

which, if any, of these documents are relevant to its needs.

(d) Identify appropriate private sector conformity assessment practices and programs and consider using the results of such practices and/or programs as appropriate in existing regulatory and procurement actions. Responsibility for the determination of appropriateness rests with each agency. Example: An agency could use the results of private sector or other governmental conformity assessment activities to schedule procurement type audits more effectively. This could allow agencies to reduce the number and extent of audits conducted at companies which are performing in accordance with contract specifications and which are under review by a third party or another agency and to concentrate agency audit efforts on companies which have shown problems in conforming to contract specifications.

(e) Consider mutual recognition of the results of other agencies' conformity assessment procedures. Example: An agency could use the results of another agency's inspection/audit of a supplier to eliminate or reduce the scope of its own inspection/audit of that supplier.

(f) Participate in efforts designed to improve coordination among governmental and private sector conformity assessment activities. These efforts include, but are not limited to, the National Cooperation for Laboratory Accreditation (NACLA) organization, the National Environmental Laboratory Accreditation Conference (NELAC), and ICSP working groups dealing with conformity assessment issues.

(g) Work with other agencies to avoid unnecessary duplication and complexity in federal conformity assessment activities. Examples: An agency can participate in another agency's conformity assessment activities by conducting joint procurement audits/inspections of suppliers that sell to both agencies. An agency can share conformity assessment information with other agencies. An agency can use conformity assessment information provided by other agencies to the extent appropriate to improve the effectiveness and efficiency in its own conformity assessment activities. Conformity assessment information may include: conformity assessment procedures and results, technical data on the operation of conformity assessment programs, processing methods and requirements for applications, fees, facility site data, complaint review procedures, and confidentiality procedures.

(h) Encourage domestic and international recognition of U.S.

conformity assessment results by supporting the work of the U.S. Government in international trade and related negotiations with foreign countries and U.S. industry in pursuing agreements with foreign national and international private sector organizations and any resulting activities/requirements resulting from those negotiations/agreements.

(i) Participate in the development of private sector conformity assessment standards to ensure that Federal viewpoints are represented.

(j) Work with other agencies to harmonize Federal requirements for quality and environmental management systems for use in procurement and regulation, including provisions which will allow the use of one quality or environmental management system per supplier facility in the Federal procurement process and the sharing and usage of audit results and related information as appropriate.

(k) Work with other ICSP members, NIST, and the private sector to develop national infrastructures for coordinating and harmonizing U.S. conformity assessment needs, practices and requirements in support of the efforts of the U.S. Government and U.S. industry to increase international market access for U.S. products.

(l) Work with other ICSP members, NIST, and the private sector as necessary and appropriate to establish criteria for the development and implementation of governmental recognition systems to meet government recognition requirements imposed by other nations and regional groups to support the efforts of the U.S. Government to facilitate international market access for U.S. products.

(m) Assign an Agency Standard Executive responsibility for coordinating the agency-wide implementation of the guidance in this part.

#### **§ 287.5 Responsibilities of an Agency Standards Executive.**

In addition to carrying out the duties described in OMB Circular A-119 related to standards activities, an Agency Standards Executive should:

(a) Promote the following goals:

(1) Effective use of agency conformity assessment related resources and participation in conformity assessment related activities of agency interest.

(2) Development and dissemination of agency technical and policy positions.

(3) Development of agency positions on conformity assessment related issues that are in the public interest.

(b) Ensure that agency participation in conformity assessment related activities

is consistent with agency missions, authorities, priorities, and budget.

(c) Cooperate with NIST in carrying out agency responsibilities under the guidance in this part.

(d) Consult with NIST, as necessary, in the development and issuance of internal agency procedures and guidance implementing the policies in this part.

(e) Establish an ongoing process for reviewing his/her agency's existing conformity assessment activities and identifying areas where efficiencies can be achieved through coordination with other agency and private sector conformity assessment activities.

(f) Work with other parts of his/her agency to develop and implement improvements in agency conformity assessment related activities.

(g) Report to NIST, on a voluntary basis, on agency conformity assessment activities for inclusion in the annual report to the Office of Management and Budget (OMB) on the agency's implementation of OMB Circular A-119.

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## **COMMODITY FUTURES TRADING COMMISSION**

### **17 CFR Part 1**

#### **Use of Electronic Signatures by Customers, Participants and Clients of Registrants**

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Reopening of comment period.

**SUMMARY:** On August 30, 1999, the Commodity Futures Trading Commission (the "Commission" or "CFTC") published in the **Federal Register** a request for public comment on proposed regulations to allow the use of electronic signatures in lieu of handwritten signatures for certain purposes under the commission's regulations. The original comment period expires October 29, 1999. 64 FR 47151 (August 30, 1999). By letter dated October 27, 1999, the Futures Industry Association Inc. requested an extension of the comment period. In order to insure that an adequate opportunity is provided for submission of meaningful comments, the Commission has determined to reopen the comment period for an additional two weeks for all interested parties.

**DATES:** Written comments must be received on or before November 12, 1999.

**ADDRESSES:** Comments on the proposed rule should be sent to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Center, 1155 21st Street, NW., Washington, DC 20581. Comments may be sent by facsimile transmission to (202) 418-5521, or by e-mail to [secretary@cftc.gov](mailto:secretary@cftc.gov). Reference should be made to "Internet Account Opening Process."

**FOR FURTHER INFORMATION CONTACT:** Lawrence B. Patent, Associate Chief Counsel, or Christopher W. Cummings, Special Counsel, Division of Trading and Markets, Commodity Futures Trading Commission, 1155 21st Street, NW., Washington, DC 20581. Telephone Number: (202) 418-5450. Facsimile Number: (202) 418-5547. Electronic Mail: [tm@cftc.gov](mailto:tm@cftc.gov).

Issued In Washington, DC on October 27, 1999, by the Commission.

**Jean A. Webb,**

*Secretary of the Commission.*

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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 January 18, 2000. 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 March 17, 2000.

**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 March 17, 2000. 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