used chrome cobalt wire mesh to reinforce the bone cement in the acetabulum for total hip replacement surgery with followup on 13 patients ranging from 6 months to 2 years. No loosening or mechanical failure of the mesh had occurred. Preston et al. (Ref. *3*) employed stainless steel mesh in the treatment of hernia. In more than 2,000 repairs and 24 years experience, the incidence of infection is 0.1 percent and the recurrence is zero. Larsen et al. (Ref. *5*) reported on 53 patients for the repair of incisional hernias with polypropylene mesh. During 8 years (1970–1978), there was no operative mortality and the mesh had been uniformly well tolerated. The recurrence rate was found to be 11 percent, a distinct improvement over the era before mesh was used.

The successful clincial use of surgical mesh is consistent with the results of animal studies (Ref. *4*). Calne (Ref. *7*) reported 1 infection and 7 recurrences in 35 patients for repair of bilaterial hernia with polyester mesh. Most of the recurrences were found to be small and asymptomatic. Cerise et al. (Ref. *8*) reported 100 cases where polyester mesh was used in repair of abdominal wall hernias. Only one serious complication, recurrent abscess with

sinus formation, occurred 20 months postoperatively. Casebolt (Ref. *6*) used polypropylene and polyester mesh for repair of abdominal wall defects. There were no mortalities reported in 33 cases over a 9-year experience. Two recurrences (6 percent) due to failure of sutures, five minor complications, and three seromas which responded to aspiration, were reported. Wound infection remains a serious potential complication, but is minimized by good surgical practice.

FDA has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel, the Orthopedic Device Classification Panel, and the Gastroenterology and Urology Device Classification Panel for surgical mesh and has concluded that classification of this device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.3500; Docket No. 78N-2651; Polytetrafluoroethylene with carbon fibers composite implant material.

The General and Plastic Surgery Device Classification Panel and the Ear, Nose, and Throat Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of polytetrafluoroethylene with carbon fibers composite implant material:

1. Identification: A polytetrafluoroethylene with carbon fibers composite implant material is an implanted, porous device material that is intended for use as a space-occupying substance in surgery of the chin, jaw, nose, and bones and tissue near the eye and ear. The device material is shaped and formed by the surgeon to conform to the patient's need.

2. Recommended classification: Class II (performance standards). Both Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: Both Panels recommend that polytetrafluoroethylene with carbon fibers composite implant material be classified into class II (performance standards) because the Panels believe that the safety and effectiveness of the material has been established through long-term clinical trials. The Panels believe that the material should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panels also believe that the sterilization of the material needs to be controlled to prevent infection. The Panels believe that general controls alone would not provide sufficient control over these characteristics. Although this device is an implant, the Panels believe that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information available to establish a performance standard.

4. Summary of data on which the recommendation is based: The General and Plastic Surgery Device Classification Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and on a review of research articles and clinical and laboratory studies submitted by Vitek, Inc., and Dow Corning Corp., manufacturers of the device. On July 23, 1976, Charles Homsy, Ph. D., Chief Executive Officer, Vitek, Inc., and Joseph Radzius, attorney for Dow Corning Corp., presented to the General and Plastic Surgery Device Classification Panel research data and studies on the device compiled by Vitek, Inc., and Dow Corning Corp. Dr. Homsy submitted to the Panel 13 articles from the scientific and clinical literature (Refs. *9* through *21*), 8 product brochures describing the material (Refs. *22* through *29*), an animal study of the safety of the material (Ref. *30*), and a supplementary bibliography of research and clinical articles published on the material (Ref. *31*). On October 28, 1976, the Panel concluded that it should review these data and the use of the device for maxillofacial reconstructive surgery. Also, the Panel requested additional supporting data from Bromley Freeman, M.D., and John Madden, M.D., who were reported to have evaluated the material. On December 16, 1976, following Panel review of the data and information supplied by Dr. Madden, the Panel recommended that the material be classified into class III (premarket approval), with premarket approval a high priority, because of the lack of convincing data on the safety of the material for human implantation. On February 24, 1977, Dr. Homsy made a second presentation to the Panel and submitted further data from the clinical literature (Refs. *32* through *37*), and additional product information on the device (Refs. *38* and *39*). Dr. Homsy presented toxicity data on the device material and a 2-year followup study of its clinical use. Following the presentation, the Panel decided not to change its recommendation that the device be classified into class III, because of the lack of longer term clinical data. However, the Panel noted that the pre-clinical laboratory and animal data presented by Dr. Homsy supported the safety of the material for further clinical evaluation. On March 24, 1978, there was a third presentation to the Panel by Dr. Homsy, Dr. Kent, and others (Ref. *40*). Dr. Kent, who is the Chairman of the Department of Oral Surgery at Louisiana State University and the project monitor for the multicenter clinical trials, presented additional, long-term clinical followup data on the material. William Boley of Dow Corning Corp. described a tissue cell culture test used for evaluation and routine screening of the material for tissue compatibility. Following the presentation, the Panel voted unanimously to change its recommendation to class II, basing its recommendation on the long-term clinical followup data presented by Dr. Kent supporting the clinical safety and effectiveness of the material.

The Ear, Nose, and Throat Device Classification Panel based its recommendation on a presentation at its January 27, 1978 meeting by Dr. Homsy and by an associate, M. Sidney Anderson, M.D., clinical associate professor, Department of Pathology, Baylor College of Medicine. Medical and scientific data, animal studies, clinical evaluations, and summaries of experience were presented to the panel to justify the safety and effectiveness of polytetrafluoroethylene material with carbon fibers.

Dr. Homsy noted that in vitro biocompatibility screening protocols were developed to guide in the selection of the material's ingredients. Both the polymer polytetrafluoroethylene and graphite fibers were found to be extremely biocompatible. Dr. Homsy stated that 2-year animal studies of both porous and nonporous forms of the material that had been implanted in the femurs of beagle dogs produced no findings of toxicological reactions.

Dr. Homsy brought to the attention of the Panel abstracts from 41 articles in the literature which dealt with animal and clinical studies. Dr. Homsy noted that there has never been a reported failure with this material due to cytotoxicity, tissue incompatibility, or system toxicity.

Dr. Homsy stated that polytetrafluoroethylene with carbon fibers was clinically introduced for use in humans in 1970. He reported precommercial clinical studies were performed in more than 499 patients with a success rate in excess of 97 percent. In cases that failed, Dr. Homsy stated that evidence indicated that failures were associated with inexperience with the operative technique and operative sepsis.

Dr. Anderson reviewed his histopathological experience with this material when used as an implant. He indicated that of 10,000 sections he has viewed, most have come from animal studies, with a limited number from human studies, primarily from the femoral medullary canal, facial skeleton, and alveolar ridge. Summarizing different tissue reactions observed, he stated: (a) Neovascularity is seen early and is enhanced by preimpregnation with blood; (b) multinucleated foreign body giant cells are related to mobility at implantation site; they decrease with time and are replaced by connective tissue; (c) collagen may be seen as early as one week with good fixation with adjacent connective tissue; (d) osteoid formation is usually preceded by bone formation and is typically followed by more dense collagenization; (e) bone ingrowth is usually in older implants, especially those in immobile locations; continuity is developed with normal bone; (f) visceral organs and regional lymph nodes are found to be normal after 6 years.

5. Risks to health identified by the General and Plastic Surgery Device Classification Panel: (a) Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result. (b) Tissue or skin necrosis (destruction): Excessive pressure from the device may cause overlying skin or adjacent tissue

destruction and may result in extrusion of the prosthesis. (c) Displacement of implant: Migration of the device below the skin may result in cosmetic deformity. (d) Bone resorption (loss): Deterioration or loss of bone near implanted prostheses such as chin prostheses, has been reported in the medical literature. The Ear, Nose, and Throad Device Classification Panel identified risks to health from use of this device similar to those above.

FDA agrees with the recommendations of both Panels and is proposing that polytetrafluoroethylene with carbon fibers composite implant material be classified into class II (performance standards). Although the device is an implant, the agency believes that premarket approval is not necessary because there is sufficient information available to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. FDA considered the following information regarding the development, in vitro evaluation, and clinical evaluation of the material: (1) The components of the device implant material, polytetrafluoroethylene and carbon fibers, are generally accepted as safe materials for human implantation. (2) the material is designed to allow tissue ingrowth into the implant. (3) The material has been studied extensively in animals. (4) The material has been accepted as safe and effective by the Ear, Nose, and Throat Device Classification Panel (Refs. *16, 41,* and *42*) for uses appropriate to the medical specialty areas covered by that Panel. (5) The material has been reviewed extensively in the clinical literature and there have been substantive followup clinical trials of the material extending to 6 years. (6) No evidence has been found that the material is toxic. (7) No substantive clinical malfunction of the device material has occurred in maxillofacial reconstructive surgery, and it has been used successfully in 97 percent of 394 cases (Ref. *40*). The agency believes that the clinical evidence of the material's safety, as well as the reported absence of toxicological problems in a 2-year dog study (Ref. *30*), support classification into class II.

Section 878.3530; Docket No. 78N–2653; Inflatable breast prosthesis.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of inflatable breast prostheses:

1. Identification: An inflatable breast prosthesis is a silicone rubber shell made of polydimethylsiloxane and polydiphenylsiloxane that is inflated after implantation with a fluid other than injectable silicone, such as sterile isotonic saline, that is intended to augment or reconstruct the female breast.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that inflatable breast prostheses be classified into class II (performance standards) because the Panel believes that the device has an established history of safe and effective use. The Panel believes that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls alone would not provide sufficient control over these characteristics. Although this device is an implant, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information available to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on the existence of several clinical reports supporting the safety and effectiveness of inflatable breast prostheses in many implant cases (Ref. 43). On March 24, 1978, Dr. Henry Jenny, M.D., presented several studies to the Panel members and stated that he believed that inflatable breast prostheses are superior to gel-filled prostheses because they do not use gel. Dr. Jenny's beliefs are based on research studies that tend to show leakage of silicone gel from the silicone shell, and on the possibility of unknown hazards from the leaking gel such as foreign body reaction and long-term toxic effects.

A recent study by the Department of Health and Human Services' Center for Disease Control, Atlanta, GA, reported mycobacterium infection in a significant number of recipients of breast prostheses. Although the significance of this observation has not yet been fully assessed, it may represent a hitherto undetected hazard associated with this device (Ref. 53).

5. Risks to health: (a) Leakage: Rupture of the device, or a faulty valve, may result in deflation of the prosthesis and may require surgical intervention to correct the resulting deformity. (b) Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result. (c) Tissue or skin necrosis (destruction): Excessive pressure from the device may cause overlying skin or adjacent tissue destruction and may result in extrusion of the prosthesis. (d) Hematoma (a localized collection of blood, usually clotted, in an organ, space, or tissue, due to a break in the wall of a blood vessel): Hematoma due to a small vesel rupture may require reoperation. (e) Fibrous capsule contracture: Contracture of the fibrous tissue surrounding the implant may result in disfigurement, physical and psychological trauma, migration of the implant, or gross leakage of the contents from the silicone shell under the skin, and may necessitate further surgery. Several claims have been made that the absence of silicone gel in this device reduces the incidence of capsular contracture. However, this claim is not well documented. (f) Displacement of implant: Migration of the prosthesis below the skin may result in cosmetic deformity.

FDA disagrees with the Panel's recommendation and is proposing that inflatable breast prostheses be classified into class III (premarket approval). This device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the agency to classify an implant into class III unless it determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the agency has determined that premarket approval is necessary. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance. The agency believes that premarket approval is necessary for this device because it presents a potential unreasonable risk of injury due to the possibility of fluid leakage from the prosthesis or contraction of the fibrous tissue capsule around the implanted prostheses, which can lead to marked asymmetry in breast contour and other potentially painful and disfiguring complications. The agency has reviewed the Panel's recommendation and additional information on inflatable breast prostheses and has concluded that the primary health hazard associated specifically with this type of breast prosthesis is leakage of the contents of the silicone shell and subsequent collapse or deformity of the breast. The agency has evaluated the frequency of leakage of inflatable breast prostheses (Refs. *44* through *48*). It is apparent that there was substantial reduction in the incidence of valve leakage during the period 1969 to 1974. This reduction in incidence is consistent with comments of the General and Plastic Surgery

Device Classification Panel during its July 23, 1976, Panel meeting. The Panel concluded that "the valves have been improved to the point where the incidence of complications is remarkably low." The agency has also reviewed the report by Dr. Snyder (Ref. *49*) regarding the reduced likelihood of valve leakage with the newer prostheses. However, the agency notes a number of cautions raised by the early evaluators and the presence of similar cautions in recent clinical literature. One evaluator warned that the mechanism of fluid loss in saline filled prostheses is unknown (Ref. *44*). This view is shared by other authors who believe that nonleakage is an absolute criterion for this device that has not yet been achieved (Refs. *50* and *51*). The agency has not seen any recent data confirming the reduced incidence of inflatable breast prosthesis leakage as reported in the March 1974, 7-month followup study (Ref. *48*). Also, the agency notes that the 1977 case report (Ref. *52*) which described the rupture of two inflatable breast prostheses during a closed compression capsulotomy (a procedure performed to release the fibrous capsule around the implant by manually squeezing the breast externally, without reoperation), with associated migration of the contents of the prosthesis. Although a considerable advance has been made in the design of the valves of these devices, the agency believes that the improvements have not been sufficiently evaluated to allay concerns about the risk of device failure and attendant complications.

Section 878.3540; Docket No. 78N–2654; Silicone gel-filled breast prosthesis.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of silicone gel-filled breast prostheses:

1. Identification: A silicone gel-filled breast prosthesis is a silicone rubber shell made of polydimethylsiloxane and polydiphenylsiloxane. The shell either contains cross-linked polymerized silicone gel, fillers, and stabilizers or is filled with injectable silicone gel at time of implantation. The device is intended for implantation to augment or reconstruct the female breast. The device does not include injectable silicone (including tissue adhesives for use in general surgery) for injection directly into the patient's body rather than into a shell; direct injection use of silicone is investigational only.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that silicone gel-filled breast prostheses be classified into class II (performance standards) because the Panel believes that this device has demonstrated a reasonably satisfactory level of performance over a long period of time. The Panel believes that the materials used in this device should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel believes that the standard for breast prostheses being developed by the American Society for Testing Materials (ASTM) could be used as the basis for further development of a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the scientific literature. The Panel believes that several postoperative complications associated with the use of the device, such as infection and implant migration, are due primarily to errors in surgical technique. The Panel also noted that implanted prostheses become encapsulated by fibrous tissue and patients may experience contracture of the fibrous capsule. Closed compression capsulotomy (a procedure performed to release the fibrous capsule around an implant by manually squeezing the breast externally, without reoperation), can be used to overcome the effects of fibrous capsule contracture.

At a Panel meeting on March 24, 1978, Henry Jenny, M.D., presented histopathologic evidence of leakage of silicone gel through the silicone outer shell and into the body (Ref. *54*). At a Panel meeting on July 6, 1978, Jerrold Abraham, M.D., presented data demonstrating the presence of silicone in the tissue adjacent to, and distant from, an intact silicone gel-filled breast prosthesis implant (Ref. *55*). Dr. Abraham noted that the metabolic fate and long-term effects of silicone in the human body are unknown. Also at the meeting, James L. Baker, M.D., Thomas M. Biggs, M.D., and Robert R. LeVier, Ph.D., of Dow Corning Corp., presented clinical and laboratory data to the Panel on the performance and toxicology of silicone gel-filled breast prostheses and component materials. These data included several animal studies, clinical studies that indicated a low rate of post-operative complications, and information on the effectiveness of various implantation techniques (Ref. *56*).

A recent study by the Department of Health and Human Services' Center for Disease Control in Atlanta, GA, reported mycobacterium infection in a large number of recipients of breast prostheses. Although the significance of this observation has not yet been assessed, it may represent a hitherto undetected hazard associated with this device (Ref. *53*).

5. Risks to health: (a) Leakage: Leakage of silicone gel due to rupture or degradation of the implant, leaching of gel through an intact implant, or leakage as a consequence of performance of a closed compression capsulotomy may result in deposition and migration of silicone gel in the body, with pain and possible toxic effects. (b) Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result. (c) Tissue or skin necrosis (destruction): Excessive pressure from the device may cause overlying skin or adjacent tissue destruction and may result in extrusion of the device. (d) Hematoma (a localized collection of blood, usually clotted, in an organ, space, or tissue, due to a break in the wall of a small blood vessel): Hematoma due to small vessel rupture may require reoperation. (e) Fibrous capsule contracture: Contracture of the fibrous tissue capsule surrounding the implant may result in disfigurement, physical and psychological trauma, migration of the implant, or gross leakage of the gel under the skin, and may necessitate further surgery. (f) Calcification of the fibrous capsule: Calcification of the fibrous tissue capsule surrounding the implant may result in cosmetic deformity and may necessitate further surgical intervention or removal of the implant (Ref. *63*). (g) Displacement of implant: Migration of the prosthesis below the skin may result in cosmetic deformity. (h) Interference with tumor detection: The implantation of gel-filled prostheses in the breast may interfere with standard cancer diagnostic techniques. (i) Postoperative lactation: Some evidence suggests that after surgical implantation of the device, a small percentage of patients taking oral contraceptives may experience lactation (Ref. *64*).

FDA disagrees with the Panel's recommendation and is proposing that silicone gel-filled breast prostheses, some of which include the transitional device, silicone, injectable (including tissue adhesive for use in general surgery), be classified into class III (premarket approval). This device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the agency to classify an implant into class III unless it determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the agency has determined that premarket approval is necessary. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance. The agency believes that premarket approval is necessary for this device because it

presents a potential unreasonable risk of injury due to (1) possible migration of silicone gel from the interior of the prosthesis to adjacent tissue (with or without rupture of the silicone rubber shell), (2) contraction of the fibrous tissue capsule which forms around the implanted prostheses and which also can lead to marked asymmetry in breast contour, hardness, and pain, and (3) possible long-term toxic effects of the silicone polymers from which the prostheses are fabricated. The agency has reviewed the Panel's recommendation and has sought additional information on silicone gel-filled mammary prostheses for both breast augmentation and reconstruction. Some of the medical literature indicates that a significant portion of patients experience complications directly associated with implantation of these devices (Refs. *61* and *63* through *67*). The silicone within the prosthesis may migrate into the body of the patient even without rupture of the solid silicone rubber shell and can be transported to distant sites by scavenger cells (Ref. *68*). Furthermore, during closed compression capsulotomy, rupture of prostheses have occurred with associated migration of silicone (Ref. *62*). Contraction of the fibrous tissue capsule that forms around implanted breast prostheses may lead to pain, hardness of the breast, and asymmetry in breast contour. One systematic study of various mammaplasty procedures reported that 9 to 40 percent of patients developed capsular contracture (Ref. *58*). Another publication documented an incidence of capsular contracture as high as 74 percent (Ref. *57*). Once contracture develops, the rate of recurrence is high, and several cases have been documented in which the fibrous capsule has become calcified, necessitating further surgical intervention (Ref. *62*). The agency notes that neither the chemical forms of silicones which leach into breast tissue nor their metabolic fates are known (Ref. *60*). Furthermore, no satisfactory independent study has thoroughly evaluated the chronic long-term toxicololgy of cross-linked silicone polymers of different molecular sizes. Although studies have been published on the toxicology of liquid silicone (Refs. *59*, *60*, and *61*), the agency believes these studies are limited in scope and require further experimental confirmation. Because young women are the recipients of a significant percentage of these implants, information regarding silicone's chronic toxic effects or possible teratogenetic effects (production of defects in offspring) is desirable and could be of substantial importance in determining the risk to these patients. Epidemiological studies on silicone are limited to several user surveys (Refs. *69* and *71*) which attempted to document the incidence of cancer after mammaplasty with silicone gel-filled prostheses. These studies are based upon questionnaires submitted to performing surgeons, with variable followup. Although the evidence of carcinogenesis in humans is inconclusive in reference to silicone (Refs. *73*, *74*, and *75*), extensive research involving laboratory animals has confirmed the "Oppenheimer effect", or solid state carcinogenesis, produced by foreign materials in the body (Ref. *72*). The agency believes that insufficient time has elapsed to permit a direct evaluation of the risk of cancer posed by the presence of silicone in the human body and that there does not exist sufficient epidemiologic data or experimental information in animals to make an inferential judgment. In this context, the agency has reviewed with concern letters from two physicians (Refs. *76* and *77*) discussing complications of "breast" plasty procedures. The agency has also received letters from physicians and legal representatives of patients describing severe untoward effects as a result of implant rupture and associated complications (Refs. *78* and *79*). These ongoing scientific debates on the safety of breast prostheses support the agency's proposal to strengthen regulatory surveillance of this device.

