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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. 2005N-0346]

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Officer	A. Corbin

Ear, Nose, and Throat Devices; Tinnitus Masker; Designation of Special Controls

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the classification regulations of tinnitus masker devices in order to specify a special control for the device. The agency is taking this action on its own initiative. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft guidance document that the agency proposes to use as a special control for the device.

**DATES:** Submit written or electronic comments on the proposed rule by [*insert date 90 days after date of publication in the Federal Register*]. See section XI of this document for the proposed effective date of a final rule based on this document.

**ADDRESSES:** You may submit comments, identified by Docket No. 2005N-0346, by any of the following methods:

### *Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

### *Written Submissions*

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions):  
Division of Dockets Management (HFA-305), Food and Drug Administration,  
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

*Instructions:* All submissions received must include the agency name and docket number or regulatory information number for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document,

into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Teresa Cygnarowicz, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2980.

**SUPPLEMENTARY INFORMATION:**

**I. Statutory and Regulatory Authorities**

The act (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94-295), SMDA (Public Law 101-629), FDAMA (Public Law 105-115), and the Medical Device User Fee and Modernization Act (Public Law 107-250), 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, defined by 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, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as preamendments devices. FDA classifies these devices after it takes the following steps: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution before May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III until FDA does the following: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act; or (3) issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a legally marketed device that has been classified into class I or class II. The agency determines whether new devices are substantially equivalent to previously marketed 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.

Under the 1976 amendments, class II devices were defined as devices for which there was insufficient information to show that general controls themselves would provide reasonable assurance of safety and effectiveness, but for which there was sufficient information to establish performance standards to provide such assurance. SMDA broadened the definition of class II devices to mean those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

## **II. Regulatory History of the Devices**

In the **Federal Register** of March 31, 2000 (65 FR 17138), FDA issued a final rule reclassifying 28 preamendments devices from class III (premarket approval) into class II (special controls). FDA also identified a summary of FDA guidance special controls that the agency believes will reasonably ensure the safety and effectiveness of the devices. For the tinnitus masker device (TMD), FDA identified labeling as the special control.

## **III. Proposed Rule**

FDA is proposing to amend the reclassification regulation of TMDs in order to designate a special control for these devices. FDA has now developed a guidance document for the device and, under the SMDA provisions, is proposing to designate the special controls that, in addition to general controls, the agency believes will reasonably assure the safety and effectiveness of these devices. FDA is identifying the guidance document entitled "Class II Special Controls Guidance Document: Tinnitus Masker Devices" as the proposed special control.

Following the effective date of a final rule based on this proposed rule, any firm submitting a premarket notification (510(k)) for a new TMD will need to address the issues covered in the special control guidance. However, the firm needs only to show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

## **IV. Risks to Health**

FDA has identified the following risks to health associated with the device in the "Class II Special Controls Guidance Document: Tinnitus Masker Devices." The first column in table 1 of this document shows the identified risks.

TABLE 1.—RISKS TO HEALTH AND RECOMMENDED MITIGATION MEASURES

Risks to Health	Recommended Mitigation Measures
Side effects, including worsening tinnitus	Section 8. Clinical Testing Section 9. Labeling
Change in hearing	Section 7. Preclinical Testing Section 8. Clinical Testing Section 9. Labeling
Adverse tissue reaction	Section 7. Preclinical Testing
Electrical hazards	Section 7. Preclinical Testing
Tissue heating or cavitation (ultrasound TMDs only)	Section 7. Preclinical Testing
Improper use	Section 9. Labeling

## V. Special Controls

FDA believes that, in addition to general controls, the class II special controls guidance document entitled “Class II Special Controls Guidance Document: Tinnitus Masker Devices” are adequate controls to address the risks to health described in section IV of this document. The class II special controls guidance document provides information on how to control the risks to health of device side effects, including worsening tinnitus, change in hearing, adverse tissue reaction, electrical hazards, tissue heating or cavitation (ultrasound TMDs only), and improper use. The draft guidance document contains specific recommendations with regard to device performance testing and other information in a 510(k) submission. In table 1 of this document, FDA has identified the risks to health associated with the use of the device in the first column and the recommended mitigation measures identified in the class II special controls guidance document in the second column. These recommendations will also help ensure that the device has appropriate performance characteristics and labeling for its use.

Following the effective date of a final rule based on this proposed rule, any firm submitting a 510(k) for a TMD will need to address the issues covered in the special controls guidance. However, the firm need only show that its

device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

## **VI. Environmental Impact**

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

## **VII. 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), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 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. The purpose of this proposed rule is to designate a special control for these devices. FDA has designated guidance documents as the special controls. FDA believes that manufacturers, including small manufacturers, are already substantially in compliance with the recommendations in the guidance documents and they will not add substantially to the information

manufacturers presently submit. FDA, therefore, believes that the rule will impose no significant economic impact on any small entities. The agency, therefore certifies that this 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 or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

### **VIII. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

### **IX. Paperwork Reduction Act of 1995**

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the special controls guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the

availability of the draft guidance document entitled "Class II Special Controls Guidance Document: Tinnitus Masker Devices."

