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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 874**

[Docket No. 98P-0833]

**Medical Devices; Exemptions From Premarket Notification; Class II Devices**

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

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from the premarket notification requirements for audiometers with certain limitations. FDA is publishing this order in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:** Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

**SUPPLEMENTARY INFORMATION:**

**I. Statutory Background**

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Pub. L. 94-295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629)), devices are to be classified into class I (general controls) if there

is information showing that the general controls of the act are sufficient to ensure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is “substantially equivalent” within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list for each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication

of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that 1 day after date of publication of the list under section 510(m)(1) of the act, FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

## **II. Criteria for Exemption**

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled “Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.” That guidance can be obtained through the World Wide Web on the CDRH home page at “<http://www.fda.gov/cdrh>” or by facsimile through CDRH Facts-on-Demand at 1-800-899-0381 or 301-827-0111. Specify “159” when prompted for the document shelf number.

## **III. Petitions**

FDA has received a petition requesting an exemption from premarket notification for the audiometer (21 CFR 874.1050).

In the **Federal Register** of November 18, 1998 (63 FR 64091), FDA published a notice announcing that this petition had been received and providing an opportunity for interested persons to submit comments on the petition by December 18, 1998. FDA received one comment that

supported the proposal. FDA has reviewed the petition and has determined that this device meets the criteria for exemption described previously, provided that certain conditions are met. The petitioner stated that manufacturers of audiometers voluntarily comply with a consensus standard for audiometers, American National Standards Institute (ANSI), S3.6 (R1996)<sup>1</sup>. FDA believes that compliance with this standard obviates the need for premarket notifications and is, therefore, issuing this order exempting these devices from the requirements of premarket notification, provided that they are in compliance with this standard, and is codifying this order in the Code of Federal Regulations. Audiometers that do not comply with this standard are not exempt from the premarket notification requirements. FDA also notes that otoacoustic emissions test devices are not exempt from the the premarket notification requirements. Because the otoacoustic emissions test device is not a type of audiometer, it is not completely covered by the ANSI standard and, therefore, is not subject to the exemption.

#### **IV. Environmental Impact**

The agency has determined under 21 CFR 25.30(h) 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.

#### **V. Analysis of Impacts**

FDA has examined the impacts of the final 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

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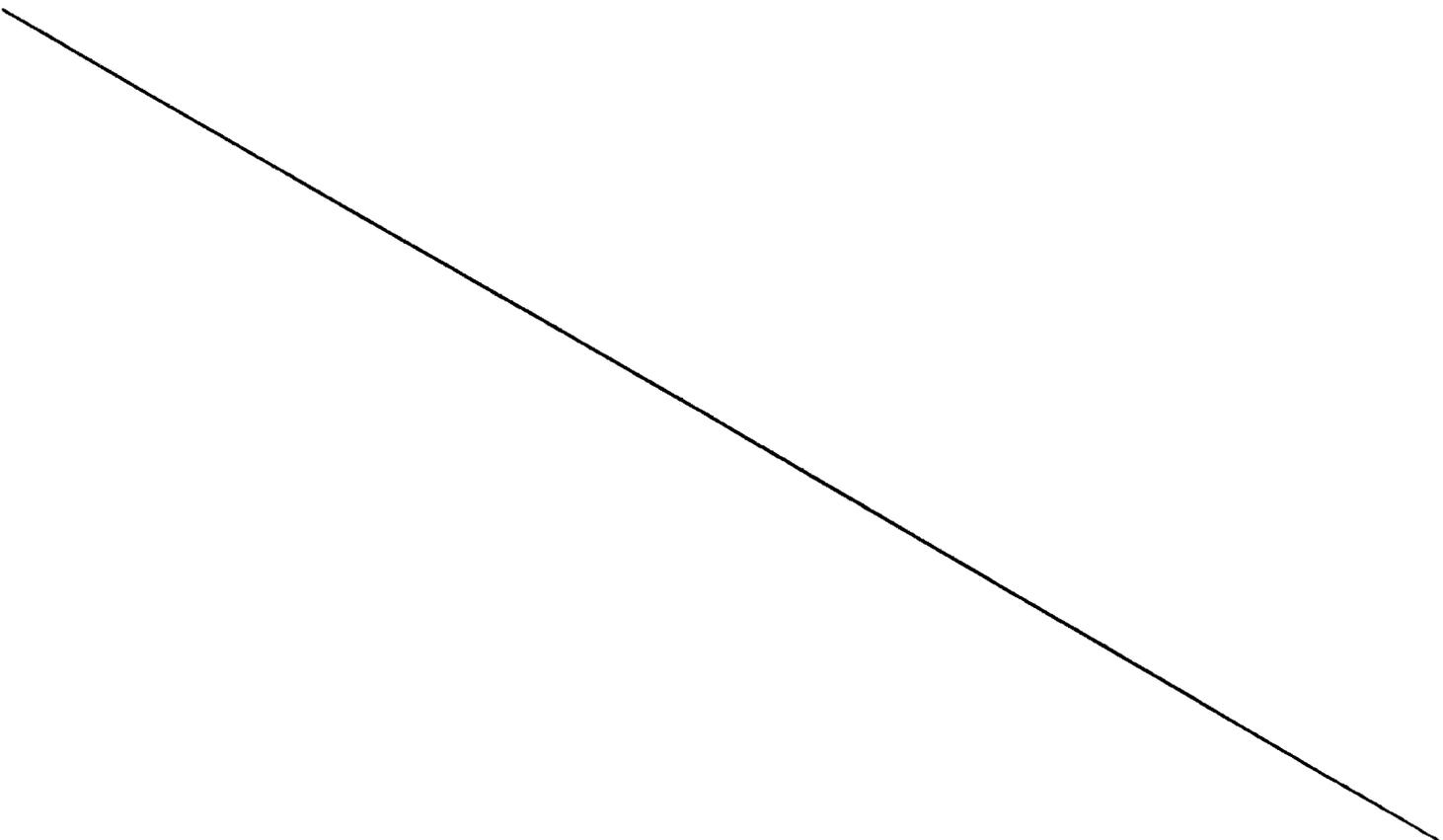
<sup>1</sup> The standard is available from the American National Standards Institute, Standards Secretariat, Acoustical Society of America, 120 Wall St., 32d Floor, New York, NY 10005–3993.