For clarity, FDA has included in the identification of the device a statement that, "[t]he device does not include injectable silicone (including tissue adhesives for use in general surgery) for injection directly into the patient's body rather than into a shell; direct injection use of silicone is investigational only." This language is to distinguish the device that is subject to the proposed regulation from the injectable silicone that has been classified into class III by section 520(l)(1) of the Federal Food, Drug, and Cosmetic Act, which sets forth the transitional provisions of the Medical Device Amendments of 1976 (21 U.S.C. 360j(l)(1)). See the **Federal Register** of December 8, 1977 (42 FR 63472–63473) and the discussion in this preamble under the heading "General and Plastic Surgery Devices Formerly Considered New Drugs." Injectable silicone (including tissue adhesives for use in general surgery) has been investigated for several years, first as a new drug and now as a class III medical device. This product may not be marketed without premarket approval. The 30-month or longer grace period applicable to devices on the market before the amendments (see section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) applies to the premarket approval of silicone gel-filled breast prostheses subject to this proposed regulation, but not to injectable silicone (including tissue adhesives for use in general surgery) for injection directly into the patient's body rather than into a shell.

Section 878.3550; Docket No. 78N–2655; Chin prosthesis.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of chin prostheses:

1. Identification: A chin prosthesis is an implanted solid silicone rubber prosthesis intended for use in chin augmentation or reconstruction.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that chin prostheses be classified into class II (performance standards) because the Panel believes that the device has an established history of safe and effective use. The Panel believes that the materials used in the device should meet a generally accepted satisfactory level of tissue compatability to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls alone would not provide sufficient control over these characteristics. Although this device is an implant, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information available to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Infection: If the materials used in the device or its construction prevent proper sterilization, infection may result. (b) Tissue or skin necrosis (destruction): Excessive pressure from the device may cause overlying skin or adjacent tissue destruction and may result in extrusion of the prosthesis. (c) Displacement of implant: Migration of the prosthesis under the skin may result in cosmetic deformity. (d) Hematoma (a localized collection of blood, usually clotted, in an organ, space, or tissue, due to a break in the wall of a blood vessel): Hematoma due to small vessel rupture may require reoperation. (e) Fibrous capsule contracture: Complications may result from contracture of the fibrous capsule which normally forms around an implanted

prosthesis. (f) Bone resorption (loss): Deterioration or loss of bone near implanted prostheses such as chin prostheses, has been reported in the medical literature.

FDA agrees with the Panel's recommendation and is proposing that chin prostheses be classified into class II (performance standards). Although the device is an implant, the agency believes that premarket approval is not necessary because solid silicone implants have an established history of safe and effective use for restoration of deficient contour of the chin and because there is sufficient information available to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. The agency has reviewed the Panel's recommendation and has reviewed pertinent clinical literature of the use of solid silicone rubber implants in mentoplasty (Refs. *81* through *84*), and notes that complications associated with silicone chin implants were reported in less than 2 percent of the cases (Refs. *81* and *82*). The clinical literature (Refs. *81, 82,* and *83*) indicates that these complications can usually be avoided by good surgical technique.

Section 878.3590; Docket No. 78N-2656; Ear prosthesis.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committeee, made the following recommendation regarding the classification of ear prostheses:

1. Identification: An ear prosthesis is an implanted solid silicone rubber prosthesis intended for use in the reconstruction of the external ear.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that ear prostheses be classified into class II (performance standards) because the Panel believes that the device has an established history of safe and effective use. The Panel believes that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls alone would not provide sufficient control over these characteristics. Although this device is an implant, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information available to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, and on a review of the literature.

5. Risks to health: (a) Infection: If the materials used in the device or its construction prevent proper sterilization, an infection to the patient may result. (b) Tissue or skin necrosis (destruction): Excessive pressure from the device may cause overlying skin or adjacent tissue destruction and may result in extrusion of the prosthesis. (c) Displacement of implant: Migration of the prosthesis under the skin may result in a cosmetic deformity. (d) Fistulae: Small fistulae may develop along the suture line.

FDA agrees with the Panel's recommendation and is proposing that ear prostheses be classified into class II (performance standards). Although the device is an implant, the agency believes that premarket approval is not necessary because of the extensive clinical acceptance of the device over a long period of time and because there is sufficient information available to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. FDA has reviewed the Panel's recommendation and some of the available literature. The agency believes that although the earlier versions of ear prostheses were relatively unsafe because of the high frequency of extrusion, the extrusion rate has been significantly reduced. Two followup studies (Refs. *85* and *86*) reveal improvements in the quality of ear prostheses and in surgical technique. The first study by Monroe (Ref. *85*) concerned 17 case histories extending 1 to 5 years, and the second study by Ohmori (Ref. *86*) involved 116 patients. Both studies involved use of improved techniques for prosthesis anchorage. Also, special precautions were taken, and in the second study the rate of rejection was reduced to 9.5 percent. The agency believes that considering the benefits from the use of this device compared with the benefits from other available procedures, such as the use of autogenous cartilage, the risks presented by the devices are acceptable.

Section 878.3610; Docket No. 78N-2657; Esophageal prosthesis.

The General and Plastic Surgery Device Classification Panel and the Ear, Nose, and Throat Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of esophageal prostheses:

1. Identification: An esophageal prosthesis is a plastic tube or tube-like device (that may have mesh reinforcement) and accessories that is implanted in, or affixed externally to, the chest and throat for restoration of the esophagus or for pharyngoesophageal continuity.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel recommends that esophageal prostheses be classified into class III (premarket approval) and that premarket approval of this device be a low priority. The Ear, Nose, and Throat Device Classification Panel recommends that the device be classified into class II (performance standards) and that establishing performance standards for this device be a low priority.

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel recommends that esophageal prostheses be classified into class III because the device is life-sustaining and life-supporting and is implanted or has components that are implanted in the human body. The Panel believes that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that sufficient information does not exist to establish a standard to provide such assurance. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness. The Ear, Nose, and Throat Device Classification Panel recommends that the device be classified into class II because the Panel believes that the device has an established history of safety and effectiveness. The Panel believes that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The Panel believes that general controls would not provide sufficient control over the performance characteristics of this device. Although the device is an implant, the Panel believes that premarket approval is not necessary because a performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Panel also believes that there is sufficient information available to establish a performance standard to provide such assurance.

4. Summary of date on which the recommendation is based: Both Panels based their recommendation on their personal knowledge of, and clincial experience with, the device, on a review of the literature. The General and Plastic Surgery Device Classification Panel noted esophageal prostheses were discussed in an article by

Fryfogle et al. (Ref. *92*) who evaluated various suture techniques employed for the placement of nonrigid silicone rubber-dacron esophageal grafts in dogs; and "found that all suture techniques resulted in the narrowing or stricture of the prosthesis." From this study it was determined that all suture techniques employed caused narrowing or stricture of the prostheses which in time leads to complications and possible failure of the prostheses. Plastic multitoothed rings, used for secured implant anchoring, did not interrupt the esophageal wall blood supply. A successful six-week followup on a single clincial case was reported (Ref. *92*).

5. Risks to health: Both Panels identified the following risks to health: (a) Infection. If the materials used in the device or its construction prevent proper sterilization of the device, infection to the patient may result. The General and Plastic Surgery Device Classification Panel identified the following additional risks to health: (b) Tissue or skin necrosis (destruction). Excessive pressure from the device may cause overlying skin or adjacent tissue destruction and may result in the extrusion of the prosthesis. (c) Leakage. Rupture of the prosthesis may lead to leakage of food into body cavities.

FDA agrees with the General and Plastic Surgery Device Classification Panel's recommendation and is proposing that esophageal prostheses be classified into class III (premarket approval). FDA disagrees with the Ear, Nose, and Throat Device Classification Panel's recommendation that esophageal prostheses be classified into class II (performance standards). The device is life-supporting and life-sustaining and is implanted or has implanted components. Also, the device presents a potential unreasonable risk of injury from food leakage that may lead to infection and failure of the device. Furthermore, local tissue necrosis due to pressure may occur, and tissue damage may result from toxicity of materials used in the device. The Federal Food, Drug, and Cosmetic Act requires the agency to classify an implant into class III unless it determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the agency has determined that premarket approval is necessary. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance. The agency has reviewed the Panels' recommendations and additional information on esophagus prostheses. The agency notes numerous reports of attempts to restore the esophagus by temporarily inserting a plastic tube (Refs. *87* and *88*) or bypass tubes into the esophagus (Ref. *89*), or by permanently implanting a synthetic prosthesis (Refs. *90*, *91*, and *92*). Complications associated with the insertion of a plastic tube or bypass tubes are perforation of the esophagus, formation of tracheal/esophageal fistula (an abnormal passage or communication), dysphagia (difficulty in swallowing), pain, regurgitation (a backward flow of undigested food), stridor (a harsh high-pitched sound in inhalation or exhalation), and ulceration. Complications associated with permanent esophageal tubes are leakage at the site of the prosthesis or esophagus anastomosis (point of surgical connection), migration of the prosthesis, and contraction of the fibrous capsule which forms around the prosthesis. The agency also notes that, in general, the authors of these reports consider the use of permanent esophageal tubes experimental. FDA has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel and of the Ear, Nose, and Throat Device Classification Panal for esophageal prostheses and has concluded that classification of this device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.3680; Docket No. 78N–2658; Nose prosthesis.

The General and Plastic Surgery Device Classification Panel and the Ear, Nose, and Throat Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nose prostheses:

1. Identification: A nose prosthesis is an implanted solid silicone rubber prosthesis intended for use in the augmentation or reconstruction of the nasal dorsum.

2. Recommended classification: Class II (performance standards). The General and Plastic Surgery Device Classification Panel recommends that establishing a performance standard for this device be a medium priority. The Ear, Nose and Throat Device Classification Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that nose prostheses be classified into class II (performance standards) because the Panels believe that the device has an established history of safe and effective use. The Panels believe that the materials used in the device should meet a generally accepted satisfactory level of tissue compatability to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panels believe that general controls alone would not provide sufficient control over these characteristics. Although this device is an implant, the Panels believe that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information availabale to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device, and on its long history of safe and effective clinical use.

5. Risks to health: (a) Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result. (b) Tissue or skin necrosis (destruction): Excessive pressure from the device may cause overlying skin or adjacent tissue destruction and may result in extrusion of the prosthesis. (c) Displacement of implant: Migration of the prosthesis under this skin may result in cosmetic deformity. (d) Hematoma (a localized collection of blood, usually clotted, in an organ, space, or tissue, due to a break in the wall of a blood vessel): Hematoma due to small vessel rupture may require reoperation. (e) Fibrous capsule contracture: Complications may result from contracture of the fibrous capsule which normally forms around an implanted prosthesis.

FDA agrees with the Panels' recommendations and is proposing that nose prostheses be classified into class II (performance standards). Although the device is an implant, the agency believes that premarket approval is not necessary because of the extensive clinical acceptance of the device over a long period of time and because there is sufficient information available to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device.

FDA has reviewed the Panels' recommendations and some of the available literature (Refs. *93* through *102*). Although some investigators (Refs. *95* and *97* through *100*) reported high extrusion rates, 20 to 50 percent, they noted that there were no significant safety problems associated with the device itself, and that the failures were largely dependent on the surgical technique or the omission of certain necessary precautions. Milward (Ref. *99*) and Chapnik (Ref. *100*) list several precautions that are necessary to minimize the problems of extrusion, migration, and infection: (1) The implants need to be buried as deeply as possible under minimum tissue tension; (2) the incision must not be in the direct line of thrust; (3) the implants should not be too large to cause undue tension in

the overlying tissues; and (4) the implant should be correctly sterilized and aseptic principles observed. Davis and Jones (Ref. *98*) noted that the position of the implant relative to the skin is a more important factor in the rejection of the implant than the grade of silastic used in its construction. Lipshutz (Ref. *97*) found that errors of judgment on the size of the prosthesis selected for insertion are the most common cause of implant problems. Anita, et al. (Ref. *101*), who used 49 implants to treat nasal depressions concluded that the extrusion rate is very low if the implantation is accompanied by proper precautions. Rees, et al. (Ref. *102*), noted that silicone rubber is widely used in surgery as an implant material because of its low tissue reaction, lack of toxicity, and nonallergenic properties. In view of the long use and established safety of the medical grade silicone rubber implants, FDA believes that performance standards and proper surgical techinques are sufficient to ensure the safety and effectiveness of the device.

The agency has reviewed the Panels' recommendations for nose prostheses and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.3720; Docket No. 78N–2659; Tracheal prosthesis.

The General and Plastic Surgery Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of tracheal prostheses:

1. Identification: A tracheal prosthesis is a tubular implant intended for use in the reconstruction of the trachea.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel recommends that tracheal prostheses be classified into class III because the device is implanted and life-supporting and life-sustaining, and it presents a potential unreasonable risk of illness or injury. The Panel believes that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of the device. The Panel also believes that insufficient information exists to determine that general controls or performance standards would be adequate to provide reasonable assurance of the safety and effectiveness of the device. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and, thus, assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, implanted prosthetic devices.

5. Risks to health: (a) Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result. (b) Tissue necrosis (destruction): Excessive pressure from the device may cause tissue destruction. (c) Airway leakage: Airway leakage of tracheal prostheses would compromise respiratory function and may cause severe additional complications, including infection and death. (d) Erosion of the innominate artery (a branch of the aorta): Rubbing of the prosthesis against the innominate artery may lead to hemmorrhage and death.

FDA agrees with the Panel's recommendation and is proposing that tracheal prostheses be classified into class III (premarket approval). The agency believes that the device is life-supporting and life-sustaining, and is implanted or has implanted components. Also, the device presents a potential unreasonable risk of illness or injury from leakage or from erosion of the artery adjacent to the implant, which can result in hemorrhage and death. The Federal Food, Drug, and Cosmetic Act requires the agency to classify an implant or a life-supporting or life-sustaining device into class III unless it determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the agency has determined that premarket approval is necessary. The agency believes that insufficient information exists to determine that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of the device.

The agency has reviewed the Panel's recommendation and additional information on tracheal prostheses and notes numerous reports of postoperative complications due to tracheal implants (Refs. *103* through *108*). A number of approaches have been attempted to reconstruct the human trachea (Refs. *103* and *104*). Attendant complications are granuloma of the suture (a foreign body reaction of the tissue to the suture material in which tumorlike masses or nodules of granulation tissue are formed), dislocation of the prosthesis (Ref. *103*), and a death rate of 15 to 37.5 percent (Refs. *103* and *104*). Also, tracheal implants have been tested in dogs (Refs. *105, 106,* and 107), and sheep (Ref. *108*); and complications of granuloma, stenosis (narrowing of the trachea), homorrhage, dislocation of the prosthesis, and pulmonary edema (the presence of abnormally large amounts of fluid in lung tissue) have been reported (Refs. *105* and *108*). The agency also notes that existing tracheal implants cannot be considered as an effective substitute for physiological mucocilliary escalators (microscopic tracheal hairs which by interacting with mucous remove inhaled particulate matter from the bronchotracheal mucosa).

Section 878.3750; Docket No. 78N–2660; External prosthesis adhesive.

The General and Plastic Surgery Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of external prosthesis adhesives:

1. Identification: An external prosthesis adhesive is a silicone-type adhesive intended for use in affixing an external prosthesis, such as an artificial nose or ear.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that external prosthesis adhesives be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls. The Panel believes that records and reports are not necessary for the device because external prosthesis adhesives have been used in clinical practice for many years with no apparent problems.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel's recommendation and is proposing that external prosthesis adhesives be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA disagrees with the Panel's recommendation that manufacturers of external prosthesis adhesives be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 878.3800; Docket No. 78N–2661; External aesthetic restoration prosthesis.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of external aesthetic restoration prostheses:

1. Identification: An external aesthetic restoration prosthesis is a device intended to construct an external artificial body structure, such as an ear, breast, or nose. The device usually is made of silicone rubber and attached to, but not implanted into, the deficient anatomy with a biocompatible adhesive.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that external aesthetic restoration prostheses be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need no additional control requirements. The Panel believes that records and reports are not necessary for the device because external aesthetic restoration prostheses have been used in clinical practice for many years with no apparent problems.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clincial experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that external aesthetic restoration prostheses be classified into class I (general controls) with exemptions from some of the requirements of the GMP regulation. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel recommendation that manufacturers of external aesthetic restoration prostheses be exempt from the records and reports regulations under section 519 of the act (21 U.S.C. 360i). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

There are two procedures by which FDA may exempt a manufacturer of a device from complying with any or all of the requirements of the GMP regulation. First, a manufacturer of a device subject to any requirement under the GMP regulation may petition the agency pursuant to section 520(f)(2)(A) of the act (21 U.S.C. 360j(f)(2)(A)) for a variance or an exemption from the requirement. A variance or exemption granted in response to such a petition applies only to the manufacturer who submitted the petition. However, FDA may conclude that an exemption granted in response to a petition may be applied to all manufacturers of the device; in this case, if the device has been classified in a final regulation, FDA will publish in the **Federal Register** a notice of its discussion and its intention to change the codified classification of the device to grant the exemption to all manufacturers of the device. Second, in classifying a medical device into class I under section 513 of the act (21 U.S.C. 360c), the agency may determine that certain of the requirements of the GMP regulation shall not apply to the device. In that instance, the exemption applies to all manufacturers of the generic type of device that is the subject of the classification regulation. The agency may grant an exemption under either procedure only if it determines that compliance with the requirement is not necessary to assure that the device will be safe and effective and otherwise in compliance with the act. Based on the second of the above procedures, the agency is proposing that a manufacturer of external aesthetic restoration prostheses be granted an exemption from the GMP regulation, except for § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

The agency previously denied without prejudice for a future filing a manufacturer's petition (80P–0328) for exemption from the requirements of the GMP regulation of its "external breast prosthesis" that is included in the generic device, the external aesthetic restoration prosthesis. The agency decided that the decision on the requested exemption should be made as an industry-wide basis through the device classification rulemaking.