## **X. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposed rule. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any written comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## **XI. Proposed Implementation Plan**

FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**. Following the effective date of a final rule exempting the device, manufacturers of TMDs will need to address the issues covered in this special controls guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

### **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 874.1 is amended by revising paragraph (e) to read as follows:

**§ 874.1 Scope.**

\* \* \* \* \*

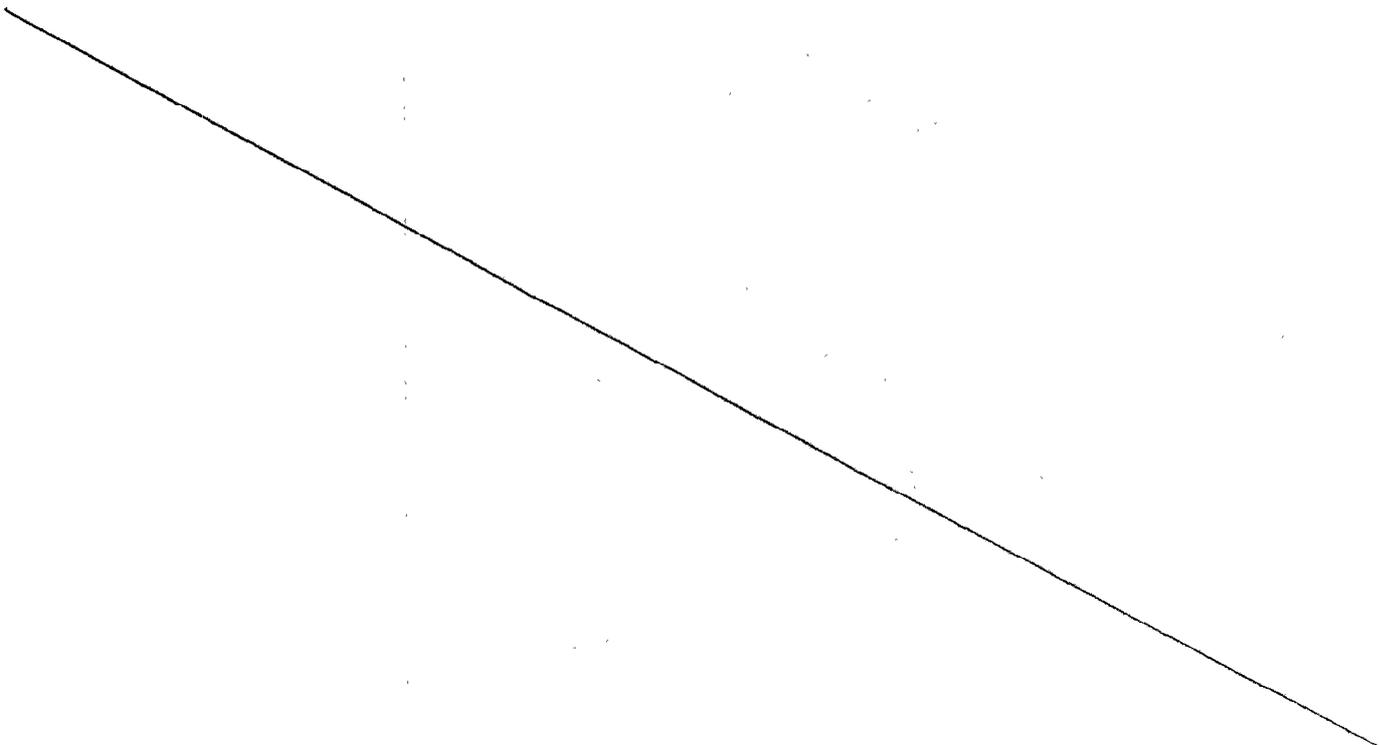
(e) Guidance documents in this part may be obtained on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

- 3. Section 874.3400 is amended by revising paragraph (b) to read as follows:

**§ 874.3400 Tinnitus masker.**

\* \* \* \* \*

(b) *Classification.* Class II (special controls). The special control for these devices is FDA’s “Class II Special Controls Guidance Document: Tinnitus Masker Devices.”



Dated: 10/7/05

October 7, 2005.

Linda S. Kahan

Linda S. Kahan, <sup>Director</sup>  
Deputy ~~Director~~  
Center for Devices and Radiological Health.  
[FR Doc. 05-???? Filed ??-??-05; 8:45 am]

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