and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule will relieve a burden and simplify the marketing of these devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

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

FDA concludes that this final 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.



**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, 21 CFR part 874 is amended as follows:

**PART 874—EAR, NOSE, AND THROAT DEVICES**

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

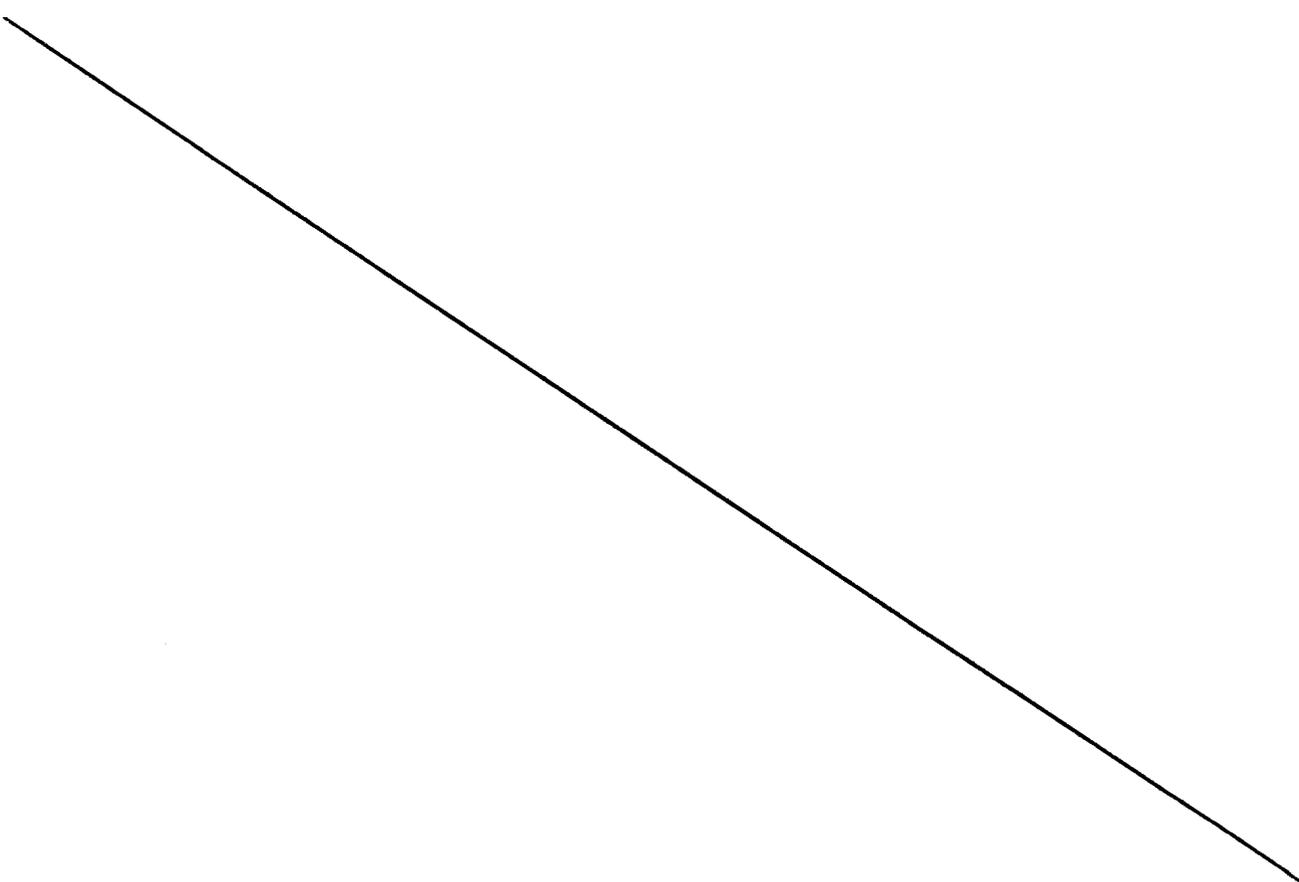
**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 874.1050 is amended by revising paragraph (b) to read as follows:

**§ 874.1050     Audiometer.**

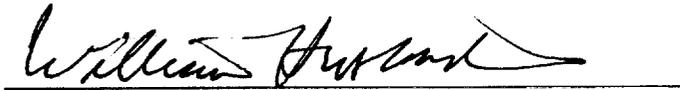
\*   \*   \*   \*   \*

(b) *Classification.* Class II. Except for the otoacoustic emission device, the device is exempt



from the premarket notification procedures in subpart E of part 807 of this chapter, if it is in compliance with American National Standard Institute S3.6-1996, "Specification for Audiometers," and subject to the limitations in § 874.9.

Dated: March 24, 1999



William K. Hubbard  
Acting Deputy Commissioner for Policy

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