Section 878.3900; Docket No. 78N–2662; Inflatable extremity splint.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of inflatable extremity splints:

1. Identification: An inflatable extremity splint is an inflatable device intended to prevent motion of a joint or of the ends of a fractured bone.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that inflatable extremity splints be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls. The Panel believes that records and reports are not necessary for the device because inflatable extremity splints have been used in clinical practice for many years with no apparent problems.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel's recommendation and is proposing that inflatable extremity splints be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of inflatable extremity splints be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 878.3910; Docket No. 78N–2663; Noninflatable extremity splint.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of noninflatable extremity splints:

1. Identification: A noninflatable extremity splint is a noninflatable device intended to prevent motion of a joint or of the ends of a fractured bone.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that noninflatable extremity splints be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls. The Panel believes that records and reports are not necessary for this device because noninflatable extremity splints have been used in clinical practice for many years with no apparent problems.

4. Summary of data on which the recommendation is based: The Panel based

its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and its history of safe and effective clinical use.

5. Risks to health: None identified.

FDA agrees with the Panel's recommendation and is proposing that noninflatable extremity splints be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of noninflatable extremity splints be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 878.3925; Docket No. 78N–2664; Plastic surgery kit and accessories.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of plastic surgery kits and accessories:

1. Identification: A plastic surgery kit and accessories is a device that is used in the reconstruction of maxillofacial deficiencies. It consists of a kit containing surgical instruments and materials intended for use in making maxillofacial impressions before molding an external prosthesis.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that plastic surgery kits and accessories be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls. The Panel believes that records and reports requirements are not necessary for the device because plastic surgery kits and accessories have been used in clinical practice for many years with no apparent problems.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and its history of safe and effective clinical use.

5. Risks to health: None identified.

FDA agrees with the Panel's recommendation and is proposing that plastic surgery kits and accessories be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of plastic surgery kits and accessories be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 878.4040; Docket No. 78N–2665; Surgical apparel.

The General and Plastic Surgery Device Classification Panel and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of surgical apparel:

1. Identification: Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel recommends that surgical masks and gowns, isolation masks, and operating room shoe covers be classified into class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority except for surgical gowns which the Panel recommends be a high priority. The Panel also recommends that surgical caps, hoods, aprons, suits and dresses, operating room shoes, and isolation gowns be classified into class I (general controls). The Panel recommends that there be no exemptions. The Anesthesiology Device Classification Panel recommends that operating room shoe covers be classified into class II. The Panel recommends that establishing a performance standard for operating room shoe covers be a low priority.

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel recommends that surgical caps, hoods, aprons, suits and dresses, operating room shoes, and isolation gowns be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. The materials used in the devices are generally acceptable and need be subject only to general controls. The General and Plastic Surgery Device Classification Panel recommends that surgical masks and gowns and isolation masks be classified into class II because the Panel believes that the materials used in these devices must be controlled to prevent transfer of bacteria, shedding, and to reduce flammability. The General and Plastic Surgery Device Classification Panel and the Anesthesiology Device Classification Panel recommend that operating room shoe covers be classified into class II because the Panels believe that the materials used in the device must be controlled to prevent transfer of bacteria and to ensure electrical conductivity. For the devices that the Panels recommended be placed in class II, the Panels believe that general controls would not provide sufficient control over the characteristics stated above. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of these devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the members' personal knowledge of, and clinical experience with, the devices and on their long history of safe and effective clinical use.

5. Risks to health: (a) Slipping (operating room shoes and shoe covers): If operating room shoes and shoe covers are not made from slip resistant materials, hazardous slips or falls may occur. (b) Infection (surgical caps, hoods, masks and gowns, operating room shoes and shoe covers, and isolation masks and gowns): Infection of the surgical wound may result from a failure of the device to provide an adequate barrier to microbal contamination. If the materials used in the device do not allow proper sterilization, an infection may result. (c) Failure of electrical conductivity (shoe covers): If flammable gases are present, accumulation of static electricity, due to failure of electrical conductivity, may result in spark injury to the patient or in an explosion. (d) Foreign body reaction (surgical caps, hoods, masks and gowns): Particles of the material may be deposited in the surgical wound and elicit a granulomatous foreign body reaction. (e) Burns and other fire injuries: Flammable materials in the device may ignite, causing burns and other fire injuries.

FDA agrees with the recommendation of the General and Plastic Surgery Device Classification Panel that surgical masks and gowns, and isolation masks be classified into class II (performance standards) and with the recommendations of the General and Plastic Surgery Device Classification Panel and the Anesthesiology Device Classification Panel that operating room shoe covers be classified into class II. However, the agency disagrees with the recommendation of the General and Plastic Surgery Device Classification Panel that surgical caps, hoods, suits and dresses, operating room shoes, and isolation gowns be classified into class I (general controls) and is proposing that these devices be classified into class II. The agency believes that a performance standard is necessary for surgical apparel because general controls alone are insufficient to control the risks to

health presented by the devices, such as microbial contamination, shedding, and flammability. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information available to establish a performance standard for these devices.

Because the agency has been unable to substantiate that surgical aprons are commonly used, no classification is proposed for this device. The agency regards surgical dresses and suits as types of surgical gowns.

FDA has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel and the Anesthesiology Device Classification Panel and concluded that the classification of the device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4060; Docket No. 78N–2666; Nonabsorbable gauze, surgical sponge, and wound dressings for external use.

The General and Plastic Surgery Device Classification Panel, and the Dental Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Neurological Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nonabsorbable gauze, surgical sponges, and wound dressings for external use:

1. Identification: Nonabsorbable gauze, a surgical sponge, or a wound dressing for external use are devices made of an open mesh fabric of cotton or synthetic materials that are intended to control bleeding, absorb body fluids, or protect wounds from contamination.

2. Recommended classification: Class I (general controls). The General and Plastic Surgery Device Classification Panel, the Dental Device Classification Panel, and the Neurological Device Classification Panel recommend that these devices be classified into class I (general controls). These three Panels recommend that there be no exemptions. The General Hospital and Personal Use Device Classification Panel recommends that these devices be classified into class I and that they be exempt from good manufacturing practice (GMP) requirements under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)), except those requirements relating to sterility and traceability.

3. Summary of reasons for recommendation: The Panels recommend that nonabsorbable gauze, surgical sponges, and wound dressings for external use be classified into class I (general controls) because general controls are sufficient to provide reasonble assurance of the safety and effectiveness of the devices. The materials used in the devices are generally acceptable and need be subject only to general controls. The General Hospital and Personal Use Device Classification Panel recommends that the manufacturer be exempt from the GMP requirements because adherence to the GMP regulation would not improve the safety and effectiveness of these devices. That Panel also recommends that the devices be sterile.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the devices.

5. Risks to health: None identified.

FDA agrees with the Panels' recommendations and is proposing that nonabsorbable gauze, surgical sponges, and wound dressings for external use be reclassified from class III (premarket approval) into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Section 520(l)(1) of the Federal Food, Drug, and Cosmetic Act, which sets forth the transitional provisions of the Medical Device Amendments of 1976 (21 U.S.C. 360j(l)(1)), classified surgical cones and dressings, other than absorbable hemostatic devices and dressings, into class III (premarket approval). In a notice published in the Federal Register of December 16, 1977 (42 FR 63472), however, FDA announced that it would not require such surgical cones and dressings to comply with, or continue to comply with, premarket approval. See the Federal Register of December 16, 1977 (42 FR 63472–63473) and the discussion in this preamble under the heading "General and Plastic Surgery Devices Formerly Considered New Drugs." Devices first intended for marketing since the amendments that are not substantially equivalent to any preamendments device, or to a postamendments device that has been reclassified, are in class III under section 513(f) of the act (21 U.S.C. 360c(f)). Because the device category surgical cones and dressings, other than absorbable hemostatic devices and dressings, includes nonabsorbable gauze, surgical sponges, and wound dressings for external use, these devices have been classified by statute into class III, although FDA has not since the December 16, 1977 notice required compliance with premarket approval requirements. This proposed regulation would reclassify nonabsorbable gauze, surgical sponges, and wound dressings for external use from class III into class I (general controls) because FDA believes that premarket approval of these devices is unnecessary. FDA specifically invites comments on the adequacy of the identification of the devices that would be reclassified.

FDA disagrees with the General Hospital and Personal Use Device Classification Panel recommendation that manufacturers of nonabsorbable gauze, surgical sponges, and wound dressings for external use be exempt from the GMP regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulations will help prevent the production of nonabsorbable gauze, surgical sponges, and wound dressings for external use that have defects that could harm users. The agency has reviewed the recommendations of the Panels for nonabsorbable gauze, surgical sponges, and wound dressings for external use and has concluded that the classification of these devices should be published in a single section and in the part of the Code of Federal Regualtions for general and plastic surgery devices.

Section 878.4100; Docket No. 78N–2667; Intestine bag.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of intestine bags:

1. Identification: An intestine bag is a device that consists of a flexible plastic bag and that is intended for use as a temporary receptacle for the intestine to prevent moisture loss during surgical procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that intestine bags be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health. The materials used in the device are generally acceptable and need be subject only to general controls.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, and on a presentation made by Parke, Davis and Co. at the December 16, 1976, meeting of the General and Plastic Surgery Device Classification Panel (Ref. *109*). This presentation included a description of the materials used in the device, how the device is used, the advantages of this product over conventional methods of intestine isolation,

and data from a rabbit peritoneal implant study to demonstrate the safety of the material used in the device.

5. Risks to health: Allergic or toxic reaction: The materials used in the construction of the device may cause an allergic or toxic reaction.

FDA agrees with the Panel's recommendation and is proposing that intestine bags be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectivness of the device.

Section 878.4120; Docket No. 78N–2669; Hydrophilic beads for wound exudate absorption.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hydrophilic beads for wound exudate absorption:

1. Identification: Hydrophilic beads for wound exudate absorption are small spherical beads made of dextran polymer that are intended to remove particulate and fluid secretion from wounds by absorption and capillary action.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that hydrophilic beads for wound exudate absorption be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel's recommendation and is proposing that hydrophilic beads for wound exudate absorption be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of hydrophilic beads for wound exudate absorption be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Pursuant to section 520(l)(1) of the transitional provisions of the Medical Device Amendments of 1976 (21 U.S.C. 360j(l)(1)), surgical cones and dressings, other than absorable hemostatic devices and dressings,were classified into class III (premarket approval). See the **Federal Register** of December 16, 1977 (42 FR 63472–63473) and the discussion in this preamble under the heading "General and Plastic Surgery Devices Formerly Considered New Drugs." Because the device category surgical cones and dressings, other than absorbable hemostatic devices and dressings, includes hydrophilic beads for wound exudate aborption, these devices were therefore classified by statute into class III. This proposed regulation thus proposes to reclassify hydrophilic beads for wound exudate absorption from class III into class I (general controls). All other devices in this transitional category remain in class III unless specifically reclassified by a final regulation based on this proposal.

Section 878.4140; Docket No. 78N–2670; Porcine burn dressing.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of porcine burn dressings:

1. Identification: A porcine burn dressing is a device made from pigskin that is intended for use as a temporary dressing in the treatment of burns.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that procine burn dressings be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable when used as dressings in contact with the body and need be subject only to general controls.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel's recommendation and is proposing that porcine burn dressings be reclassified from class III into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. the agency has reviewed the Panel's recommendation and the medical literature or porcine skin xenografts and notes the general clinical acceptance of these temporary burn dressings for alleviating pain, providing a physical barrier against infection and contamination, and improving pliability of burn eschar with consequent reduction in the period of immobilization of burn patients (Refs. *110* through *114*).

Section 520(l)(1) of the Federal Food, Drug, and Cosmetic Act, which sets forth the transitional provisions of the Medical Device Amendments of 1976 (21 U.S.C. 360j(l)(1)), classified surgical cones and dressings other than absorbable hemostatic devices and dressings into class III (premarket approval). In a notice published in the **Federal Register** of December 16, 1977 (42 FR 63472), however, FDA announced that it would not require such surgical cones and dressings to comply with, or continue to comply with, premarket approval. See the **Federal Register** of December 16, 1977 (42 FR 63472–63473) and the discussion in this preamble under the heading "General and Plastic Surgery Devices Formerly Considered New Drugs." Devices first intended for marketing since the amendments that are not substantially equivalent to any preamendments device, or to a postamendments device that has been reclassified, are in class III under section 513(f) of the act (21 U.S.C. 360c(f)). Because the device category, surgical cones and dressings other than absorbable hemostatic devices and dressings, includes porcine burn dressings, this device has been classified by statute into class III, although FDA has not since the December 16, 1977 notice required compliance with premarket approval requirements. This proposed regulation would reclassify porcine burn dressing from class III into class I (general controls) because FDA believes that premarket approval of the device is unnecessary. FDA specifically invites comments on the adequacy of the identification of the device that would be reclassified and on whether porcine burn dressings, like other burn dressings, ought to be classified into class II (performance standards) rather than class I.

Section 878.4160; Docket No. 78N–2671; Surgical cameras and accessories.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of surgical camera and accessories:

1. Identification: A surgical camera and accessories is a device that is intended to record operative procedures and that consists

of a camera and associated equipment, which may include a sound track.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from records and reports requirements under section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that surgical cameras and accessories be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that records and reports requirements are not necessary for the device because surgical cameras and accessories have been used in clinical practice for many years with no apparent problems.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and its history of safe and effective clinical use.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that surgical cameras and accessories be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA disagrees with the Panel recommendation that manufacturers of surgical cameras and accessories be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 878.4200; Docket No. 78N-2672; Introduction/drainage catheter and accessories.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of introduction/drainage catheters and accessories:

1. Identification: An introduction/drainage catheter is a device that consists of a flexible single lumen or multilumen tube intended for use in the introduction of fluids, medications, or contrast material into body cavities; the evaluation of physiological parameters, such as venous pressure; or the drainage of fluids from body cavities. Examples include irrigation and drainage catheters, pediatric catheters, peritoneal catheters, and other general surgical catheters. A catheter accessory is a component of this device intended to facilitate the manipulation of, or to assist in the insertion of, an introduction/drainage catheter into various parts of the body. Examples include adaptors, connectors, and catheter needles.

2. Recommended classification: The Panel recommends that introduction/drainage catheters be classified into class II (performance standards). The Panel recommends that establishing a performance standard for introduction/drainage catheters be a low priority. The Panel recommends that catheter accessories be classified into class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that introduction/drainage catheters be classified into class II (performance standards) because the Panel believes that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls could not provide sufficient control over these characteristics. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel recommends that catheter accessories be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in catheter accessories are generally acceptable and need be subject only to general controls.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices.

5. Risks to health: The Panel identified the following risks to health for introduction/drainage catheters: (a) Infection: If the materials used in the device or its construction prevent sterilization, an infection may result. (b) Introduction of foreign substances: A catheter may transfer particulate matter from the interior of the catheter into the patient. (c) Adulteration of medication: Decomposition or adulteration of medication may occur if the medication interacts chemically with the catheter materials. The Panel did not identify any risks to health for catheter accessories.

FDA agrees with the Panel's recommendation for introduction/drainage catheters and is proposing that these devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard for these devices.

FDA disagrees with the Panel's recommendation for catheter accessories and is proposing that these devices be classified into class II. The agency believes that catheter accessories can present the same risks to health as the catheters themselves: infection, introduction of foreign substances, and adulteration of medication. The agency believes that a performance standard is necessary for catheter accessories because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information available to establish a performance standard for these devices.

Section 878.4300; Docket No. 78N-2674; Implantable clip.

The General and Plastic Surgery Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of implantable clips:

1. Identification: An implantable clip is a stainless steel or tantalum device intended to connect internal tissues to aid healing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that implantable clips be classified into class II (performance standards) because the Panel believes that the device has an established history of safe and effective use. The Panel believes that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls alone would not provide sufficient control over these characteristics. Although this device is an implant, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information available to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommentation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Tissue necrosis (destruction): Excessive pressure from the device on the skin may cause overlying or adjacent tissue destruction. (b) Leakage: Leakage, due to a failure of the device to maintain the connection between tissues, may cause complications, such as infection or hemorrhage. (c) Allergic or toxic reactions: Materials used in the device may cause an allergic or toxic reaction.

FDA agrees with the Panel's recommendation and is proposing that implantable clips be classified into class

II (performance standards). Although the device is an implant, the agency believes that premarket approval is not necessary because implantable clips have an established history of safe and effective use and because there is sufficient information to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device, such as adverse tissue reactions and faulty clip strength due to variations in the material composition of the device.

Section 878.4320; Docket No. 78N-2675; Removable skin clip.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of removable skin clips:

1. Identification: A removable skin clip is a device intended to temporarily connect external tissues to aid healing.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that removable skin clips be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel believes that the materials used in the device are generally acceptable and need be subject only to general controls.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on its history of safe and effective clinical use.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that removable skin clips be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 878.4350; Docket No. 78N-2676; Cryosurgical unit and accessories.

The General and Plastic Surgery Device Classification Panel, the Obstetrical and Gynecological Device Classification Panel, and the Gastroenterology and Urology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of cryosurgical units and accessories:

1. Identification:

(a) Cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories:

Identification: A cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories is a device intended to destroy tissues during surgical procedures by applying extreme cold.

(b) Cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories:

Identification: A cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures, including urological applications, by applying extreme cold.

(c) Cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator, and accessories:

Identification: A cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator, and accessories, is a device intended to destroy tissue during surgical procedures by applying extreme cold. The device is intended to treat disease conditions such as tumors, skin cancers, acne scars, and hemangiomas (benign tumors consisting of newly-formed blood vessels), and to treat various benign or malignant gynecological conditions affecting vulvar, vaginal, or cervical tissue. The device is not used for urological applications.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel recommends that the devices be classified into class II (performance standards), and that establishing a performance standard be a high priority. The Obstetrical and Gynecological Device Classification Panel recommends that the devices be classified into class II and that establishing a performance standard be a low priority. The Gastroenterology and Urology Device Classification Panel recommends that liquid nitrogen cryosurgery devices for urological applications, such as liquid nitrogen cryoprobe treatment of advanced prostate carcinoma and benign prostate hypertrophy be classified into class III (premarket approval) and that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel and the Obstetrical and Gynecological Device Classification Panel recommend that cryosurgical units and accessories be classified into class II because the devices are complex in design and have critical performance requirements. The General and Plastic Surgery Device Classification Panel made the following additional recommendations: (a) Explosion-proof electrical circuits should be incorporated in cryosurgical devices used in the operating room.

