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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 99N-2550]

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. FDA is proposing to amend the regulation in order that manufacturers may use state-of-the-art methods to address technical data in hearing aid labeling. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on or before (*insert date 75 days after date of publication in the Federal Register*). If FDA receives any significant adverse comment regarding this rule, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA then and will proceed to respond to the comments under this proposed rule using the usual notice and comment procedures. Any parties interested in commenting on this document should do so at this time.

If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on the direct final rule ends. The direct final rule will be effective (*insert date 135 days after date of publication in the Federal Register*).

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ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: David A. Segerson, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850 301-594-2080.

SUPPLEMENTARY INFORMATION:

I. Regulatory Framework

This proposed rule is a companion to the direct final rule published in the final rules section of this issue of the **Federal Register**. This companion proposed rule is substantively identical to the direct final rule. This proposed rule will provide a procedural framework to finalize the rule in the event the agency receives a significant adverse comment and the direct final rule is withdrawn. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comments. A detailed discussion of this rule is set forth in the preamble of the direct final rule. If no significant comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation document within 30 days after the comment period ends confirming that the direct final rule will go into effect on (*insert date 135 days after date of publication in the Federal Register*). Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If FDA receives a significant adverse comment regarding this rule, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends and will proceed to respond to the comments under this rule using usual notice-and-comment procedures. 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 a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment requesting a change in provisions of the hearing aid rule unrelated to the subject matter addressed in the American National Standards Institute's (ANSI) standard will not be considered a significant adverse comment, because it is outside the scope of the rule. On the other hand, a comment recommending an additional change to the rule may be considered a significant adverse comment if the comment demonstrates why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to an amendment, paragraph, or section of this rule and that provision can be severed from the remainder of the rule, FDA may adopt as final those provisions of the rule that are not the subject of a significant adverse comment.

II. Background

In the **Federal Register** of February 15, 1977 (42 FR 9286), FDA published final regulations establishing requirements for professional and patient labeling of hearing aids (§ 801.420 (21 CFR 801.420)) and governing conditions for sale of hearing aids (§ 801.421 (21 CFR 801.421)). The regulations became effective on August 15, 1977. Section 801.421(b)(1) of the 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. Section 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 regulation 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 definitive hearing aid characteristics, and 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 newly revised standard into § 801.420(c)(4).

In 1996, ASA revised the standard again (ANSI S3.22–1996) (ASA 70–1996). The standard describes air-conduction hearing aid measurement methods that are particularly suitable for specification and tolerance purposes. Among the test methods described are output sound pressure level (SPL with a 90-dB input SPL, full-on gain, frequency response, harmonic distortion, equivalent input noise, current drain, induction-coil sensitivity, and static and dynamic characteristics of automatic gain control hearing aids) the standard gives specific configurations for measuring the input SPL to a hearing aid. The standard also describes allowable tolerances in relation to values specified by the manufacturer for certain parameters. Appendices are provided to describe an equivalent substitution method, characteristics of battery simulators, and additional tests to characterize the electroacoustic performance of hearing aids more completely.

FDA is now incorporating the 1996 standard into § 801.420(c)(4). This will allow hearing aid manufacturers to use the up-to-date methods to determine the technical data values for hearing aids. In addition, FDA is removing from § 801.420(c)(4) the address for “American National Standards Institute” and is adding in its place the address for “Acoustical Society of America.”

III. Environmental Impact

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.

IV. Analysis of Impacts

FDA has examined the impact of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), 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, this 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 proposed rule amends the existing hearing aid regulation to refer to the updated consensus standard that is used to determine the technical data in hearing aid labeling. Communications from manufacturers to FDA show that they are prepared to be in compliance with this standard immediately. The agency, therefore, certifies that this proposed rule, if finalized, will not have a significant economic impact on a substantial number of small entities. This proposed rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of \$100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year.

V. Paperwork Reduction Act of 1995

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

VI. Request for Comments

Interested persons may, on or before (*insert date 75 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this companion proposed rule. The comment period runs concurrently with the comment period for the direct final rule. 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 the brackets in the heading of this document. Comments will be considered to determine whether to amend or revoke this proposed rule. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered as comments regarding the direct final rule and this proposed rule. In the event the direct final rule is withdrawn, all comments received regarding the direct final rule and this companion proposed rule will be considered comments on this proposed rule.

List of Subjects in 21 CFR Part 801

Hearing aids, Incorporation by reference, Medical devices, Professional and patient labeling.

