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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

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A. Corbin

[Docket No. FDA-2008-N-0148]

Medical Devices; Hearing Aids; Technical Data Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing hearing aid labeling to reference the most recent version of the consensus standard used to determine the technical data to be included in labeling for hearing aids. We are proposing to amend the regulations to require manufacturers to use state-of-the-art methods to provide technical data in hearing aid labeling. FDA is also proposing to amend the regulations to update an address and remove an outdated requirement. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments by *[insert date 75 days after date of publication in the **Federal Register**]*. The Director of the Office of the **Federal Register** approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 801.420(c)(4) (21 CFR 801.420(c)(4)) as of *[insert date 135 days after date of publication in the **Federal Register**]*.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2008-N-0148, by any of the following methods:

Ch0734 FDA.2008.N.0148

NPR

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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 previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, 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.regulations.gov> and insert the docket number(s), 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: Eric A. Mann, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4242.

SUPPLEMENTARY INFORMATION:

I. Why Is This Proposed Rule Being Issued as a Companion Proposed Rule?

This proposed rule is a companion to the direct final rule that is published in the final rules section of this issue of the **Federal Register**. The direct final rule amends the regulations governing hearing aid labeling to reference the most recent version of the consensus standard used to determine the technical data to be included in labeling for hearing aids. We are amending this rule to require manufacturers to use state-of-the-art methods to provide technical data in hearing aid labeling. FDA also is amending the rule to update an address and eliminate an outdated provision. The direct final rule and this companion proposed rule are identical. We are publishing the direct final rule because we believe the rule contains noncontroversial changes and we anticipate that it will receive no significant adverse comment. A detailed discussion of the rule is set forth in the preamble of the direct final rule. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, we will publish a confirmation document within 30 days after the comment period ends confirming when the direct final rule will go into effect.

You can find additional information about FDA's direct final rulemaking procedures in the guidance document entitled "Guidance for FDA and Industry: Direct Final Rule Procedures" (62 FR 62466, November 21, 1997). This guidance document may be accessed at <http://www.fda.gov/opacom/morechoices/industry/guidance.htm>.

If we receive any significant adverse comment regarding the direct final rule, we will withdraw the direct final rule within 30 days after the comment period ends and proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment rulemaking procedures under the Administrative Procedure Act (APA) (5 U.S.C. 552a *et seq.*). The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the APA (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

II. What Is the Background of the Rulemaking?

In the **Federal Register** of February 15, 1977 (the 1977 final rule) (42 FR 9286), FDA published a final rule establishing requirements for professional and patient labeling of hearing aids and governing conditions for sale of hearing aids (§ 801.420 and § 801.421 (21 CFR 801.421)). The regulations became effective on August 15, 1977. Section 801.421(b)(1) of the current regulations provides that, before the sale of a hearing aid to a prospective user, a hearing aid dispenser is to provide the prospective user with a copy of the User Instructional Brochure. Current § 801.420(c)(4) requires that technical data useful in selecting, fitting, and checking the performance of a hearing aid be provided in the brochure or in separate labeling that accompanies the device. The 1977 final rule further required that the technical data values provided in the brochure or other labeling be determined according to the test procedures established by the Acoustical Society of America (ASA) in the American National Standard “Specification of Hearing Aid Characteristics,” ANSI S3.22–1976 (ASA 70–1976), which was incorporated by reference in the regulation.

ANSI S3.22 (ASA 70–1976) established measurement methods and specifications for several important hearing aid characteristics. The standard provided a method of ascertaining whether a hearing aid, after being manufactured and shipped, met the specifications and design parameters stated by the manufacturer for a particular model, within the tolerance stated by the standard.

In 1982, ASA revised the standard (ANSI S3.22–1982) (ASA 70–1982). In a final rule published in the **Federal Register** of July 24, 1985 (50 FR 30153), FDA incorporated the revised standard into § 801.420(c)(4). ASA revised the

standard again in 1987 (ANSI S3.22–1987) (ASA 70–1987). In a final rule published in the **Federal Register** of December 21, 1989 (54 FR 52395), FDA incorporated the revised standard into § 801.420(c)(4). In 1996, ASA revised the standard again (ANSI S3.22–1996) (ASA 70–1996). In a final rule published in the **Federal Register** of November 3, 1999 (64 FR 59618), FDA incorporated the revised standard into § 801.420(c)(4).