(b) Cryoprobes and their attachments should be able to withstand repeated sterilization. (c) Temperature monitors in the device should be accurate. (d) The thermocouple location in cryoprobe tips should be stated in the product labeling. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of these devices. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The Gastroenterology and Urology Device Classification Panel recommends that liquid nitrogen cryosurgical devices and accessories for urological applications be classified into class III (premarket approval) because the Panel believes that satisfactory performance has not been demonstrated for urological applications, such as treatment of advanced prostate carcinoma with or without metastasis, benign prostatic hypertrophy with obstruction and for high-risk individuals not suited for surgery by other methods. The Panel also believes that a significant problem exists with these liquid nitrogen cryosurgical devices in regard to accurate temperature monitoring and control. The Panel does not believe that there is sufficient information available to establish a performance standard that would provide reasonable assurance of the safety and effectiveness of liquid nitrogen cryosurgical devices for urological applications. Therefore, these devices should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the devices and, thus, assure their safety and effectiveness.

4. Summary of data on which the recommendation is based: The General and Plastic Surgery Device Classification Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices, and on a presentation December 16, 1976, by Andrew Gage, M.D., Veterans Administration Hospital, Buffalo, NY (Ref. *115*). The General and Plastic Surgery Device Classification Panel noted that it was unable to identify a documented instance of malfunction of a cryosurgical device which resulted in harm to a patient or user. The Panel stressed that user knowledge of the devices is the most important factor in their safe and effective use. The Obstetrical and Gynecological Device Classification Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices. The Panel reviewed the clinical literature on the devices and cited representative data from the literature (Ref. *116*). The Obstetrical and Gynecological Device Classification Panel believes that sufficient data have been accumulated on gynecological cryosurgery (for example, treatment of vulvar, vaginal, and cervical tissue for various benign, premalignant, and malignant conditions) to demonstrate the effectiveness of this therapy. The Gastroenterology and Urology Device Classification Panel based its class III recommendation for liquid nitrogen cooled cryosurgical units and accessories used in urological applications on the Panel members' personal knowledge of, and clinical experience with the devices and their knowledge of the medical literature (Refs. *117* through *122*).

5. Risks to health: The General and Plastic Surgery Device Classification Panel identified the following risks to health: (a) Explosion: Improper design of nitrous oxide or liquid nitrogen containers and cylinders may lead to explosion in the presence of flammable gases. (b) Freezing "burns:" Improper insulation of cryoprobes and accessory tubing may lead to freezing "burns" of the user's or operator's hands or other tissues. (c) Electrical shock: Improper electrical design of the devices may lead to electrical shock. The Obstetrical and Gynecological Device Classification Panel identified the following risks to health: (d) Excessive tissue damage: Poor design of the device could cause unnecessary cryosurgical tissue "burns" when the device comes in contact with the patient's vulva, vagina, or cervix. (e) Electrical shock: Malfunction of the device could result in electrical shock.

(f) Adverse tissue reaction: Cryoprobe tip materials could cause a local tissue or systemic reaction when the tip comes in contact with the patient. The Gastroenterology and Urology Device Classification Panel identified the following risks to health in urological applications of liquid nitrogen cooled cryosurgical devices: (g) Excessive tissue damage: Difficulty in controlling the rate of tissue freezing, due to the low boiling point (−196° C) of liquid nitrogen and the difficulty in measuring tissue temperature, may cause unnecessary tissue destruction and sloughing. (h) Fistula formation: Inaccurate temperature regulation in the device may cause unintended freezing of tissue and lead to fistula formation and urinary tract infection. (i) Failure to freeze: Inaccurate temperature measurement by the device may prevent effective freezing of tissue. (j) Incontinence: Freezing injury to the external sphincter muscle may lead to urinary incontinence. (k) Immunity factor: The inadequacy of the patient's immune system to react may lead to spread of cancer. Overreaction of the immune system may result in destruction of other tissue.

FDA agrees with the recommendations of the General and Plastic Surgery Device Classification Panel, the Obstetrical and Gynecological Device Classification Panel, and the Gastroenterology and Urology Device Classification Panel and is proposing that liquid nitrogen cryosurgical units and accessories intended for use in urological applications be classified into class III (premarket approval) and that all other cryosurgical units and accessories intended for other uses be classified into class II (performance standards).

The agency is proposing that liquid nitrogen cooled cryosurgical devices intended for use in urological applications be classified into class III because of the potential for these devices to cause excessive tissue damage due to difficulty in controlling the rate of tissue freezing. The agency believes that liquid nitrogen cooled cryosurgical units and accessories intended for use in urological applications present a potentially unreasonable risk of injury. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard for urological applications using a liquid nitrogen cooled cryosurgical unit.

The agency believes that a performance standard is necessary for all cryosurgical units, other than liquid nitrogen cryosurgical units intended for use in urological applications, because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices, other than a liquid nitrogen cooled cryosurgical unit intended for use in urological applications. The agency recognizes that cryosurgical probes are surgical tools and as such, rely heavily on the training and experience of the user. Standardization of temperature monitoring capabilities, such as the location of thermocouple in the probe and the response time, is necessary to estimate the desired temperature, to compare various results, and to serve as a quality control check of the instrument. The agency has not proposed classifications for a cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator, and accessories intended for use in urological applications because there is no known use of these devices for that purpose. The agency has reviewed the Panels' recommendations for cryosurgical units and accessories and has concluded that the classification of the devices should be published in the part of the Code of the Federal Regulations for general and plastic surgery devices.

Section 878.4370; Docket No. 78N–2677; Surgical drapes and drape accessories.

The General and Plastic Surgery Device Classification Panel, the Gastroenterology and Urology Device Classification Panel, the Ear, Nose, and Throat Device Classification Panel, the Ophthalmic Device Classification Panel, and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of surgical drapes and drape accessories:

1. Identification: Surgical drapes and drape accessories are devices made of natural or synthetic materials intended for use as protective patient coverings, such as to isolate a site of surgical incision from microbial and other contamination. Examples of surgical drapes and drape accessories are plastic wound protectors that usually adhere to the skin around a surgical incision or that are placed in the wound to cover its exposed edges, Kelly pads that are placed beneath a patient or limb to absorb drainage from a surgical wound, and latex drapes with self-retaining finger cots that are used during transurethral prostatectomy for repeated insertion of the surgeon's finger into the rectum.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel, the Gastroenterology and Urology Device Classification Panel, and the Ophthalmic Device Classification Panel recommended that surgical drapes and drape accessories be classified into class II (performance standards). The Panels recommended that establishing a performance standard for these devices be a high priority. The Gastroenterology and Urology Device Classification Panel recommends that plastic wound protectors be classified into class II (performance standards) and that establishing a standard for these devices be a low priority. The General Hospital and Personal Use Device Classification Panel recommends that Kelly pads be classified into class I (general controls) and that this device be exempt from premarket notification procedures under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and from the good manufacturing practice regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The Gastroenterology and Urology Device Classification Panel recommends that latex drapes with self-retaining finger cots be classified into class I with no exemptions. The Ear, Nose, and Throat Device Classification Panel recommends that surgical drapes for ear, nose, and throat use be classified into class I and that the devices be exempt from premarket notification under section 510(k) of the act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel recommends that surgical drapes and drape accessories be classified into class II (performance standards) because the Panel believes that a performance standard is necessary to control the materials used in the devices to ensure their effectiveness as a contamination barrier. The Panel believes that surgical drapes and drape accessories should be constructed of materials that are nonflammable and that shed as little particulate matter (lint) as possible. The Gastroenterology and Urology Device Classification Panel recommends that surgical drapes, drape accessories and plastic wound protectors be classified into class II because the Panel also believes that performance standards are necessary to ensure that they are effective as a

contamination barrier, adequately cover the surgical field, are impermeable to water, and are nonflammable, and to ensure that the materials used in the devices meet a generally acceptable satisfactory level of tissue compatibility. The Ophthalmic Device Classification Panel recommends that surgical drapes and drape accessories be classified into class II because the Panel believes that performance standards are necessary to control the flammability, sterility, and antistatic action associated with these devices. All three Panels believe the general controls alone would not provide sufficient control over the performance characteristics of these devices. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information available to establish a standard. The General Hospital and Personal Use Device Classification Panel recommends that Kelly pads be classified into class I with the exemptions described above, the Gastroenterology and Urology Device Classification Panel recommends that latex drapes with self-retaining finger cots be classified into class I with no exemptions, and the Ear, Nose, and Throat Device Classification Panel recommends that surgical drapes for ear, nose, and throat use be classified into class I with an exemption from premarket notification because these Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The General Hospital and Personal Use Device Classification Panel also recommends that Kelly pads be sterile. The recommended exemptions from premarket notification procedures and the good manufacturing practice regulation are based on the belief that the materials used in the devices are generally acceptable and need be subject only to general controls.

4. Summary of data on which the recommendations are based: The Panels based their recommendations on their members' personal knowledge of, and clinical experience with, the device. In addition, the General and Plastic Surgery Device Classification Panel reviewed two articles that described the possible hazard of peritonitis (inflammation of the membrane lining the abdomino-pelvic walls) as a result of granuloma (tumorlike masses of fibrous tissue) formed around lint particles shed from surgical drapes (Refs. *123* and *124*). That Panel also reviewed an article which described the flammability of disposable surgical drapes (Ref. *125*).

5. Risks to health: The General and Plastic Surgery Device Classification Panel identified the follwing risk to health: (a) Foreign body reaction: Particles of the materials used in the devices may be deposited in the surgical wound and may elicit a granulomatous foreign body reaction. The Gastroenterology and Urology Device Classification Panel identified the following risk to health: (b) Infection: Infection of the surgical wound may result from the failure of the device to provide an adequate barrier to microbial contamination. The Ophthalmic Device Classification Panel identified the following risks to health: (c) Infection: If the materials used in the device or its construction prevent sterilization, an infection may result. (d) Allergic or toxic reaction: Materials used in the devices may cause an allergic or toxic reaction in the patient. All three Panels identified the following risk to health: (e) Burns and other fire injuries: Flammable materials used in the device may ignite, causing burns and other fire injuries. The General Hospital and Personal Use Device Classification Panel identified no risks to health for Kelly pads. The Ear, Nose, and Throat Device Classification Panel identified no risks to health for surgical drapes for ear, nose, and throat use.

FDA has considered the Panels' recommendations described above and is proposing that surgical drapes and drape accessories be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of these devices. The agency also believes that there is sufficient information available to establish a performance standard for these devices.

Because the agency has determined that surgical drapes and drape accessories should be classified into class II rather than class I, the agency is not required to publish a regulation adopting or rejecting the General Hospital and Personal Use Device Classification Panel's recommendation that Kelly pads be exempt from the premarket notification procedures under section 510(k) and the good manufacturing practice regulation under section 520(f) of the act or the Ear, Nose, and Throat Device Classification Panel's recommendation that surgical drapes for ear, nose, and throat use be exempt from premarket notification.

The agency has reviewed the Panels' recommendations for surgical drapes and drape accessories and has concluded that the classification of these devices should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4380; Docket No. 78N-2678; Aerosol drape adhesive.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of aerosol drape adhesives:

1. Identification: An aerosol drape adhesive is a device that is a substance intended to be sprayed on the skin to keep surgical drapes in place.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that aerosol drape adhesives be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls. The Panel does not believe that this device requires performance standards to control the identified risks to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, and on a presentation by Dr. Robert Buchanan and Mrs. Janet Turner of Parke, Davis and Co., at the December 16, 1976, meeting of the General and Plastic Surgery Device Classification Panel (Ref. *126*). Dr. Buchanan described three safety studies in rabbits that were designed to demonstrate the noninterference of aerosol drape adhesives in the healing process and the absence of acute, systemic, and local toxicity. Dr. Buchanan also described studies involving human volunteers that showed that the device performed acceptably under operating room conditions without sensitizing the skin. Although allergic or toxic skin reaction to materials in aerosol drape adhesives is always a potential complication, the Panel believes that the probability of occurrence is low.

5. Risks to health: Allergic or toxic reaction: Materials in aerosol drape adhesives may cause an allergic or toxic reaction.

FDA agrees with the Panel's recommendation and is proposing that aerosol drape adhesives be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 878.4400; Docket No. 78N-2679; Electrosurgical cutting and coagulation device and accessories.

The General and Plastic Surgery Device Classification Panel, the Anesthesiology Device Classification Panel, the Neurological Device Classification Panel, and the Cardiovascular Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of electrosurgical cutting and coagulation devices and accessories:

1. Identification: An electrosurgical cutting and coagulation device and accessories is a device that uses high-frequency electrical current and that is intended for the surgical removal of tissue and for the control of bleeding.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that electrosurgical cutting and coagulation devices and accessories be classified into class II (performance standards) because the Panels believe that performance standards would help reduce the frequency and seriousness of burns and electrical shock to patients and operators. The Anesthesiology Device Classification Panel also believes that radiofrequency leakage should be controlled to minimize possible adverse biological effects and interference with other equipment. The Cardiovascular Device Classification Panel notes that there are three devices included in this generic type of device, electrosurgical electrodes, the electrosurgical device, and electrosurgical electrode gels, and recommends that all three be classified into class II because the Panel believes that performance characteristics, such as those involving the design and output energy levels, must be controlled by standards to prevent electrical shock and burn injury. All of the Panels believe that the materials used in the device should meet a generally accepted level of tissue compatibility. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Electrical shock and burns: Improper electrical design or grounding of the devices and excessive leakage current may result in severe electrical shock and associated burns. (b) Fire and explosion: The possibility of a fire or explosion exists when the device is used in the presence of flammable articles such as flammable skin preparations or surgical drapes. An explosion may result from the ignition of accumulated bowel or bladder gases during surgery. (c) Cataract formation: There is the possibility of cataract formation when the device is used near the eye. (d) Pacemaker interference: The device may cause electronic interference with cardiac function in patients fitted with pacemakers. (e) Radiofrequency interference: Improper electromagnetic shielding, resulting in radiofrequency interference to or from other equipment, may lead to erroneous readings. These inaccurate readings could result in hazardous or inappropriate therapy. (f) Radiofrequency irradiation: The possibility exists of adverse biological effects as a result of radiofrequency irradiation produced by the device. (g) Allergic or toxic reaction: Materials used in the electrodes or electrode gel may cause an allergic or toxic reaction. (h) Burns: Inadequate design of patient electrode return plates and conductive gels could cause burns to the patient. (i) Cardiac arrhythmias: Excessive electrical leakage current from the device may result in cardiac arrhythmias. (j) Inadequate cutting or coagulation: Improper electrical design of the device may result in inadequate cutting or coagulation.

FDA agrees with the Panels' recommendations and is proposing that electrosurgical cutting and coagulation devices and accessories be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

The agency has reviewed the recommendations of the Panels for electrosurgical cutting and coagulation devices and accessories and has concluded that the classification of the devices should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4450; Docket No. 78N-2681; Nonabsorbable gauze for internal use.

The General and Plastic Surgery Device Classification Panel and the Neurological Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nonabsorbable gauze for internal use:

1. Identification: Nonabsorbable gauze for internal use is a device made of an open mesh fabric of cotton or synthetic material intended to control bleeding, absorb body fluids, and protect wounds from contamination.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel recommends that nonabsorbable gauze for internal use be classified into class II (performance standards) because the Panel believes that the materials used in the device must be controlled to ensure that the devices shed as little particulate matter (lint) as possible and that x-ray detectable gauzes be of sufficient size and radiopacity. The Panel noted the existence of United States Pharmacopoeia (USP) performance standards for gauzes. The Neurological Device Classification Panel recommends that nonabsorbable gauze for internal use be classified into class II because it comes into direct contact with, and may contaminate, the surgical wound or produce an adverse tissue reaction. The Panels believe the materials should meet a generally accepted satisfactory level of tissue compatibility and thus minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device. Additionally, the General and Plastic Surgery Device Classification Panel reviewed literature compiled by a Panel member (Refs. *127* through *130*).

5. Risks to health: (a) Foreign body reaction: Particles of the materials used in the device may be deposited in the surgical wound and cause a granulomatous foreign body reaction. (b) Allergic or toxic reaction: The material in the gauze may cause an allergic or toxic reaction.

FDA agrees with the Panels' recommendations and is proposing that nonabsorbable gauze for internal use be reclassified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health, such as particulate matter contamination and inadequate radiopacity, presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 520(l)(1) of the Federal Food, Drug, and Cosmetic Act, which sets forth the transitional provisions of the Medical Device Amendments of 1976 (21 U.S.C. 360j(l)(1)), classified surgical cones and dressings other than absorbable hemostatic devices and dressings, into class III (premarket approval). In a notice published in the **Federal Register** of December 16, 1977 (42 FR 63472), however, FDA announced that it would not require such surgical cones and dressings to comply with, or continue to comply with, premarket approval. See the **Federal Register** of December 16, 1977 (42 FR 63472–63473) and the discussion in this preamble under the heading "General and Plastic Surgery Devices Formerly Considered New Drugs." Devices first intended for marketing since the amendments that are not substantially equivalent to any preamendments device, or to a postamendments device that has been reclassified, are in class III under section 513(f) of the act (21 U.S.C. 360c(f)). Because the device category, surgical cones and dressings other than absorbable hemostatic devices and dressings, includes nonabsorbable gauze for internal use, this device has been classified by statute into class III, although FDA has not since the

December 16, 1977 notice required compliance with premarket approval requirements. This proposed regulation would reclassify nonabsorbable gauze for internal use from class III into class II (performance standards) because FDA believes that premarket approval of the device is unneccessary. FDA specifically invites comments on the adequacy of the identification of the device that would be reclassified.

The agency has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel and the Neurological Device Classification Panel for nonabsorbable gauze for internal use and has concluded that the classification of the device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4460; Docket No. 78N-2682; Surgeon's glove.

The General and Plastic Surgery Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of surgeon's gloves:

1. Identification: A surgeon's glove is a device made of a rubber polymer compound that is intended to be worn by operating room personnel and is used to protect the surgical wound from contamination and cross-infection.

2. Recommended classification: Class II (performance standards). The General and Plastic Surgery Device Classification Panel recommends that establishing a performance standard for this device be a medium priority. The General Hospital and Personal Use Device Classification Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that surgeon's gloves be classified into class II (performance standards) because the Panels believe that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The General and Plastic Surgery Device Classification Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on an article by Dr. William C. Beck (Ref. *131*), which refers to the standards for surgical gloves developed by the American Society for Testing and Materials (Ref. *132*). Both Panels emphasized the need for a flexible standard that recognizes the variety of glove types and, at the same time, establishes basic levels of glove safety and efficacy.

5. Risks to health: Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result.

FDA agrees with the recommendations of both Panels and is proposing that surgeon's gloves be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. The agency has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel and of the General Hospital and Personal Use Device Classification Panel for surgeon's gloves, and has concluded that the classification of the device should be published in the part of the Code of Federal Regulations for general and plastic surgery.