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

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.

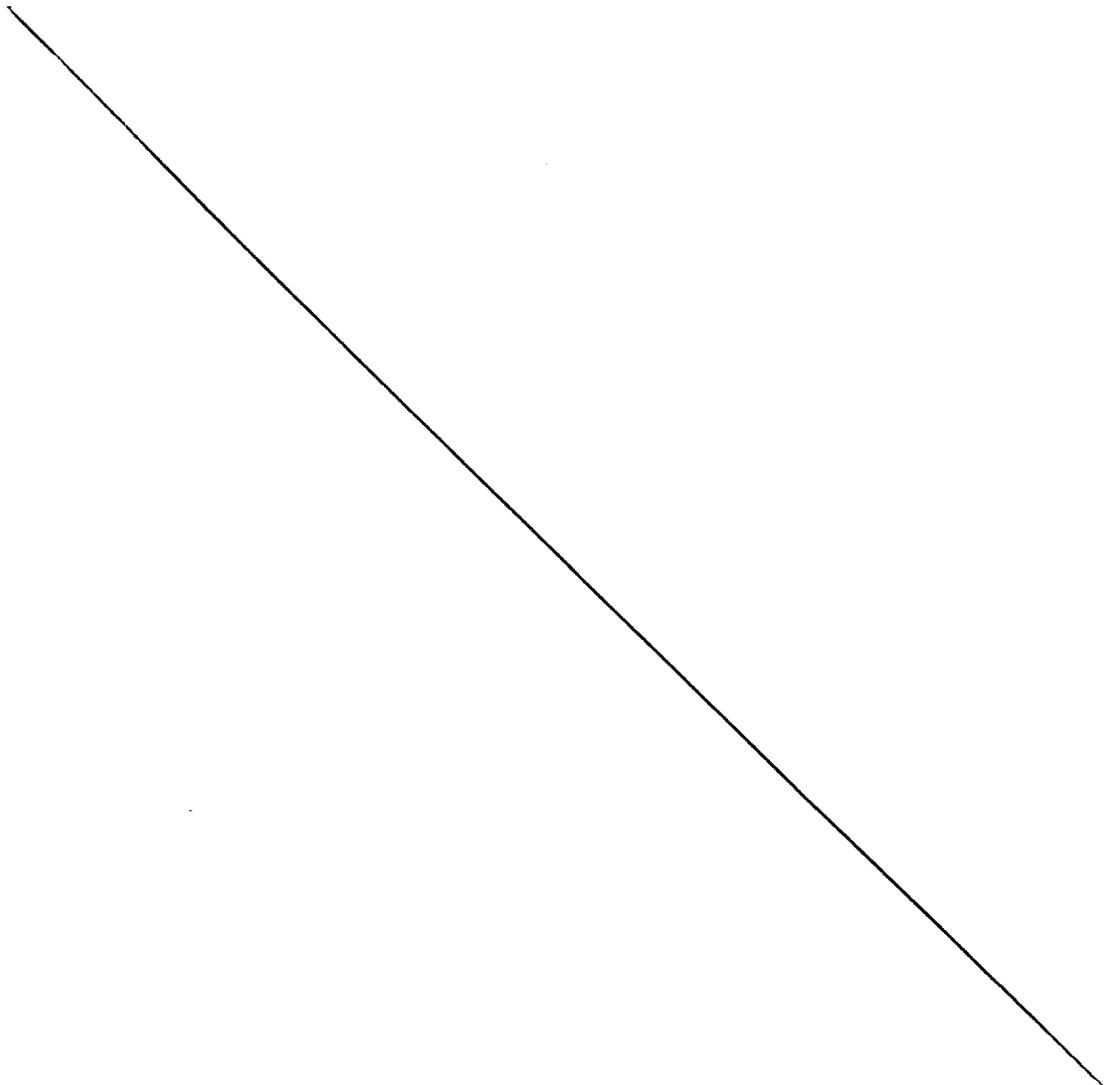
2. Section 801.420 is amended by revising the second and third sentences in paragraph (c)(4) to read as follows:

§ 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 S3.22–1996 (ASA 70–1996) (Revision of ANSI S3.22–1987), which is incorporated 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. 240, Rockville, MD 20850, and at the Office of the Federal Register, 800
North Capitol St. NW., suite 700, Washington, DC. * * *

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Dated: 10/19/99
October 19, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



Margaret M. Dotzel
Acting Associate Commissioner for Policy



[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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