In 2003, ASA revised the standard again (ANSI S3.22–2003). The 1996 version of the standard was written prior to the development of digital hearing aids. Therefore, some of the test procedures described in the 1996 version of the standard, designed for assessment of analogue hearing aids, were modified to accommodate digital technology. The major differences between the two versions of the standard are as follows:

- In the 1996 standard, the gain control was set to a specific reference test position for automatic gain control (AGC) hearing aids and for all other types of hearing aids. In the 2003 standard, AGC hearing aids are tested in AGC mode only for those tests associated with AGC functions and are operated in non-AGC mode for all other tests.

- In the 2003 standard, the tolerance for setting the gain control to reference test setting (RTS) has been widened to ± 1.5 dB from ± 1.0 dB.

FDA is now incorporating the 2003 standard into § 801.420(c)(4).

III. What Does This Companion Proposed Rule Do?

In this rule, FDA is proposing to:

- Amend § 801.420(c)(4) to change the identification of the standard from “American National Standard ‘Specification of Hearing Aid Characteristics,’ ANSI S3.22–1996 (ASA 70–1996) (Revision of ANSI S3.22–1987)” to “American National Standard ‘Specification of Hearing Aid Characteristics,’ ANSI S3.22–2003 (Revision of ANSI S3.22–1996)”. FDA is also proposing to

update an address in this section, changing “1350 Piccard Dr., rm. 240,” to “1350 Piccard Dr., rm. 150,”.

- Remove § 801.420(d). This section requires that manufacturers submit to FDA for review their User Instructional Brochure and other labeling for each type of hearing aid on or before August 15, 1977. This section was included with the initial hearing aid rule in 1977. It was intended to provide for an initial FDA review of the labeling to meet the new requirements. This section is outdated and is no longer necessary.

IV. What is the Legal Authority for This Proposed Rule?

This proposed rule is authorized by sections 201, 301, 501, 502, 701, and 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 371, and 374).

V. What is the Environmental Impact of This Proposed Rule?

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

VI. What is the Economic Impact of This Proposed Rule?

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 not a significant regulatory action as defined by 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 proposed rule would amend the existing hearing aid regulation to refer to the updated consensus standard that is used to determine the technical data in hearing aid labeling. It does not impose any new requirements. Communications from manufacturers to FDA show that they are prepared to comply with this standard immediately. The agency, therefore, certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. How Does the Paperwork Reduction Act of 1995 Apply to This Proposed Rule?

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the companion direct final rule have been approved by OMB in accordance with the PRA under the regulations

governing labeling of medical devices (21 CFR part 801, OMB control number 0910-0485).

VIII. What Are the Federalism Impacts of This Proposed Rule?

FDA has analyzed this proposed 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. How Do You Submit Comments on This Proposed Rule?

Interested persons may submit to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, written or electronic comments on this recommendation. Submit electronic comments to *<http://www.regulations.gov>*. Two copies of any written comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the name of the device and 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *<http://www.regulations.gov>*.

List of Subjects in 21 CFR Part 801

Incorporation by reference, Labeling, Medical devices, Reporting and recordkeeping requirements.

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 801 be amended as follows:

PART 801—LABELING

*ing
5-28-08
per CFR
Knee Books*

- 1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

- 2. Section 801.420 is amended by revising the second and third sentences of paragraph (c)(4) and by removing paragraph (d) to read as follows:

and adding a new 4th sentence in the introductory

§ 801.420 Hearing aid devices; professional and patient labeling.

* * * * *

(c) * * *

(4) * * * The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard "Specification of Hearing Aid Characteristics," ANSI S3.22-2003 (Revision of ANSI S3.22-1996) (Includes April 2007 Erratum). The Director of the Office of the **Federal Register** approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005-3993, or are available for inspection at the Regulations Staff, CDRH (HFZ-215), FDA, 1350 Piccard

Dr., rm. 150, Rockville, MD 20850, or at the National Archives and Records
Administration (NARA). * * *

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Dated: 5/19/08

May 19, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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