Section 878.4470; Docket No. 78N-2683; Surgeon's gloving cream.

The General and Plastic Surgery Device Classification Panel an FDA advisory committee, made the following recommendation regarding the classification of surgeon's gloving cream:

1. Identification: Surgeon's gloving cream is an ointment intended to lubricate the user's hands before putting on surgeon's gloves.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that surgeon's gloving cream be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel recommendation and is proposing that surgeon's gloving cream be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 878.4580; Docket No. 78N-2686; Surgical lamp.

The General and Plastic Surgery Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Neurological Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of surgical lamps:

1. Identification: A surgical lamp (including a fixture) is a device that is intended to provide visible illumination for the surgical field or for examination of the patient.

2. Recommended classification: Both the General and Plastic Surgery Device Classification Panel and the Neurological Device Classification Panel recommend that the device be classified into class I (general controls) and that there be no exemptions. The General Hospital and Personal Use Device Classification Panel recommends that the device be classified into class II and that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel and the Neurological Device Classification Panel recommend that surgical lamps and lamp fixtures be classified into class I because the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The General Hospital and Personal Use Device Classification Panel recommends that surgical lamps and lamp fixtures be classified into class II (performance standards) because the Panel believes the electrical properties of the device must be controlled through an electrical safety standard and that a standard is needed to control the spectrum emitted by the device to reduce the risk of tissue dessication (drying). The Panel also believes a standard is necessary to assure that the mounting mechanism for the device is of sufficient strength to prevent the device from falling, and that the lenses and diffusers are made of nonbreakable materials or are protected by a safety system. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: The General Hospital and Personal Use Device Classification Panel Identified the following risks to health: (a) Electrical shock: Improper device design and construction or device malfunction could result in electrical shock. (b) Tissue dessication (drying): If the operating room lamp contains a high concentration of light in the infrared region of the spectrum, patient tissue dessication may result. (c) Traumatic injury: The supporting and mounting mechanisms for this device should be of sufficient strength to prevent the device from falling and injuring the patient or operating room personnel. (d) Cuts due to falling glass: Bulbs, lenses, and diffusers could break and

cause cuts to patients and operating room personnel. The General and Plastic Surgery Device Classification Panel and the Neurological Device Classification Panel identified no risks to health.

FDA agrees with the recommendation of the General Hospital and Personal Use Device Classification Panel and is proposing that surgical lamps and lamp fixtures be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device to limit potentially hazardous ultraviolet radiation (types A, B, and C), particularly from xenon lamps, xenon-mercury lamps, and high-intensity discharge (HID) mercury lamps, and from more intense sources where such radiation is unnecessary for illumination and is potentially hazardous. The agency also believes that a performance standard is necessary to ensure electrical safety. The agency disagrees with the recommendations of the General and Plastic Surgery Device Classification Panel and the Neurological Device Classification Panel recommendations that surgical lamps be classified into class I (general controls) because the agency believes that general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. The agency has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel, the Neurological Device Classification Panel, and the General Hospital and Personal Use Device Classification Panel for surgical lamps and has concluded that classification of this device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4630; Docket No. 78N-2687; Dermatologic ultraviolet lamp.

The General and Plastic Surgery Device Classification Panel and the Physical Medicine Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of dermatologic ultraviolet lamps:

1. Identification: A dermatologic ultraviolet lamp is a device (including a fixture) that provides ultraviolet radiation that is intended primarily for the treatment of dermatologic disorders or for tanning.

2. Recommended classification: Class II (performance standards). The General and Plastic Surgery Device Classification Panel recommends that establishing a performance standard for this device be a low priority. The Physical Medicine Device Classification Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that dermatologic ultraviolet lamps be classified into class II (performance standards) because the Panels believe that the electrical and optical properties of the device must be controlled to prevent electrical shock, overexposure because of timer malfunction and burns to eyes and skin. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. In addition, the Physical Medicine Device Classification Panel recommends that the device should be sold only by prescription.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Burns to skin and eyes: Improper shielding of eyes or overexposure of ultraviolet radiation to skin may result in burns. Also, excessive ultraviolet and infrared radiation from this device can be harmful to the eyes and skin. (b) Aging of skin: Excessive exposure to ultraviolet radiation may result in accelerated aging of the skin. (c) Skin cancer: Excessive irradiation of the skin with ultraviolet lamps is correlated with increased incidence of skin cancer. (d) Photosensitivity: Exposure of patients with photosensitive skin to ultraviolet light may induce photosensitivity reactions.

FDA agrees with the Panels' recommendations and is proposing that dermatologic ultraviolet lamps be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Under the Radiation Control for Health and Safety Act (42 U.S.C. 263b-n), FDA has issued a performance standard for sunlamp products in § 1040.20 (21 CFR 1040.20). This standard addresses certain of the risks to health described above.

The agency notes that this device is occasionally used in the treatment of conditions for which the value of ultraviolet irradiation is unsubstantiated. These uses, such as for treatment of bronchial asthma or tuberculosis, are probably rooted deeply in the evolution and history of medicine rather than in experimental and objective demonstration of the effectiveness of ultraviolet irradiation for these conditions. In this context, the agency urges caution and believes that proper labeling of this device should be required.

FDA has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel and the Physical Medicine Device Classification Panel for dermatologic ultraviolet lamps and has concluded that the classification of this device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4650; Docket No. 78N-2688; Aorto-saphenous vein ostia marker.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of aorto-saphenous vein ostia markers:

1. Identification: An aorto-saphenous vein ostia marker is an implanted stainless steel ring that is intended to mark the anastomosis (point of surgical connection) of the aorta and the coronary bypass saphenous vein graft to allow radiologic identifcation of or catheterization of the bypass vein graft.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that aorta-saphenous vein ostia markers be classified into class II (performance standards) because the Panel believes that the device has an established history of safe and effective use. The Panel believes that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls alone would not provide sufficient control over these characteristics. Although this device is an implant, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information available to establish a performance standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, and on an article describing the use of radiographic markers in 100 patients with no complications (Ref. *133*).

5. Risks to health: Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result.

FDA agrees with the Panel's recommendation and is proposing that aorta-saphenous vein ostia markers be classified into class II (performance standards). Although the device is an implant, the agency believes that premarket approval is not necessary because of the historical acceptance of surgical stainless steel as a safe implant material in a wide range of surgical procedures, especially orthopedic procedures. In support of this view, the agency notes the article by Harth (Ref. *134*), which cites the common use of type 316 stainless steel and other stainless steel alloys in orthopedic devices. The agency believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. The agency also believes that there is sufficient information available to establish a performance standard for this device.

Section 878.4660; Docket No. 78N–2689; Skin marker.

The General and Plastic Surgery Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of skin markers:

1. Identification: A skin marker is a pen-like device intended to write on the patient's skin for the purpose of outlining surgical incision sites or marking anatomical sites for accurate blood pressure measurement.

2. Recommended classification Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that skin markers be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel's recommendation and is proposing that skin markers be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 878.4680; Docket No. 78N–2690; Nonpowered, single patient, portable suction apparatus.

The General and Plastic Surgery Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of nonpowered, single patient, portable suction apparatus:

1. Identification: A nonpowered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system that is intended to provide a vaccum used for suction drainage of surgical wounds.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that nonpowered, single patient, portable suction apparatus be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

FDA agrees with the Panel's recommendation and is proposing that nonpowered, single patient, portable suction apparatus be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 878.4700; Docket No. 78N–2691; Surgical Micropscope and accessories.

The General and Plastic Surgery Device Classification Panel, the Ear, Nose, and Throat Device Classification Panel, the Neurological Device Classification Panel, and the Ophthalmic Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of surgical microscopes and accessories:

1. Identification: A surgical miscroscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.

2. Recommeded classification: The General and Plastic Surgery Device Classification Panel recommends that surgical misroscopes be classified into class I (general controls). The Panel recommends that there be no exemptions. The Neurological Device Classification Panel, the Ear, Nose, and Throat Device Classification Panel, and the Ophthalmic Device Classification Panel recommend that surgical microscopes be classified into class II (performance standards). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Neurological Device Classification Panel, the Ear, Nose, and Throat Device Classification Panel, and the Ophthalmic Device Classification Panel recommend that surgical microscopes and accessories be classified into class II (performance standards) because the Panels believe that standards must be applied to the electrical and mechanical design and operating performance of this device to ensure patient and operator safety. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The General and Plastic Surgery Device Classification Panel recommends that surgical microscopes and accessories be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: The General and Plastic Surgery Device Classification Panel identified no risks to health. The Neurological Device Classification Panel, the Ear, Nose, and Throat Device Classification Panel, and the Ophthalmic Device Classification Panel identified the following risk to health: (a) Electrical shock: Excessive leakage current or a malfunction of the device could result in electrical shock to the operator. The Neurological Device Classification Panel identified the following additional risk to health: (b) Burns: Excessively heated areas on the device may result in operator injury. Also, excessive heating of the operating field may result in tissue destruction by dehydration. The Ophthalmic Device Classification Panel identified the folllowing additional risk to health: (c) Traumatic injury: If the device accidentally falls, the patient could be injured.

FDA agrees with the recommendations of the Neurological Device Classification Panel, the Ear, Nose, and Throat Device Classification Panel, and the Ophthalmic Device Classification Panel and is proposing that surgical microscopes and accessories be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device to control the hazard of electrical shock. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. FDA disagrees with the General and Plastic Surgery Device Classification Panel's

recommendation that surgical microscopes and accessories be classified into class I (general controls). The agency believes that general controls are insufficient to control the risks to health presented by the device. The agency has reviewed the Panels' recommendations for surgical microscopes and accessories and has concluded that the classification of the device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4730; Docket No. 78N–2692; Surgical skin degreaser or adhesive tape solvent.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of surgical skin degreasers and adhesive tape solvents:

1. Identification: A surgical skin degreaser or an adhesive tape solvent is a device that consists of 1,1,2-trichloro-1,2,2-trifluoroethane and that is intended for use as a solvent for surface skin oil or as a solvent for adhesive tape.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that surgical skin degreasers and adhesive tape solvents be classified into class II (performance standards) because the Panel believes that actue and chronic toxicity may result from excessive inhalation of high concentrations of the chemical. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel believes that proper labeling should note the hazards of chronic skin contact, of acute or chronic toxicity when used in large amounts, and of use in improperly ventilated rooms.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the literature submitted by the Miller-Stephenson Chemical Company, Inc. (Refs. *135, 136,* and *137*).

5. Risks to health: (a) Allergic or toxic reaction: Materials used in the device may cause an allergic or toxic reaction. (b) Ventricular fibrillation (rapid arrhythmic contractions of the heart muscle): Taken internally, this device may cause ventricular fibrillation. (c) Eye irritation: If this device contacts the eye, eye irritation may result. (d) Tissue damage: Prolonged exposure at high concentration levels may damage some internal organs such as the liver and kidneys.

FDA disagrees with the Panel's recommendation and is proposing that surgical skin degreasers or adhesive tape solvents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency agrees with the Panel that proper labeling of this device should be required.

Section 878.4750; Docket No. 78N–2693; Implantable staple.

The General and Plastic Surgery Device Classification Panel and the Gastroenterology and Urology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of implantable staples:

1. Identification: An implantable staple is an implanted stainless steel or tantalum staple-like device intended to connect internal tissues to aid healing.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel recommends that this device be classified into class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority. The Gastroenterology and Urology Device Classification Panel recommends that the device be classified into class III (premarket approval) if intended for urological applications. The Panel recommends that premarket approval be a low priority.

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel recommends that implantable staples be classified into class II (performance standards) because the Panel believes that the device has an established history of safe and effective use. The Panel believes that the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility to reduce the risk of rejection by the body and to minimize any potential for long-term adverse tissue reaction. The Panel believes that general controls alone would not provide sufficient control over these characteristics. Although this device is an implant, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information available to establish a performance standard. The Panel believes that complications of tissue necrosis (destruction) and failure to maintain the connection between tissues are usually due to errors in surgical technique (staples improperly spaced or improperly applied).

The Gastroenterology and Urology Device Classification Panel recommends that implantable staples for urological uses be classified into class III because of the known undesirable effects of the device in certain of these uses. The Panel was concerned that when used in making ileal conduits, the staples may cause the formation of urinary calculi. The Panel believes that premarket approval is necessary to assure the safety and effectiveness of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that sufficient information does not exist to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: The General and Plastic Surgery Device Classification Panel identified the following risks to health: (a) Tissue necrosis (destruction): Excessive pressure from the device may cause tissue destruction. (b) Leakage: Leakage of body fluids, due to failure of the device to maintain the connection between tissues, may result in complications, such as infection or hemorrhage. The Gastroenterology and Urology Device Classification Panel identified the following risk to health: (c) Formation of calculi (abnormal deposits in the body, usually composed of mineral salts): Calculi may form when the staples are exposed to urine as may occur in certain urinary diversion surgical techniques.

FDA agrees with the recommendation of the General and Plastic Surgery Device Classification Panel and is proposing that implantable staples be classified into class II (performance standards). The agency disagrees with the recommendation of the Gastroenterology and Urology Device Classification Panel that the device be classified into class III (premarket approval) for urological applications. Although the agency understands the concern of the Gastroenterology and Urology Device Classification Panel over potential complications when implanted staples are exposed to urine in certain urological surgical uses, the agency concludes that the risks of implantable staples for these uses can be reduced adequately by appropriate warning labeling against use of the device where it may be exposed to urine. Although the device is an implant, the agency believes that premarket approval is not necessary because the agency believes that standards for the device materials would be sufficient to assure the safety and effectiveness of the device. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. The agency also believes that there is sufficient information available to establish a performance standard for this device. The agency has reviewed articles in the literature in which Kahn (Ref. *138*) and Mallina et al. (Ref. *139*)

cite the generally recognized safe use of stainless steel and tantalum surgical staples. Albert indicates that stapling devices marketed in the United States have been sufficiently perfected so as to substantially assist surgery of the gastrointestinal tract (Ref. *140*). Albert also describes two generally well-recognized advantages of surgical stapling devices, reduced operating time and reduced blood flow from the surgical site as compared with suturing by hand. The agency has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel and of the Gastroenterology and Urology Device Classification Panel for implantable staples, and has concluded that the classification of the device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4760; Docket No. 78N-2694; Removable skin staple.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of removable skin staples:

1. Identification: A removable skin staple is a device intended to temporarily connect external tissues to aid healing.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that removable skin staples be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel does not believe that this device requires performance standards to control the identified risks to health. The materials used in the device are generally acceptable and need be subject only to general controls.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and its history of safe and effective clinical use.

5. Risks to health: (a) Tissue necrosis (destruction): Excessive pressure from the device may cause tissue destruction. (b) Leakage: Leakage of body fluids, due to failure of the device to maintain the connection between tissues, may result in complications, such as infection. (c) Migration of tissue: Failure of the staples to hold the tissue adequately may lead to migration of tissue.

FDA agrees with the Panel's recommendation and is proposing that removable skin staples be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Section 878.4780; Docket No. 78N-2695; Powered suction pump.

The General and Plastic Surgery Device Classification Panel and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of powered suction pumps:

1. Identification: A powered suction pump is a portable, AC-powered device that includes a bacterial filter to remove contaminants from the discharged air and that is intended to remove infectious material or fluids from the body either at the patient's bedside, as a wound drainage suction pump, or in the operating room, as a breathing system suction pump.

2. Recommended classification: Class II (performance standards). The General and Plastic Surgery Device Classification Panel recommends that establishing a performance standard for this device be a high priority. The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that powered suction pumps be classified into class II (performance standards) because the Panels believe that the bacterial filters used in the device are frequently ineffective. The Panels emphasized that instructions on the use of the filters, especially the frequency of their replacement, should be included in the device's labeling. The Anesthesiology Device Classification Panel believes that the amount of negative pressure generated by the device must be controlled to make sure that excessive negative pressure does not cause trauma to the patient's tissues, yet sufficient negative pressure be generated to be effective. That Panel noted the development of standards for this device by both the Z-79 committee of the American National Standard institute and by the British Standard Institute (BS 4199). Both Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the members' personal knowledge of, and clinical experience with, the device. The General and Plastic Surgery Device Classification Panel also based its recommendation on unpublished data from hospital tests in an intensive care unit; these data showed that inefficient or overused filters can result in the escape of bacteria into the air from the pump during the suctioning of fluids from the site of infection. The members of that Panel were particularly concerned about this hazard of airborne bacterial contamination caused by inefficient or overused filters.

5. Risks to health: (a) Airborne bacterial contamination: Inefficient or overused bacterial filters may result in contamination of other patients and hospital personnel by airborne bacteria. (b) Trauma to tissues: Excessive negative pressure caused by vacuum regulator malfunction, or lack of a regulator, may cause trauma to the patient's tissues.

FDA agrees with the recommendations of both Panels and is proposing that powered suction pumps be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

FDA has reviewed the recommendations of both the General and Plastic Surgery Device Classification Panel and the Anesthesiology Device Classification Panel for powered suction pumps and has concluded that the classification of the device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4800; Docket No. 78N-2696; Manual surgical intrument for general use.

The General and Plastic Surgery Device Classification Panel, the Cardiovascular Device Classification Panel, the Dental Device Classification Panel, the Ear, Nose, and Throat Device Classification Panel, the Gastroenterology and Urology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, the Neurology Device Classification Panel, the Obstetrical-Gynecological Device Classification Panel, and the Orthopedic Device Classification Panel, made the following recommendations regarding the classification of manual surgical instruments for general use:

1. Identification: A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended for use in various geneal surgical procedures. Surgical intruments that have specialized uses in specific medical specialty areas are classified in separate regulations published in the part of this subchapter for devices used by that medical specialty. Manual surgical instruments for general use may include: An applicator, a clip applier, a biopsy brush, a manual dermabrasion brush, a scrub brush, a cannula, a ligature carrier, a chisel, a clamp, a contractor, a curette, a cutter, a dissector, an elevator, a skin graft expander, a file, forceps, a gouge, an instrument guide, a needle guide, a hammer, a hemostat, an amputation hook, a ligature passing and knot-

tying instrument, a knife, a blood lancet, a mallet, a disposable or reusable aspiration and injection needle, a disposable or reusable suturing needle, an osteotome, pliers, a rasp, a retainer, a retractor, a saw, a scalpel, a blade, a scapel handle, a one-piece scapel, a snare, a spatula, a stapler, a disposable or reusable stripper, a stylet, measuring tape, and calipers.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel and the Orthopedic Device Classification Panel recommend that manual surgical instruments for general use be classified into class I (general controls). The Panels recommend that there be no exemptions. The Gastroenterology and Urology Device Classification Panel recommends that the cannula be classified into class I and that the needle be classified into class II. The Obstetrical-Gynecological Device Classification Panel recommends that the cerclage needle be classified into class II. The Cardiovascular Device Classification Panel recommends that the biopsy needle be classified into class II with low priority. The Dental Device Classification Panel recommends that the surgical knife be classified into class I. The Neurology Device Classification Panel recommends that the manual saw, the ligature passing and knot-tying instrument, the retractor, and the hemostatic clip applier be classified into class I. The General Hospital and Personal Use Device Classification Panel recommends that the blood lancet be classified into class I. The Ear, Nose, and Throat Device Classification Panel recommends that the ear, nose and throat speculum be classified into class I and that the mastoid chisel, the ear cannula, the ear speculum holder, the elevator retractor, the cannula, the tonsil dissector, the tonsil suturing needle, the nasal chisel, and the nasal gouge be classified into class II with low priority.

