the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.246 [Amended]

■ 2. In paragraph (b)(3) of § 522.246, remove ''057926 and 059130'' and in its place add ''057926, 059130, and 061690''.

Dated: May 21, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–12160 Filed 5–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. FDA–2008–N–0148]

Medical Devices; Hearing Aids; Technical Data Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending 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 amending the regulations to require that manufacturers may use state-of-the-art methods to provide technical data in hearing aid labeling. FDA is also amending the regulations to update an address and remove an outdated requirement. FDA is amending the regulations in accordance with its direct final rule procedures. Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule under FDA's usual procedures for notice and comment rulemaking to provide a procedural framework to finalize the rule in the event we receive a significant adverse comment and withdraw this direct final rule.

DATES: This rule is effective October 15, 2008. 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 October 15, 2008. Submit written or electronic comments by August 18, 2008. If we receive no significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

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

Electronic Submissions

Submit electronic comments in the following way:

<bullet≤ Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

<bullet≤ FAX: 301–827–6870.

<bullet≤ 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. 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:

<bullet≤ 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.

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

FDA is now incorporating the 2003 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.

II. What Does This Direct Final Rulemaking Do?

In this direct final rule, FDA is:

<bullet≤ Amending § 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) (Includes April 2007 Erratum)''. FDA also is updating an address in this section, changing ''1350 Piccard Dr., rm. 240,'' to ''1350 Piccard Dr., rm. 150,''.

<bullet≤ Removing § 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.

III. What Are the Procedures for Issuing a Direct Final Rule?

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA announced the availability of the guidance document entitled ''Guidance for FDA and Industry: Direct Final Rule Procedures'' that described when and how FDA will employ direct final rulemaking. We believe that this rule is appropriate for direct final rulemaking because it is intended to make noncontroversial changes to existing regulations. We anticipate no significant adverse comment.

Consistent with FDA's procedures on direct final rulemaking, elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule that is identical to this direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as comments regarding this direct final rule.

If we receive any significant adverse comment, we intend to withdraw this final rule before its effective date by publication of a notice in the **Federal Register** within 30 days after the comment period ends. 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 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 Administrative Procedure Act (APA) (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or 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.

If we withdraw the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule under the usual notice-and-comment procedures under the APA (5 U.S.C. 552a *et seq.*). If we receive no significant adverse comment during the specified comment period, we intend to publish a confirmation document in the **Federal Register** within 30 days after the comment period ends.

IV. What is the Legal Authority for This Direct Final Rule?

This direct final 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 Direct Final 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 Direct Final Rule?

FDA has examined the impacts of the final 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 direct final 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 direct final 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. 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 direct final 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 direct final 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 Direct Final Rule?

This final 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 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 Direct Final Rule?

FDA has analyzed this direct 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. How Do You Submit Comments on This Direct Final Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this direct final rule. Submit a single copy of electronic comments or two paper copies of any mailed 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.

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 through FDMS only.

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, 21 CFR part 801 is 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 of and adding a new fourth sentence to paragraph (c)(4) introductory text and by removing paragraph (d) 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 S3.22–2003 (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: May 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–11910 Filed 5–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2008–0414]

RIN 1625–AA08

Special Local Regulations for Marine Events; Pasquotank River, Elizabeth City, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing special local regulations for the ''Carolina Cup Regatta'', a powerboat race to be held on the waters of the Pasquotank River, Elizabeth City, North Carolina. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of the Pasquotank River adjacent to Elizabeth City, North Carolina during the powerboat races.

DATES: This rule is effective from 7:30 a.m. on June 6, through 6:30 p.m., June 8, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0414 and are available online at *http://www.regulations.gov.* They are also available for inspection or copying at two locations: the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and the Fifth Coast Guard District, Office of Prevention, Room 416, 431 Crawford Street, Portsmouth, VA 23704 between 10 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Dennis Sens, Project Manager, Fifth Coast Guard District, Prevention Division, (757) 398–6204 or e-mail at *Dennis.M.Sens@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act