Authority: 21 U.S.C. 321, 341, 343, 343–1, 348, 349, 371, 379e.

§ 165.110 [Amended]

2. Section 165.110 *Bottled water* is amended in the table in paragraph (b)(4)(iii)(A) by removing the superscript ''1'' after the entries for ''Antimony,'' ''Beryllium,'' ''Cyanide,'' ''Nickel,'' and ''Thallium,'' and by removing the footnote to the table; in the table in paragraph (b)(4)(iii)(C) by removing the superscript ''1'' after the entries for ''Diquat,'' ''Endothall,'' ''Glyphosate,'' and ''2,3,7,8–TCDD (Dioxin),'' and by removing the footnote to the table; and by removing the note that follows paragraph (b)(4)(iii)(G)(*3*)(*iv*).

Dated: May 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12382 Filed 5–6–98; 3:57 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. 98N–0249]

Ear, Nose, and Throat Devices; Classification of the Nasal Dilator, the Intranasal Splint, and the Bone Particle Collector

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the nasal dilator, intranasal splint, and the bone particle collector into class I and exempt these devices from premarket notification procedures. FDA is also publishing the recommendations of the Ear, Nose, and Throat Devices Panel (the panel) regarding the classification of the devices. After considering public comments on the proposed classifications, FDA will publish a final regulation classifying the devices. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments by August 10, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Harry R. Sauberman, Center for Devices and Radiological Health (HFZ–420), Food and Drug Administration, 9200 Corporate Blvd, Rockville, MD 20850, 301– 594–2080.

SUPPLEMENTARY INFORMATION:

I. Background

The act, as amended by the 1976 amendments (Pub. L. 94–295), the SMDA (Pub. L. 101–629), and FDAMA (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval). Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments) are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee), (2) published the panel's recommendations for comment, along with a proposed regulation classifying the device, and (3) published a final regulation classifying the device. A device that is first offered in commercial distribution after May 28, 1976, and which FDA determines to be substantially equivalent to a device classified under this scheme, is classified into the same class as the device to which it is substantially equivalent. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A device that was not in commercial distribution prior to May 28, 1976, and that has not been found by FDA to be substantially equivalent to a legally marketed predicate device, is classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process.

In the **Federal Register** of November 6, 1986 (51 FR 40378), FDA published a final rule classifying ear, nose and throat devices. At that time, FDA was not aware that the nasal dilator, the intranasal splint, and the bone particle collector were preamendments devices and inadvertently omitted classifying them.

II. Device Descriptions

FDA is proposing the following device descriptions based on the panel's recommendations (Ref. 1) and the agency's review:

(1) The nasal dilator is a device intended to provide temporary relief from breathing difficulties resulting from structural abnormalities in the nose. The external nasal dilator is described as a device constructed from layers of fabric material with a flat plastic spring inserted between the layers, with a skin adhesive applied to adhere to the skin of the nose. The device is placed externally on the lower third of the nose. The external nasal dilator acts with a pulling force to open the nares and the nasal valves thereby decreasing nasal airway resistance and increasing nasal air flow. The internal nasal dilator is constructed from metal or plastic and is placed inside the nostrils. It acts by pushing the nostrils open or by gently pressing on the columella, thereby decreasing nasal airway resistance and increasing nasal airflow;

(2) The intranasal splint is a device intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity. The intranasal splint is constructed from plastic, silicone, or absorbent material and is placed in the nasal cavity after surgery or trauma; and

(3) The bone particle collector is a filtering device intended to be inserted into the suction tube line during the early stages of otologic surgery to collect bone particles for future use.

III. Recommendations of the Panel

In a public meeting held on October 25, 1990, the panel made classification recommendations for the nasal dilator, the intranasal splint, and the bone particle collector. The panel recommended that the devices be classified in class I (general controls). No recommendation was made to exempt these devices.

IV. Summary of the Reasons for the Recommendations

The panel concluded that the safety and effectiveness of the nasal dilator, intranasal splint, and bone particle collector can be reasonably assured by general controls. Specifically, the panel believed that the safety and effectiveness of the nasal dilator,

intranasal splint, and the bone particle collector can be reasonably assured by: (1) Registration and listing (section 510 of the act), and (2) the general requirements concerning reports (21 CFR 820.180), complaint files (21 CFR 820.198), and good manufacturing practices requirements (section 520(f) of the act (21 U.S.C. 360j(f)).

V. Risks to Health

The panel identified no specific risks associated with the use of the intranasal splint or the bone particle collector. The panel identified two potential risks to health associated with use of the nasal dilator: (1) The device could be lost inside a wide nose (internal dilator), and (2) the device can cause ulceration of skin or mucous membrane which could lead to infection. The panel further concluded that the risk of injury resulting from a dislodged dilator or from skin ulceration is low.

VI. Summary of the Data Upon Which the Proposed Recommendation Is Based

The panel based its recommendations on expert testimony presented to the panel and on the panel members' personal knowledge of and clinical experience with the nasal dilator, the intranasal splint, and the bone particle collector.

VII. FDA's Tentative Finding

FDA tentatively concurs with the recommendations of the panel that the nasal dilator, the intranasal splint, and the bone particle collector should be classified into class I (general controls) because the agency believes that sufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the devices. Consistent with the purpose of the act, class I (general controls) as defined by section 513(a)(1)(A) of the act would provide the least amount of regulation necessary to reasonably assure that current and future nasal dilators, intranasal splints, and bone particle collectors are safe and effective.