3. Summary of reasons for recommendation: In those cases in which the Panels recommend that manual surgical instruments for general use be classified into class I, the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of those devices. These devices have been in common use in medical practice for many years in a variety of surgical procedures. Several Panels (listed above) recommend that certain manual surgical instruments which are identified above be classified into class II because the Panels believe that the design of these devices must be controlled to prevent tissue trauma, and that the materials used in these devices should meet a generally accepted satisfactory level of tissue compatibility. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of these devices. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of these devices and that there is sufficient information available to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, these devices and their history of safe and effective clinical use.

5. Risks to health: (a) Tissue trauma: Poor manufacturing resulting in dullness, snags, burs, brittleness, or breakage of the devices may cause trauma to tissue. (b) Adverse tissue reaction: The materials used in the device, or particles or fragments falling off of the device, may cause an adverse tissue reaction in the patient.

FDA agrees with the recommendations of the General and Plastic Surgery Device Classification Panel and the Orthopedic Device Classification Panel and is proposing that manual surgical instruments for general use by classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. The agency disagrees with the recommendations of the other Panels listed above that certain manual surgical instruments for general use be classified into class II (performance standards). The agency has noted that the Panels' concerns regarding these devices fall into three categories: Manufacturing quality control (which is addressed by FDA's good manufacturing practice regulation for medical devices), design deficiencies, and the safety (inertness) of the materials used in the devices. However, the agency believes that the skill of the user is, by far, the initial factor in the safe and effective use of these devices and that a performance standard governing design and materials would not significantly increase their safety and effectiveness.

The agency has reviewed the Panels' recommendations for manual surgical instruments for general use and has concluded that the classification of these devices should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4810; Docket No. 78N-2697; Laser surgical instrument for use in general and plastic surgery and in dermatology.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of laser surgical instruments for use in general and plastic surgery and in dermatology:

1. Identification: A laser surgical instrument for use in general and plastic surgery and in dermatology is a carbon dioxide or argon gas laser device that is intended to cut, destroy, or remove tissue by light energy.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that laser surgical instruments for use in general and plastic surgery and dermatology be classified into class II (performance standards) because these devices are complex in design and the Panel believes that a performance standard is necessary to control the hazards accompanying the use of these devices, including retinal burns to the operator. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices, and on a presentation by Leon Goldman, M.D., Director, Laser laboratory, University of Cincinnati Medical Center, on the medical uses of lasers (Ref. 141). Dr. Goldman indicated that there has been no evidence of carcinogenicity in humans associated with the use of lasers in over 16 years of experience. This conclusion is further supported experimentally by in vitro tests and in vivo tests in animals.

5. Risks to health: Retinal burns: Unintentional exposure of the human eye to laser radiation may cause the retina of the patient or operator to be burned and the damage to be irreversible.

FDA agrees with the Panel's recommendation and is proposing that laser surgical instruments for use in general and plastic surgery and in dermatology be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. The agency notes that the Bureau of Radiological Health of the Food and Drug Administration has developed a safety performance standard under authority of the Radiation Control for Health and Safety Act of 1968 (21 CFR Part 1040) and that this performance standard is applicable to medical laser (Ref. 142). Although the retinal burn hazard from laser radiations being contolled by this performance standard, retinal burns can occur if the device is not used properly. Electrical safety standards are needed to control the hazard of electrical shock to the patient or operator. The present performance standard, supplemented by an electrical safety standard, would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish the latter standard for this device.

The agency notes that clinical literature describing the use of lasers raises the concern that tumor cells may be spread to adjacent tissues by the force of impact of a pulsed laser beam. This effect was described by Hoye, Ketcham, and Riggle (Ref. *143*). Airborne tumor cells, recovered from laser treated mice, were placed in the open axilla of the tested mice, resulting in a 65 percent increase of new tumor growth. These researchers believe that tumor cells may be forced into blood vessels and lymphatics by the laser treatment of such lesions, thereby increasing the probability of metastasis. The agency invites comment on this aspect of laser safety.

Section 878.4820; Docket No. 78N–2698; AC-powered, battery-powered, and pneumatically-powered surgical instrument motors and accessories/attachments.

The General and Plastic Surgery Device Classification Panel, the Cardiovascular Device Classification Panel, the Ophthalmic Device Classification Panel, the Orthopedic Device Classification Panel, and the Neurological Device Classifícation Panel, FDA advisory committees, made the following recommendations regarding the classification of AC-powered, battery-powered, and pneumatically-powered surgical instrument motors and their accessories/attachments:

1. Identification: AC-powered, battery-powered, and pneumatically-powered surgical instrument motors are devices intended for use in surgical procedures to provide power to operate the devices' various accessories or attachments to cut hard or soft tissue or bone. The accessories and attachments may include the bur, chisel (osteotome), dermabrasion brush, dermatome, drill bit, hammerhead, pin driver, and saw blade.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel, the Cardiovascular Device Classification Panel, the Ophthalmic Device Classification Panel and the Orthopedic Device Classification Panel recommend that the AC-powered surgical instrument motor be classified into class II (performance standards). The General and Plastic Surgery Device Classification Panel and the Cardiovascular Device Classification Panel recommend that establishing a performance standard for the AC-powered surgical instrument motor be a medium priority. The Orthopedic Device Classification Panel recommends that establishing a performance standard for this device be a low priority. The Ophthalmic Device Classification Panel recommends that the battery-powered surgical instrument motor be classified into class I (general controls) and that there be no exemptions.

The General and Plastic Surgery Device Classification Panel and the Neurological Device Classification Panel recommend that the pneumatically-powered surgical instrument motor be classified into class II. The General and Plastic Surgery Device Classification Panel recommends that establishing a performance standard for this device be a medium priority, and the Neurological Device Classification Panel recommends that establishing a performance standard for this device be a low priority. The Ophthalmic Device Classification Panel, the Cardiovascular Device Classification Panel, and the Orthopedic Device Classification Panel recommend that this device be classified into class I (general controls) with no exemptions.

The General and Plastic Surgery Device Classification Panel recommends that the following accessories/attachments for powered surgical instrument motors be classified into class I (general controls): Chisels (osteotomes), hammerheads, pin drivers, and saw blades. The Panel recommends that there be no exemptions. The General and Plastic Surgery Device Classification Panel also recommends that the following accessories/attachments for powered surgical instrument motors be classified into class II: burs, dermabrasion brushes, dermatomes, and drill bits. The Panel recommends that establishing a performance standard for these devices be a low priority. The Cardiovascular Device Classification Panel recommends that saw blade accessories/attachments for powered surgical instrument motors be classified into class II. The Panel recommends that establishing a performance standard for these devices be a low priority. The Orthopedic Device Classification Panel recommends that pneumatic-powered orthopedic surgical instrument accessories/attachments be classified into class I (general controls) and that there be no exemptions. The Neurological Device Classification Panel recommends that powered surgical saws and accessories be classified into class II and that establishing a performance standard for these devices be a low priority.

3. Summary reasons for recommendation: The General and Plastic Surgery Device Classification Panel, the Cardiovascular Device Classification Panel, the Ophthalmic Device Classification Panel, and the Orthopedic Device Classification Panel recommend that AC-powered surgical instrument motors be classified into class II (performance standards) because the Panels believe that a performance standard is necessary to control the electrical properties of the device to ensure electrical safety. The Panels believe that general controls would not provide sufficient control over these characteristics. The four Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Ophthalmic Device Classification Panel recommends that battery-powered surgical instrument motors be classified into class I (general controls) because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

The General and Plastic Surgery Device Classification Panel and the Neurological Device Classification Panel recommend that pneumatically-powered surgical instrument motors be classified into class II because the Panels believe that the design and performance characteristics of the device must be controlled by a standard to prevent explosion, thermal injury, or gas embolism. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

The Ophthalmic Device Classification Panel and the Cardiovascular Device Classification Panel recommend that pneumatically-powered surgical instrument motors be classified into class I because the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

The Orthopedic Device Classification Panel recommends that pneumatically-powered orthopedic surgical instrument motors and accessories/attachments be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and the effectiveness of the device. The Orthopedic Device Classification Panel also recommends that the device's labeling specify the torque produced by the devices at various gas pressures.

The General and Plastic Surgery Device Classification Panel recommends that chisels (osteotomes), hammerheads, pin drivers, and saw blades used as accessories/attachments for powered surgical instrument motors be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The materials used in the devices are generally acceptable and need be subject only to general controls.

The General and Plastic Surgery Device Classification Panel recommends that burs, dermabrasion brushes, dermatomes, and drill bits used as accessories/attachments for powered surgical instrument motors be classified into class II because the Panel believes that the physical and material properties of these devices must be controlled to ensure that a malfunction, such as loss of sharpness or strength, intolerance to torque, or overheating, does not occur. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of these devices. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information available to establish a performance standard. The Cardiovascular Device Classification Panel recommends that saw blades used as accessories/attachments for powered surgical instrument motors be classified into class II because the Panel believes that the materials used in the device must have the mechanical strength to withstand the forces applied to the device during use. The Neurological Device Classification Panel recommends that

accessories for pneumatically-powered instruments be classified into class II in order to control the hazard to health of exhaust gas exiting near the operating site, which could result in gas embolism. The Neurological Device Classification Panel believes that general controls alone would not provide sufficient control over the performance characteristics of the accessories to the devices. The Panel believes that a performance standard would provide reasonable assurance of their safety and effectiveness and that there is sufficient information available to establish a performance standard.

4. Summary of data on which the recommendation is based: The five Panels based their recommendations on their members' personal knowledge of, and clinical experience with, the devices.

5. Risks to health: The General and Plastic Surgery Device Classification Panel, the Cardiovascular Device Classification Panel, the Ophthalmic Device Classification Panel, and the Orthopedic Device Classification Panel identified the following risk to health for AC-powered surgical instrument motors: (a) Electrical injury: Improper electrical design of the device may cause electrical injury to the patient or user. The Cardiovascular Device Classification Panel identified the following additional risk to health: (b) Cardiac arrhythmia: Cardiac arrhythmia may result from patient exposure to electrical leakage current from the device. The Ophthalmic Device Classification Panel identified no risks to health for battery-powered surgical instrument motors. The Orthopedic Device Classification Panel identified the following additional risk to health for AC-powered surgical instrument motors: (c) Explosion: Electrical arcing from the AC-powered devices in an atmosphere containing explosive anesthesia gases could result in an explosion. The General and Plastic Surgery Device Classification Panel and the Orthopedic Device Classification Panel identified the following risk to health for pneumatically-powered surgical instrument motors: (d) Explosion: Inadequate stress tolerance of tubing, gauges, and connectors, deficiencies in pressurized gas tanks and valves, or inaccurate pressure gauges and regulators may result in hazardous operation or explosion. The General and Plastic Surgery Device Classification Panel identified the following additional risk to health for pneumatically-powered surgical instrument motors: (e) Thermal injury: Excessive heat generated in the tissue-cutting process from improperly designed or constructed devices may cause injury to adjacent tissues. The Neurological Device Classification Panel and the Orthopedic Device Classification Panel identified the following additional risk to health for pneumatically-powered surgical instrument motors: (f) Gas embolism: Exit of exhaust gas near the operating site may result in gas embolism. The Ophthalmic Device Classification Panel and the Cardiovascular Device Classification Panel identified no risks to health for the pneumatically-powered surgical instrument motor.

The General and Plastic Surgery Device Classification Panel identified no risks to health for the following accessories/attachments for powered surgical instrument motors: Chisels (osteotomes), hammerheads, pin drivers, and saw blades. The General and Plastic Surgery Device Classification Panel identified the following risks to health for the following accessories/attachments for powered surgical instrument motors: Burs, dermabrasion brushes, dermatomes, and drill bits; and the Cardiovascular Device Classification Panel identified the same risks to health for saw blades used as accessories/attachments for powered surgical instrument motors: (f) Tissue damage: Distintegration of these powered device attachments during an operation may increase the zone of tissue destruction in the patient. (g) Injury to patient or operator: Breakage or fragmentation of these powered device accessories during use in surgery could cause injury to the patient or the operator.

FDA has considered the recommendations of the five Panels and is proposing that the generic type of device, the AC-powered, battery-powered, and pneumatically-powered surgical instrument motors and their accessories/attachments, be classified into class II (performance standards). The agency believes that the various powered surgical instrument motors and their accessories/attachments that are subject to various recommendations by the five Panels are essentially included in the same generic type of device and present essentially the same risks to health. FDA believes that performance standards are necessary for these devices and their accessories/attachments because general controls alone are insufficient to control the risks to health presented by the devices. FDA believes that the risks to health from use of a powered device and its accessories/attachments, such as tissue damage from disintegration of an accessory or attachment during surgery, may increase the zone of tissue destruction in the patient and that the breakage of the accessory or attachment could cause injury to the patient or the operator. FDA believes that electrical, structural, and performance standards would provide reasonable assurance of the safety and effectiveness of the devices and their accessories/attachments. The agency also believes that there is sufficient information to establish performance standards for these devices and their accessories/attachments.

FDA disagrees with the recommendation of the Ophthalmic Device Classification Panel that battery-powered surgical instrument motors be classified into class I (general controls) and is proposing that the battery-powered device be classified into class II. The agency also disagrees with the recommendations of the Ophthalmic Device Classification Panel, the Cardiovascular Device Classification Panel, and the Orthopedic Device Classification Panel that pneumatically-powered surgical instrument motors be classified into class I (general controls) and is proposing that the pneumatically-powered device be classified into class II. The agency also disagrees with the recommendation of the General and Plastic Surgery Device Classification Panel that chisels (osteotomes), hammerheads, pin drivers, and saw blades be classified into class I, and the recommendation of the Orthopedic Device Classification Panel that pneumatic-powered orthopedic surgical instrument accessories/attachments be classified into class I. For the reasons stated above, the agency believes that a performance standard is necessary for all three types of powered surgical instrument motors and their accessories/attachments because general controls alone are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information available to establish a performance standard for these devices.

The agency has reviewed the recommendations of the five Panels and has concluded that the classification of the device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4930; Docket No. 78N-2703; Suture retention device.

The General and Plastic Surgery Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of suture retention devices:

1. Identification: A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, that is intended to aid the wound healing process by distributing suture tension over a larger area in the patient.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from registration, device listing, and premarket notification under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) and exempt from records and reports requirements under section 519 of the act (21 U.S.C. 360i).

3. Summary of reasons for recommendation: The Panel recommends that suture retention devices be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The materials used in the device are generally acceptable and need be subject only to general controls. The Panel

recommends that the manufacturer be exempt from registration, device listing, premarket notification, and records and reports requirements because adherence to these regulations would not improve the safety and effectiveness of the device and because suture retention devices have been used in clinical practice for many years with no apparent problems.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and its history of safe and effective clinical use.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that suture retention devices be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA disagrees with the Panel's recommendation that manufacturers of suture retention devices be exempt from all requirements under section 510 of the act (21 U.S.C. 360). Under section 510(g)(4), the agency may exempt a manufacturer from section 510 only upon a finding that compliance with this section is not necessary for the protection of the public health. In the case of suture retention devices, the agency cannot make the required finding. FDA also disagrees with the Panel's recommendation that manufacturers of suture retention devices be exempt from records and reports regulations under section 519 of the act (21 U.S.C. 360i.). See the discussion in this preamble under the heading "Exemptions for Class I Devices," for a complete explanation of the agency's policies concerning exemptions.

Section 878.4950; Docket No. 78N-2704; Manual operating table and accessories and manual operating chair and accessories.

The General and Plastic Surgery Device Classification Panel, the Orthopedic Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of manual operating tables and accessories and manual operating chairs and accessories:

1. Identification: A manual operating table and accessories and a manual operating chair and accessories are nonpowered devices, usually with movable components, intended for use in diagnostic examinations or surgical procedures in order to support the patient.

2. Recommended classification: The Panels recommend that the device be classified into class I (general controls). The Panels recommend no exemptions. The Anesthesiology Device Classification Panel recommends that conductive patient restraints, an accessory of the table or chair, be classified into class II (performance standards). That Panel recommends that establishing a performance standard for the conductive patient restraints be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that manual operating tables and accessories and manual operating chairs and accessories be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. The materials used in the devices are generally acceptable and need be subject only to general controls. The Anesthesiology Device Classification Panel recommends that conductive patient restraints, an accessory of the table or chair, be classified into class II because that Panel believes that the design of the device and materials used in the restraints must be controlled to assure adequate restraint capability to prevent patient injury resulting from falling or from hitting extremities on the operating table. When the restraints are used in the presence of flammable anesthetic gases, the Panel recommends that conductive material should be used in their construction to prevent fire or explosion from a build-up of static electricity. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of the restraints. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the restraints and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the members' personal knowledge of, and clinical experience with, the devices.

5. Risks to health: The General and Plastic Surgery Device Classification Panel, the Orthopedic Device Classification Panel, and the General Hospital and Personal Use Device Classification Panel identified no risks to health presented by these devices. The Anesthesiology Device Classification Panel identified the following risks to health with respect to conductive patient restraints, an accessory to the table or chair: (a) Patient injury: If the restraint capabilities of the device are inadequate, the patient may fall or injure extremities on the operating table. (b) Failure of electrical conductivity: An accumulation of static electricity, due to a failure of electrical conductivity of the device, may result in injury to the patient or in an explosion in the presence of flammable gases.

FDA agrees with the recommendations of the General and Plastic Surgery Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Orthopedic Device Classification Panel and is proposing that manual operating tables and accessories and manual operating chairs and accessories be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. FDA disagrees with the Anesthesiology Device Classification Panel's recommendation and is proposing that conductive patient restraints, an accessory of the table or chair, be classified into class I, with no exemptions. Because users are familiar with these simple devices and have used them successfully for many years without significant problems, the agency believes that a performance standard is unnecessary. The agency believes that general controls, including appropriate labeling regarding the conductivity or nonconductivity of the device and warnings against use of the nonconductive device in the presence of flammable anesthetic agents, are sufficient to control the risks to health presented by the device. The agency has reviewed the Panels' recommendations for manual operating tables and accessories and manual operating chairs and accessories and has concluded that the classification of these devicese should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.4960; Docket No. 78N-2705; Air or AC-powered operating table and accessories and air or AC-powered operating chair and accessories.

The General and Plastic Surgery Device Classification Panel, the Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Orthopedic Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of air or AC-powered operating tables and accessories and air or AC-powered operating chairs and accessories:

1. Identification: An air or AC-powered operating table and accessories and an air or AC-powered operating chair and accessories are air or electrically-powered devices, usually with movable components, intended for use in supporting the patient during diagnostic examinations or surgical procedures.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel recommends that these devices be classified into class I (general controls). The panel recommends that there be no exemptions. The Anesthesiology

Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Orthopedic Device Classification Panel recommend that these devices be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard for these devices be a high priority. The General Hospital and Personal Use Device Classification Panel and the Orthopedic Device Classification Panel recommend that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel recommends that air or AC-powered operating tables and accessories and air or AC-powered operating chairs and accessories be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The materials used in the devices are generally acceptable and need no additional requirements. The Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Orthopedic Device Classification Panel recommend that air or AC-powered operating tables and accessories and air or AC-powered operating chairs and accessories be classified into class II (performance standards) because the Panels believe that the electrical properties of the devices must be controlled through an electrical safety standard. The Panels recommend that AC-powered operating tables and AC-powered operating chairs have proper padding and are designed so that it is possible to operate the devices manually in the event of a power failure. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the members' personal knowledge of, and clinical experience with, the devices.

5. Risks to health: The General and Plastic Surgery Device Classification Panel identified no risks to health. The General Hospital and Personal Use Device Classification Panel, the Orthopedic Device Classification Panel, and the Anesthesiology Device Classification Panel identified the following risk to health: (a) Electrical shock: If the devices malfunction or are not properly grounded, the patient may receive an electrical shock. The Anesthesiology Device Classification Panel identified these additional risks to health: (b) Soft tissue or joint trauma: Hyper-extension or improper kidney bar design may cause soft tissue or joint trauma: (c) Peripheral nerve injury: Open table joints, protrusions, failure of the controls, or inadequate padding may cause peripheral nerve injury in unconscious, anesthetized patients: (d) Injury to the extremities: Improper design of the devices may cause injury to the extremities.

FDA agrees with the recommendations of the Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Orthopedic Device Classification Panel and is proposing that air or AC-powered operating tables and accessories and air or AC-powered operating chairs and accessories be classified into class II (performance standards). The agency disagrees with the General and Plastic Surgery Device Classification Panel's recommendation that these devices be classified into class I (general controls). The agency has reviewed clinical literature (Refs. *144* through *147*) that describe a wide variety of hazards associated with AC-powered medical devices used in hospitals and operating rooms. The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information available to establish a performance standard for these devices. The agency has reviewed the Panels' recommendations for air or AC-powered operating chairs and accessories and air or AC-powered operating tables and accessories and has concluded that the classification of these devices should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.5070; Docket No. 78N–2709; Air-handling apparatus for a surgical operating room.

The General and Plastic Surgery Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of air-handling apparatus for surgical operating rooms:

1. Identification: Air-handling apparatus for a surgical operating room is a device that is intended to reduce the possibility of infection in the patient by producing a directed, non-turbulent flow of air that has been filtered to remove particulate matter and microorganisms and thereby providing an area free of contaminants.

2. Recommended classification: Class II (performance standards). Both the General Hospital and Personal Use Device Classification Panel and the General and Plastic Surgery Device Classification Panel recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: Both Panels recommend that air-handling apparatus for surgical operating rooms be classified into class II (performance standards) because the Panels believe that a performance standard is necessary to assure that the filters in the device are effective in preventing the passage of microorganisms. Performance characteristics, including the accuracy and reliability of, and any limitations on, the device's functions, should be described in the labeling. Hospital personnel should take precautions to ensure that dust and other particulates do not plug the device's filters and thus reduce air flow or change the air flow pattern. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations upon the Panel members' personal knowledge of, and clinical experience with, the device. Alexander Irons, consultant to the General Hospital and Personal Use Device Classification Panel, mentioned several publications that evaluate clean room technology. An article by Wardle, Irons, and Green (Ref. *148*) discusses an investigation of the use of ultra-clean operating rooms to control infection. A comparison of an ultra-clean operating room with a conventional operating room showed that portable, unidirectional air flow enclosures reduced microbial contamination 100-fold. In another study (Ref. *149*), a vertical downflow room consisting of an integrated clean air operating room system was evaluated by comparing the room's microbiological and particulate contamination levels with the levels observed in an earlier evaluation of a horizontal air flow system. The comparison showed that the vertical downflow room had significantly lower microbiological and particulate contamination levels than the horizontal flow room. A third study evaluated the microbiological aspects of clean room technology as applied to surgery (Ref. *150*). The Panel also considered an article evaluating particulate air filters prepared by the Wilmot Castle Co. under a contract with the Jet Propulsion Laboratory (Ref. *151*). The article concludes that: (a) Areas of particulate penetration may be related to increased velocity of particles through holes in the filter media or frames; (b) the efficiency level of a filter should be tested before each use; and (c) high efficiency particulate air filters having an efficiency exceeding 99.99 percent can remove from a gas stream all particles of a size greater than 0.5 micrometer.

5. Risks to health: Both the General and Plastic Surgery Device Classification Panel and the General Hospital and Personal Use Device Classification Panel identified the following risk to health: (a) Infection: If the device's filter is not effective in preventing the passage of microorganisms, microorganisms may come into contact with the patient and cause infection. Also, if the air flow pattern is interrupted by dust or other particulates plugging the filters or by a power failure, organisms transmitted from the

hospital staff could cause infection in the patient. The General Hospital and Personel Use Device Classification Panel identified an additional risk to health: (b) Electrical injury: Improper design of the device or a device malfunction could result in an electrical injury to the patient or operating room personnel.

FDA agrees with both Panels' recommendations and is proposing that air-handling apparatus for surgical operating rooms be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. The agency has reviewed the Panels' recommendations for air-handling apparatus for surgical operating rooms and has concluded that classification of this device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.5350; Docket No. 78N-2711; High-frequency needle-type epilator.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of high-frequency needle-type epilators:

1. Identification: A high-frequency needle-type epilator is a device intended to destroy a hair follicle by applying DC current blended with high-frequency AC current at the tip of a fine needle that has been inserted close to the hair shaft, under the skin, and into the hair follicle.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommeds that high-frequency needle-type epilators be classified into class II (performance standards) because the Panel believes that standards are necessary to control the electrical properties of the device. High-frequency needle-type epilators are potentially harmful if not designed and used properly. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on a presentation by Ervin Epstein, M.D., a dermatologist consultant to the Panel (Ref. *154*). Dr. Epstein explained that during electrolysis using a high-frequency needle-type epilator an electrified needle is inserted into the hair follicle and current is applied for 20 seconds or more. An observable tissue reaction occurs in the form of minute liberation or "bubbling" of gas from the tissue. The hair is then removed with a tweezer. Dr. Epstein described two potential hazards involved in this technique: (a) Improper positioning of the needle in the follicle or cutting of the hair with the needle, both of which result in improper treatment, and (b) incorrect polarity, which results in the deposit of metal from the needle in the tissue. He described the procedure as uncomfortable and lengthy, and stated that swelling in the area being treated would be likely. He also stated that the technique is permanent, in that individual hair follicles are destroyed, but that the stimulus for hair growth in an area is never permanently removed.

5. Risks to health: (a) Electrical injury: Because the device applies electrical energy to the body, electrical injury may result. (b) Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result. (c) Scarring: Scarring may result from the tendency of the patient's body to produce keloid scars or from the use of improper depilating techniques by the operator.

FDA agrees with the Panel recommendation and is proposing that high-frequency needle-type epilators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Section 878.5360; Docket No. 78N-2712; High-frequency tweezer-type epilator.

The General and Plastic Surgery Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of high-frequency tweezer-type epilators:

1. Identification: A high-frequency tweezer-type epilator is an electrical device intended for hair removal. The device provides a high-frequency electric current at the tip of a tweezer used for removing hair.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel recommends that high-frequency tweezer-type epilators be classified into class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel recommends that high-frequency tweezer-type epilators be classified into class III (premarket approval) to assure that manufacturers demonstrate satisfactory performance of the device and, thus, assure its safety and effectiveness. No substantial data now exist to provide this assurance. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is insufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of the device, and on the absence of convincing clincial and scientific data demonstrating a specific action of the device on the process of hair removal. The Panel reviewed a number of journal articles (Ref. *155*), clincial evaluations (Refs. *156, 157, 162,* and *163*), an affidavit (Ref. *161*), and reports (Refs. *158, 159,* and *160*) which evaluate the claimed effectiveness of the device as a hair removal instrument. Also, the Panel heard presentations by a manufacturer of the device (Ref. *165*). In the Panel's judgment, the information presented in support of the device has not provided reasonable assurance of its safety and effectiveness.

5. Risks to health: (a) Cataracts: Non-ionizing radiation emitted from the device may cause heating of the lens of the eye and lead to cataract formation (opacity of the lens of the eye). (b) Pacemaker interference: Patients with pacemakers may experience arrhythmias from the use of the device. (c) Non-ionizing radiation exposure: The 27 megahertz electromagnetic radiation emitted at the tip of the tweezer may be potentially hazardous.

FDA agrees with the General and Plastic Surgery Device Classification Panel recommendation and is proposing that high-frequency tweezer-type epilators be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness or injury to the patient because the device may expose the patient to unnecessary radiation which may result in cataract formation or other adverse biological effects. In this regard, the high-frequency tweezer-type epilators may have high risks compared with the benefits to be achieved. The agency believes that insufficient information exists to determine that general controls or performance standards will provide reasonable assurance of the safety and effectiveness of the device. In reviewing the reports listed in the reference section, the agency notes numerous discrepancies among Dr. Morowitz's arguments (Refs. *159* and *160*), Dr. Pierce's findings in support of the instrument (Ref. *161*), and the work of Dr. Sternberg and Dr. Klein (Refs. *162* and *163*). Dr. Sternberg's and Dr. Klein's

histological analyses do not support Dr. Morowitz's prediction of "extensive cell damage" upon application of the device (Ref. *164*). No experimental evidence has been presented to support Dr. Pierce's statement (Ref. *161*) that "numerous pathologists" and "eminent dermatologists" have obtained research data showing "destructive changes in dermal papilla" caused by high-frequency tweezer-type epilators.

The agency notes numerous inconsistencies in the arguments of proponents of the high-frequency tweezer epilator. For example, the hair "release" phenomenon described by Dr. Pierce (REf. *161*) is allegedly caused by the action of the device when current is conducted via the hair filament to the hair root which is supposedly destroyed. However, Dr. Klein and Dr. Sternberg indicated that the hairs are merely plucked out with the instrument (Refs. *162* and *163*). The agency also concludes that the evidence provided by Dr. Hershberger (Ref. *158*) on the properties of hair does not justify the inference that following tweezer contact with the filament of hair, the hair root is permanently destroyed.

Section 878.5650; Docket No. 78N–2714; Topical oxygen chamber for extremities.

The General and Plastic Surgery Device Classification Panel and the Physical Medicine Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of topical oxygen chambers for extremities:

1. Identification: A topical oxygen chamber for extremities is a chamber that hermetically surrounds a chronic skin ulceration on a patient's arm or leg and that aids healing by allowing the topical application of humidified oxygen at a pressure slightly greater than atmospheric pressure.

2. Recommended classification: Class II (performance standards). The General and Plastic Surgery Device Classification Panel recommends that establishing a performance standard for this device be a medium priority. The Physical Medicine Device Classification Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that topical oxygen chambers for extremities be classified into class II because the Panels believe that the hazards associated with this device, including fire and explosion, infection transmitted from one patient to another, and injury resulting from improper pressure levels within the sleeves, must be controlled. The Panels believe that general controls would not provide sufficient control over these characteristics. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. *166* through *169*). The results of Dr. Fisher's clinical studies (Refs. *167* and *168*) demonstrated that topical hyperbaric oxygen therapy considerably shortened the healing time for vascular lesions. In controlled experiments where the efficacy of this mode of treatment was compared with conventional treatment, a superior result was achieved with oxygen therapy. The healing response depended on the degree of vascularization of the tissues; negative results were obtained with chronic ulcers of the avascular type (those not supplied with blood vessels), such as ulcers resulting from osteomyelitis. Torelli (Ref. *169*) indicated that the treatment of decubitus ulcers (bed sores) with the hyperbaric oxygen chamber is effective, practical, and safe.

5. Risks to health: (a) Infection: If the materials used in the device or its construction prevent proper sterilization, an infection may result. (b) Fire: Pure oxygen used in this device is highly combustible and hazardous when an open flame is present. (c) Decrease of local tissue circulation: Greater than 22 millimeters of mercury oxygen pressure in the chamber occludes arterial circulation, which leads to a decrease in local tissue circulation.

FDA agrees with the Panels' recommendations and is proposing that topical oxygen chambers for extremities be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. The agency has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel and the Physical Medicine Device Classification Panel for topical oxygen chambers for extremities and has concluded that the classification of the device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.5900; Docket No. 78N–2716; Nonpneumatic tourniquet.

The General and Plastic Surgery Device Classification Panel and the Gastroenterology and Urology Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nonpneumatic tourniquets:

1. Identification: A nonpneumatic tourniquet is a device consisting of a strap or tubing that is intended to be wrapped around a patient's arm or leg and tightened to reduce circulation in the limb.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel and the Gastroenterology and Urology Device Classification Panel recommend that this device be classified into class I (general controls). The Panels recommend that there be no exemptions.

3. Summary of reasons for recommendation: The Panels recommend that nonpneumatic tourniquets be classified into class I (general controls) because the Panels believe that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panels do not believe that this device requires performance standards to control the identified risks to health. The materials used in the device are generally acceptable and need be subject only to general controls.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Tissue necrosis (destruction); If nonpneumatic tourniquets are applied too tightly, excessive pressure on the limb may result in tissue destruction.

FDA agrees with the Panels' recommendations and is proposing that nonpneumatic tourniquets be classified into class I (general controls) with no exceptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel and the Gastroenterology and Urology Devices Classification Panel for nonpneumatic tourniquets, and has concluded that the classification of the device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

Section 878.5910; Docket No. 78N–2717; Pneumatic tourniquet.

The General and Plastic Surgery Device Classification Panel and the Orthopedic Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of pneumatic tourniquets:

1. Identification: A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit and an inflatable cuff that is intended to be wrapped around a patient's arm or leg and inflated to reduce circulation in a limb.

2. Recommended classification: The General and Plastic Surgery Device Classification Panel recommends that this device be classified into class II (performance standards) and that establishing a performance standard for this device be a high priority. The Orthopedic Device Classification Panel recommends that this

device be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The General and Plastic Surgery Device Classification Panel recommends that pneumatic tourniquets be classified into class II (performance standards) because the Panel believes that inadequate control of the presssure applied to the patient's body by the device may result in tissue destruction. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Orthopedic Device Classification Panel recommends that pneumatic tourniquets be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device because they reported no knowledge of specific hazards to health presented by the device.

4. Summary of data on which the recommendation is based: The Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: The General and Plastic Surgery Device Classification Panel identified the following risk to health: Tissue destruction: Excessive pressure applied to the patient's body, due to unstable pressure setting, may cause tissue destruction. The Orthopedic Device Classification Panel identified no risks to health.

FDA agrees with the recommendation of the General and Plastic Surgery Device Classification Panel and is proposing that pneumatic tourniquets be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device. The agency disagrees with the recommendation of the Orthopedic Device Classification Panel that pneumatic tourniquets be classified into class I (general controls). This device is known to exert excess pressure on the tissue if there are faulty or improper pressure control mechanisms. The accurate functioning of this device is critical in some surgical procedures. Therefore, the agency believes that a malfunction could cause a potential health hazard that introduces unnecessary risk to the patient and that could be reduced by a performance standard. The agency has reviewed the recommendations of the General and Plastic Surgery Device Classification Panel and the Orthopedic Device Classification Panel for pneumatic tourniquets and has concluded that the classification of the device should be published in the part of the Code of Federal Regulations for general and plastic surgery devices.

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The following information has been placed in the Dockets Management Branch (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

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(*157*) Letter dated August 9, 1976, from Eugene J. Van Scott, M.D., to Harold E. Pierce, M.D., with Dr. Van Scott's "Study Comparing Effects of Manual Epilation versus Removal by Depilatron on Regrowth of Hair" (unpublished).

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(*162*) "Microscopic Study of Effects of Depilatron Epilation on the Hair Structure" (unpublished), James H. Sternberg, M.D., Asst. Clinical Professor of Medicine (Dermatology), School of Medicine, UCLA, and Arnold W. Klein, M.D., Asst. Clinical Professor of Medicine (Dermatology), School of Medicine, UCLA, undated. This report was reviewed by the General and Plastic Surgery Panel on March 24, 1978.

(*163*) "A Study Using Human Volunteers to Determine if Depilatron Epilation is Painful" (unpublished), by James H. Sternberg, M.D., and Arnold W. Klein, M.D. This report was reviewed by the General and Plastic Surgery Panel on March 24, 1978.

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Environmental Impact

The agency has determined under 21 CFR 25.24(b)(12) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 (formerly 5.1; see 46 FR 26052; May 11, 1981)), it is proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 878, to read as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

Subpart A—General Provisions

Sec.
878.1 Scope.

Subpart B—General and Plastic Surgery Diagnostic Devices

878.1800 Speculum and accessories.

Subpart C—[Reserved]

Subpart D—General and Plastic Surgery Prosthetic Devices

878.3250 External facial fracture fixation appliance.
878.3300 Surgical mesh.
878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.
878.3530 Inflatable breast prosthesis.
878.3540 Silicone gel-filled breast prosthesis.
878.3550 Chin prosthesis.
878.3590 Ear prosthesis.
878.3610 Esophageal prosthesis.
878.3680 Nose prosthesis.
878.3720 Tracheal prosthesis.
878.3750 External prosthesis adhesive.
878.3800 External aesthetic restoration prosthesis.
878.3900 Inflatable extremity splint.
878.3910 Noninflatable extremity splint.
878.3925 Plastic surgery kit and accessories.

Subpart E—General and Plastic Surgery Surgical Devices

878.4040 Surgical apparel.
878.4060 Nonabsorbable gauze, surgical sponge, and wound dressing for external use.
878.4100 Intestine bag.
878.4120 Hydrophilic beads for wound exudate absorption.
878.4140 Porcine burn dressing.
878.4160 Surgical camera and accessories.
878.4200 Introduction/drainage catheter and accessories.
878.4300 Implantable clip.
878.4320 Removable skin clip.
878.4350 Cryosurgical unit and accessories.
878.4370 Surgical drapes and drape accessories.
878.4380 Aerosol drape adhesives.
878.4400 Electrosurgical cutting and coagulation device and accessories.
878.4450 Nonabsorbable gauze for internal use.
878.4460 Surgeon's glove.
878.4470 Surgeon's gloving cream.
878.4580 Surgical lamp.
878.4630 Dermatological ultraviolet lamp.
878.4650 Aorto-saphenous vein ostia marker.
878.4600 Skin marker.
878.4680 Nonpowered, single patient, portable suction apparatus.
878.4700 Surgical microscope and accessories.
878.4730 Surgical skin degreaser or adhesive tape solvent.
878.4750 Implantable staple.
878.4760 Removable skin staple.
878.4780 Powered suction pump.
878.4800 Manual surgical instrument for general use.
878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.
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Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))

Subpart A—General Provisions

§ 878.1 Scope.