On November 21, 1997, the President signed FDAMA into law. Section 206 of FDAMA, in part, added a new section 510(l) to the act (21 U.S.C. 360(l)). Under section 501 of FDAMA, new section 510(l) became effective on February 19, 1998. New section 510(l) provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury (hereafter ''reserved criteria''). FDA has determined that these devices do not meet the reserved criteria and, therefore, they are exempt from the premarket notification requirements.

The agency, therefore, proposes to classify the nasal dilator, the intranasal splint, and the bone particle collector into class I, and to exempt them from the premarket notification requirements .

VIII. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Ear, Nose, and Throat Devices Panel, 35th meeting, transcript and meeting minutes, October 25–26, 1990.

IX. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by Subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so it is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. For these three devices, FDA is proposing that they be classified into class I, the lowest level of control allowed. In addition, FDA is proposing to exempt them from premarket notification requirements. These devices would be subject to a minimal level of control. The agency, therefore, certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

XI. Paperwork Reductions Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XII. Comments

Interested persons may, on or before August 10, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 874 be amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 874.3900 is added to subpart D to read as follows:

§ 874.3900 Nasal dilator.

(a) *Identification.* A nasal dilator is a device intended to provide temporary relief from breathing difficulties resulting from structural abnormalities in the nose. These devices decrease airway resistance and increase nasal airflow. The external nasal dilator is

constructed from layers of fabric material with a flat plastic string inserted between the layers, with a skin adhesive applied to adhere to the skin of the nose. The external dilator acts with a pulling action to open the nares. The internal nasal dilator is constructed from metal or plastic and is placed inside the nostrils. It acts by pushing the nostrils open or by gently pressing on the columella.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

3. Section 874.4780 is added to subpart E to read as follows:

§ 874.4780 Intranasal splint.

(a) *Identification.* An intranasal splint is a device intended to minimize bleeding and edema to prevent adhesions between the septum and the nasal cavity. The intranasal splint is constructed between the septum and the nasal cavity. The intranasal splint is constructed from plastic, silicone, or absorbent material and is placed in the nasal cavity after surgery or trauma.

(b) *Classification.* Class I (general controls). The device is exempted from the premarket notification procedures in subpart E of part 807 of this chapter.

4. Section 874.4800 is added to subpart E to read as follows:

§ 874.4800 Bone particle collector.

(a) *Identification.* A bone particle collector is a filtering device intended to be inserted into the suction tube during the early stages of otologic surgery to collect bone particles for future use.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

Dated: May 1, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–12312 Filed 5–8–98; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–209682–94]

RIN 1545–AS39

Adjustments Following Sales of Partnership Interests

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Postponement of hearing and requests to videoconference hearing.

SUMMARY: This document postpones the public hearing on proposed regulations relating to the optional adjustments to the basis of partnership property following certain transfers of partnership interests under section 743, the calculation of gain or loss under section 751(a) following the sale or exchange of a partnership interest, the allocation of basis adjustments among partnership assets under section 755, the allocation of a partner's basis in its partnership interest to properties distributed to the partner by the partnership under section 732(c), and the computation of a partner's proportionate share of the adjusted basis of depreciable property (or depreciable real property) under section 1017. In addition, this document announces that persons outside the Washington, DC area who wish to testify at the public hearing on the proposed regulations may request that the Service videoconference the public hearing to their sites.

DATES: Requests to videoconference the hearing to other sites must be received by Friday, May 29, 1998.

ADDRESSES: Requests must be sent to: CC:DOM:CORP:R (REG–209682–94), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Requests may also be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–209682–94), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW, Washington, DC. Alternatively, taxpayers may submit requests electronically via the internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting requests directly to the IRS internet site at http://www.irs.ustreas.gov/prod/tax__regs/comments.html.

FOR FURTHER INFORMATION CONTACT: LaNita VanDyke of the Regulations Unit, Assistant Chief Counsel (Corporate), (202) 622–7180 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and notice of public hearing appearing in the **Federal Register** on Thursday, January 29, 1998 (63 FR 4408), announced that a public hearing with respect to proposed regulations relating to adjustments to a partner's basis in its partnership interest and a partnership's basis in its assets would be held on Wednesday, July 8, 1998, beginning at 10 a.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington DC, and that requests to speak and outlines of oral comments should be received by Wednesday, June 24, 1998.

Subsequent to this announcement, the Service received a request that the hearing be videoconferenced. The Service recognizes that other persons outside the Washington, DC area may also wish to testify through videoconferencing. Those persons should now request to do so.

Requests to include other videoconferencing sites must be received by Friday, May 29, 1998. If the Service receives sufficient indications of interest to warrant videoconferencing to a particular city and if the Service has videoconferencing facilities in that city, the Service will accommodate the requests.

Accordingly, the public hearing originally scheduled for July 8, 1998, is postponed. The Service will issue a document in the **Federal Register** announcing the new date, time, and any videoconference sites of the public hearing.

Cynthia Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 98–12340 Filed 5–8–98; 8:45 am]

BILLING CODE 4830–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[LA–46–1–7384b; FRL–6008–9]

Approval and Promulgation of State Implementation Plans; Louisiana: Site-Specific Revision for the Exxon Company Baton Rouge Refinery

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this action, the EPA proposes to approve a site-specific revision to the Louisiana 15% Rate-of-Progress State Implementation plan. The revision extends the date of compliance for the installation of particular Volatile Organic Liquid storage tank controls for storage tanks located at the Baton Rouge Refinery of Exxon Company, U.S.A. Specifically, the revision extends the compliance date of the requirement for the installation of guide pole sliding cover gaskets on 33 storage tanks until the earlier of the next scheduled downtime of the subject tanks or December 2005.

In the Rules and Regulations Section of this **Federal Register**, the EPA is approving the State's SIP revision as a direct final rule without prior proposal