(a) This part sets forth the classification of general and plastic surgery devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a general and plastic surgery 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.

Subpart B—General and Plastic Surgery Diagnostic Devices

§ 878.1800 Speculum and accessories.

(a) *Identification.* A speculum is a device that is intended for insertion into a body cavity to facilitate observation. It is either non-illuminated or illuminated and may have various accessories.

(b) *Classification.* Class I (general controls).

Subpart C—[Reserved]

Subpart D—General and Plastic Surgery Prosthetic Devices

§ 878.3250 External facial fracture fixation appliance.

(a) *Identification.* An external facial fracture fixation appliance is a metal apparatus used during surgery to immobilize maxillofacial bone fragments in their proper facial relationship for surgical reconstruction and repair.

(b) *Classification.* Class I (general controls).

§ 878.3300 Surgical mesh.

(a) *Identification.* A surgical mesh is an implanted metallic or polymeric screen intended for use in reinforcing soft tissue or bone where weakness exists. Examples of surgical mesh are metallic and polymeric mesh for hernia repair, and acetabular and cement restrictor mesh used in orthopedic surgery.

(b) *Classification.* Class II (performance standards).

§ 878.3500 Polytetrafluoroethylene with carbon fibers composite implant material.

(a) *Identification.* A polytetrafluoroethylene with carbon fibers composite implant material is an implanted, porous device material that is intended for use as a space-occupying substance in surgery of the chin, jaw, nose, and bones and tissue near the eye and ear. The device material is shaped and formed by the surgeon to conform to the patient's need.

(b) *Classification.* Class II (performance standards).

§ 878.3530 Inflatable breast prosthesis.

(a) *Identification.* An inflatable breast prosthesis is a silicone rubber shell made of polydimethylsiloxane and polydiphenylsiloxane that is inflated after implantation with a fluid other than injectable silicone, such as sterile isotonic saline, that is intended to augment or reconstruct the female breast.

(b) *Classification.* Class III (premarket approval).

§ 878.3540 Silicone gel-filled breast prosthesis.

(a) *Identification.* A silicone gel-filled breast prosthesis is a silicone rubber shell made of polydimethylsiloxane and polydiphenylsiloxane. The shell either contains cross-linked polymerized silicone gel, fillers, and stabilizers or is filled with injectable silicone gel at time of implantation. The device is intended for implantation to augment or reconstruct the female breast. The device does not include injectable silicone (including tissue adhesives for use in general surgery) for injection directly into the patient's body rather than into a shell; direct injection use of silicone is investigational only.

(b) *Classification.* Class III (premarket approval).

§ 878.3550 Chin prosthesis.

(a) *Identification.* A chin prosthesis is an implanted solid silicone rubber prosthesis intended for use in chin augmentation or reconstruction.

(b) *Classification.* Class II (performance standards).

§ 878.3590 Ear prosthesis.

(a) *Identification.* An ear prosthesis is an implanted solid silicone rubber prosthesis intended for use in the reconstruction of the external ear.

(b) *Classification.* Class II (performance standards).

§ 878.3610 Esophageal prosthesis.

(a) *Identification.* An esophageal prosthesis is a plastic tube or tube-like device (that may have mesh reinforcement) and accessories that is implanted in, or affixed externally to, the chest and throat for restoration of the esophagus or for pharyngoesophageal continuity.

(b) *Classification.* Class III (premarket approval).

§ 878.3680 Nose prosthesis.

(a) *Identification.* A nose prosthesis is an implanted solid silicone rubber prosthesis intended for use in the augmentation or reconstruction of the nasal dorsum.

(b) *Classification.* Class II (performance standards).

§ 878.3720 Tracheal prosthesis.

(a) *Identification.* A tracheal prosthesis is a tubular implant intended for use in the reconstruction of the trachea.

(b) *Classification.* Class III (premarket approval).

§ 878.3750 External prosthesis adhesive.

(a) *Identification.* An external prosthesis adhesive is a silicone-type adhesive intended for use in affixing an external prosthesis, such as an artificial nose or ear.

(b) *Classification.* Class I (general controls).

§ 878.3800 External aesthetic restoration prosthesis.

(a) *Identification.* An external aesthetic restoration prosthesis is a device intended to construct an external artificial body structure, such as an ear, breast, or nose. The device usually is made of silicone rubber and attached to, but not implanted into, the deficient anatomy with a biocompatible adhesive.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 878.3900 Inflatable extremity splint.

(a) *Identification.* An inflatable extremity splint is an inflatable device intended to prevent motion of a joint or of the ends of a fractured bone.

(b) *Classification.* Class I (general controls).

§ 878.3910 Noninflatable extremity splint.

(a) *Identification.* A noninflatable extremity splint is a noninflatable device intended to prevent motion of a joint or of the ends of a fractured bone.

(b) *Classification.* Class I (general controls).

§ 878.3925 Plastic surgery kit and accessories.

(a) *Identification.* A plastic surgery kit and accessories is a device that is used in the reconstruction of maxillofacial

deficiencies. It consists of a kit containing surgical instruments and materials intended for use in making maxillofacial impressions before molding an external prosthesis.

(b) *Classification.* Class I (general controls).

Subpart E—General and Plastic Surgery Surgical Devices

§ 878.4040 Surgical apparel.

(a) *Identification.* Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns.

(b) *Classification.* Class II (performance standards).

§ 878.4060 Nonabsorbable gauze, surgical sponge, and wound dressing for external use.

(a) *Identification.* Nonabsorbable gauze, a surgical sponge, or a wound dressing for external use are devices made of an open mesh fabric of cotton or synthetic materials that are intended to control bleeding, absorb body fluids, or protect wounds from contamination.

(b) *Classification.* Class I (general controls).

§ 878.4100 Intestine bag.

(a) *Identification.* An intestine bag is a device that consists of a flexible plastic bag and that is intended for use as a temporary receptacle for the intestine to prevent moisture loss during surgical procedures.

(b) *Classification.* Class I (general controls).

§ 878.4120 Hydrophilic beads for wound exudate absorption.

(a) *Identification.* Hydrophilic beads for wound exudate absorption are small spherical beads made of dextran polymer that are intended to remove particulate and fluid secretion from wounds by absorption and capillary action.

(b) *Classification.* Class I (general controls).

§ 868.4140 Porcine burn dressing.

(a) *Identification.* A porcine burn dressing is a device made from pigskin that is intended for use as a temporary dressing in the treatment of burns.

(b) *Classification.* Class I (general controls).

§ 878.4160 Surgical camera and accessories.

(a) *Identification.* A surgical camera and accessories of a device that is intended to record operative procedures and that consists of a camera and associated equipment, which may include a sound track.

(b) *Classification.* Class I (general controls).

§ 878.4200 Introduction/drainage catheter and accessories.

(a) *Identification.* An introduction/drainage catherer is a device that consists of a flexible single lumen or multilumen tube intended for use in the introduction of fluids, medications, or contrast material into body cavities; the evaluation of physiological parameters, such as venous pressure; or the drainage of fluids from body cavities. Examples include irrigation and drainage catheters, pediatric catheters, perionteal catheters, and other general surgical catheters. A catheter accessory is a component of this device intended to facilitate the manipulation of, or to assist in the insertion of, an introduction/drainage catheter into various parts of the body. Examples include adaptors, connectors, and catheter needles.

(b) *Classification.* Class II (performance standards).

§ 878.4300 Implantable clip.

(a) *Identification.* An implantable clip is a stainless steel or tantalum device intended to connect internal tissues to aid healing.

(b) *Classification.* Class II (performance standards).

§ 878.4320 Removable skin clip.

(a) *Identification.* A removal skin clip is a device intended to temporarily connect external tissues to aid healing.

(b) *Classification.* Class I (general controls).

§ 878.4350 Cryosurgical unit and accessories.

(a) Cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories:

(1) *Identification.* A cryosurgical unit with a liquid nitrogen cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures by applying extreme cold.

(2) *Classification.* (i) Class III (premarket approval) when intended for use in various urological applications, such as treatment of prostate carcinoma.

(ii) Class II (performance standards) when intended for other surgical procedures.

(b) Cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories:

(1) *Identification.* A cryosurgical unit with a nitrous oxide cooled cryoprobe and accessories is a device intended to destroy tissue during surgical procedures, including urological applications, by applying extreme cold.

(2) *Classification.* Class II (performance standards).

(c) Cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator, and accessories:

(1) *Identification.* A cryosurgical unit with a carbon dioxide cooled cryoprobe or a carbon dioxide dry ice applicator, and accessories, is a device intended to destroy tissue during surgical procedures by applying extreme cold. The device is intended to treat disease conditions other than urological applications such as tumors, skin cancers, acne scars, and hemangiomas (benign tumors consisting of newly-formed blood vessels), and to treat various benign or malignant gynecological conditions affecting vulvar, vaginal, or cervical tissue. The device is not used for urological applications.

(2) *Classification.* Class II (performance standards).

§ 878.4370 Surgical drapes and drape accessories.

(a) *Identification.* Surgical drapes and drape accessories are devices made of natural or synthetic materials intended for use as protective patient coverings, such as to isolate a site of surgical incision from microbial and other contamination. Examples of surgical drapes and drape accessories are plastic wound protectors that usually adhere to the skin around a surgical incision or that are placed in the wound to cover its exposed edges, Kelly pads that are placed beneath a patient or limb to absorb drainage from a surgical wound, and latex drapes with self-retaining finger cots that are used during transurethral prostatectomy for repeated insertion of the surgeon's finger into the rectum.

(b) *Classification.* Class II (Performance standards).

§ 878.4380 Aerosol drape adhesive.

(a) *Identification.* An aerosol drape adhesive is a device that is a substance intended to be sprayed on the skin to keep surgical drapes in place.

(b) *Classification.* Class I (general controls).

§ 878.4400 Electrosurgical cutting and coagulation device and accessories.

(a) *Identification.* An electrosurgical cutting and coagulation device and accessories is a device that uses high-

frequency electrical current and that is intended for the surgical removal of tissue and for the control of bleeding.

(b) *Classification.* Class II (performance standards).

§ 878.4450 Nonabsorbable gauze for internal use.

(a) *Identification.* Nonabsorbable gauze for internal use is a device made of an open mesh fabric of cotton or synthetic material intended to control bleeding, absorb body fluids, and protect wounds from contamination.

(b) *Classification.* Class II (performance standards).

§ 878.4460 Surgeon's glove.

(a) *Identification.* A surgeon's glove is a device made of a rubber polymer compound that is intended to be worn by operating room personnel and is used to protect the surgical wound from contamination and cross-infection.

(b) *Classification.* Class II (performance standards).

§ 878.4470 Surgeon's gloving cream.

(a) *Identification.* Surgeon's gloving cream is an ointment intended to lubricate the user's hands before putting on surgeon's gloves.

(b) *Classification.* Class I (general controls).

§ 878.4580 Surgical lamp.

(a) *Identification.* A surgical lamp (including a fixture) is a device that is intended to provide visible illumination for the surgical field or for examination of the patient.

(b) *Classification.* Class II (performance standards).

§ 878.4630 Dermatologic ultraviolet lamp.

(a) *Identification.* A dermatologic ultraviolet lamp is a device (including a fixture) that provides ultraviolet radiation that is intended primarily for the treatment of dermatologic disorders or for tanning.

(b) *Classification.* Class II (performance standards). See § 1040.20.

§ 878.4650 Aorto-saphenous vien ostia marker.

(a) *Identification.* An aorto-saphenous vien ostia marker is an implanted stainless steel ring that is intended to mark the anastomosis (point of surgical connection) of the aorta and the coronary bypass saphenous vien graft to allow radiologic identification of or catheterization of the bypass vien graft.

(b) *Classification.* Class II (performance standards).

§ 878.4660 Skin marker.

(a) *Identification.* A skin marker is a pen-like device intended to write on the patient's skin for the purpose of outlining surgical incision sites or marking anatomical sites for accurate blood pressure measurement.

(b) *Classification.* Class I (general controls).

§ 878.4680 Nonpowered, single patient, portable suction apparatus.

(a) *Identification.* A nonpowered, single patient, portable suction apparatus is a device that consists of a manually operated plastic, disposable evacuation system that is intended to provide a vacuum used for suction drainage of surgical wounds.

(b) *Classification.* Class I (general controls).

§ 878.4700 Surgical microscope and accessories.

(a) *Identification.* A surgical microscope and accessories is an AC-powered device intended for use during surgery to provide a magnified view of the surgical field.

(b) *Classification.* Class II (performance standards).

§ 878.4730 Surgical skin degreaser or adhesive tape solvent.

(a) *Identification.* A surgical skin degreaser or an adhesive tape solvent is a device that consists of 1,1,2-trichloro-1,2,2-trifluoroethane and that is intended for use as a solvent for surface skin oil or as a solvent for adhesive tape.

(b) *Classification.* Class I (general controls).

§ 878.4750 Implantable staple.

(a) *Identification.* An implantable staple is an implanted stainless steel or tantalum staple-like device intended to connect internal tissues to aid healing.

(b) *Classification.* Class II (performance standards).

§ 878.4760 Removable skin staple.

(a) *Identification.* A removable skin staple is a device intended to temporarily connect external tissues to aid healing.

(b) *Classification.* Class I (general controls).

§ 878.4780 Powered suction pump.

(a) *Identification.* A powered suction pump is a portable, AC-powered device that includes a bacterial filter to remove contaminants from the discharged air and that is intended to remove infectious material or fluids from the body either at the patient's bedside, as a wound drainage suction pump, or in the operating room, as a breathing system suction pump.

(b) *Classification.* Class II (performance standards).

§ 878.4800 Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended for use in various general surgical procedures. Surgical instruments that have specialized uses in specific medical specialty areas are classified in separate regulations published in the part of this subchapter for devices used by that medical specialty. Manual surgical instruments for general use may include: An applicator, a clip applier, a biopsy brush, a manual dermabrasion brush, a scrub brush, a cannula, a ligature carrier, a chisel, a clamp, a contractor, a curette, a cutter, a dissector, an elevator, a skin graft expander, a file, forceps, a gouge, an instrument guide, a needle guide, a hammer, a hemostat, an amputation hook, a ligature passing and knot-tying instrument, a knife, a blood lancet, a mallet, a disposable or reusable aspiration and injection needle, a disposable or reusable suturing needle, an osteotome, pliers, a rasp, a retainer, a retractor, a saw, a scalpel, a blade, a scalpel handle, a one-piece scalpel, a snare, a spatula, a stapler, a disposable or reusable stripper, a stylet, measuring tape, and calipers.

(b) *Classification.* Class I (general controls).

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

(a) *Identification.* A laser surgical instrument for use in general and plastic surgery and in dermatology is a carbon dioxide or argon gas laser device that is intended to cut, destroy, or remove tissue by light energy.

(b) *Classification.* Class II (performance standards).

§ 878.4820 AC-powered, battery-powered, and pneumatically-powered surgical instrument motors and accessories/attachments.

(a) *Identification.* AC-powered, battery-powered, and pneumatically-powered surgical instrument motors are devices intended for use in surgical procedures to provide power to operate the devices' various accessories or attachments to cut hard or soft tissue and bone. The accessories and attachments may include the bur, chisel (osteotome), dermabrasion brush, dermatome, drill bit, hammerhead, pin driver, and saw blade.

(b) *Classification.* Class II (performance standards).

§ 878.4930 Suture retention device.

(a) *Identification.* A suture retention device is a device, such as a retention bridge, a surgical button, or a suture bolster, that is intended to aid the wound healing process by distributing suture tension over a larger area in the patient.

(b) *Classification.* Class I (general controls).

§ 878.4950 Manual operating table and accessories and manual operating chair and accessories.

(a) *Identification.* A manual operating table and accessories and a manual operating chair and accessories are nonpowered devices, usually with movable components, intended for use during diagnostic examinations or surgical procedures in order to support the patient.

(b) *Classification.* Class I (general controls).

§ 878.4960 Air or AC-powered operating table and accessories and air or AC-powered operating chair and accessories.

(a) *Identification.* An air or AC-powered operating table and accessories and an air or AC-powered operating chair and accessories are air or electrically-powered devices, usually with movable components, intended for use during diagnostic examinations or surgical procedures to support the patient.

(b) *Classification.* Class II (performance standards).

Subpart F—General and Plastic Surgery Therapeutic Devices

§ 878.5070 Air-handling apparatus for a surgical operating room.

(a) *Identification.* Air-handling apparatus for a surgical operating room is a device that is intended to reduce the possibility of infection in the patient by producing a directed, non-turbulent flow of air that has been filtered to remove particulate matter and microorganisms and thereby providing an area free of contaminants.

(b) *Classification.* Class II (performance standards).

§ 878.5350 High-frequency needle-type epilator.

(a) *Identification.* A high-frequency needle-type epilator is a device intended to destroy a hair follicle by applying DC current blended with high-frequency AC current at the tip of a fine needle that has been inserted close to the hair shaft, under the skin, and into the hair follicle.

(b) *Classification.* Class II (performance standards).

§ 878.5360 High-frequency tweezer-type epilator.

(a) *Identification.* A high-frequency tweezer-type epilator is an electrical device intended for hair removal. The device provides a high-frequency electric current at the tip of a tweezer used for removing hair.

(b) *Classification.* Class III (premarket approval).

§ 878.5650 Topical oxygen chamber for extremities.

(a) *Identification.* A topical oxygen chamber for extremities is a chamber that hermetically surrounds a chronic skin ulceration on a patient's arm or leg and that aids healing by allowing the topical application of humidified oxygen at a pressure slightly greater than atmospheric pressure.

(b) *Classification.* Class II (performance standards).

§ 878.5900 Nonpneumatic tourniquet.

(a) *Identification.* A nonpneumatic tourniquet is a device consisting of a strap or tubing that is intended to be wrapped around a patient's arm or leg and tightened to reduce circulation in the limb.

(b) *Classification.* Class I (general controls).

§ 878.5910 Pneumatic tourniquet.

(a) *Identification.* A pneumatic tourniquet is an air-powered device consisting of a pressure-regulating unit and an inflatable cuff that is intended to be wrapped around a patient's arm or leg and inflated to reduce circulation in a limb.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before March 22, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments regarding the general provisions are to be identified with the docket number found in brackets in the heading of this document. Comments regarding a particular device are to be indentified with the docket number for that device found in the "Panel Recommendation" section. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The Food and Drug Administration has carefully analyzed the economic effects of this proposed 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 proposed rule has been carefully analyzed, and it has been determined that this proposal does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules proposing classification of devices into class I generally maintain the status quo: These devices are now subject to only 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 proposed rules, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were established. Similiarly, 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.

Dated: December 16, 1981.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 82–1192 Filed 1–18–82; 8:45 am]

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

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

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

Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday. Comments on this program are still invited.

Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408.

List of Public Laws

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

Last Listing January 6, 1982