

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 801

[Docket No. 99N-4955]

Amendment of Various Device Regulations to Reflect Current American Society for Testing and Material Citations

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending certain references in various medical device regulations. The amendments update the references in those regulations to various standards of the American Society for Testing and Materials (ASTM) to reflect the current standards designations. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedures for notice-and-comment, to provide a procedural framework to finalize the rule in the event that the agency receives any significant adverse comment and withdraws the direct final rule.

DATES: This rule is effective [*insert date 135 days after date of publication in the Federal Register*]. Submit written comments on or before [*insert date 75 days after date of publication in the Federal Register*]. If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish in the **Federal Register** a document confirming the effective date of the direct final rule within 30 days after the comment period on this direct final rule ends. If the agency receives any adverse comments, FDA intends to withdraw this final rule by publication in the **Federal Register** of a document within 30 days after the comment period ends. The Director of the Office of the Federal Register approves the incorporation by
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reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in § 801.410(d)(2) (21 CFR 801.410(d)(2)) and § 801.430(f)(2) (21 CFR 801.430(f)(2), effective *[insert date 135 days after date of publication in the Federal Register]*).

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: Philip L. Chao, Office of Policy, Planning, and Legislation (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3380.

SUPPLEMENTARY INFORMATION:

I. Background

The ASTM notified FDA that ASTM had been working on a project to help Federal agencies update and maintain the ASTM standards that are referenced in the Code of Federal Regulations (CFR's). Use of consensus standards such as those developed by ASTM is consistent with the purposes of the National Technology Transfer and Advancement Act of 1995, signed into law on March 7, 1996 (Public Law 104-113). As part of the ASTM project, ASTM informed FDA that many ASTM standards cited in FDA's food additive and device regulations were out-of-date and provided a list of standards with their current year designations. ASTM listed 58 different regulations which, in its opinion, needed to be updated.

FDA examined the ASTM's documentation and, upon closer examination, found that 56 of the 58 different FDA regulations identified by ASTM cited obsolete ASTM standards or that, in some cases, cited ASTM standards that had been withdrawn. Most regulations involved direct and indirect food additives, although two of the affected regulations involved medical devices. Consequently, through this rulemaking, FDA is revising the device regulations identified by ASTM that contain obsolete or withdrawn ASTM standards to reflect the current ASTM standards designations. FDA will update the citations for the food additive regulations in a separate rulemaking.

This direct final rule amends §§ 801.410(d)(2) and 801.430(f)(2) by incorporating by reference into the regulation the updated standard as follows:

- Section 801.410 *Use of impact-resistant lenses in eyeglasses and sunglasses*—The agency is amending paragraph (d)(2) by removing “ASTM Method D 1415–68 ‘Test for International Hardness of Vulcanized Rubber,’” and by adding in its place “ASTM Method D 1415–88, Standard Test Method for Rubber Property—International Hardness,” and also by removing “ASTM Method D 412–68 ‘Tension Test of Vulcanized Rubber,’” and by adding in its place “ASTM Method D 412–97, Standard Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension,”.

- Section 801.430 *User labeling for menstrual tampons*—The agency is amending paragraph (f)(2) by removing “(ASTM), D 3492–83, ‘Standard Specification for Rubber Contraceptives (Condoms)’” and by adding in its place “(ASTM) D 3492–96, Standard Specification for Rubber Contraceptives (Male Condoms)”.

In addition, FDA is updating in § 801.410(d)(2) the address for the American Society for Testing Materials.

II. Additional Information

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA described when and how it will employ direct final rulemaking. FDA believes this rule is appropriate for direct final rulemaking because FDA views this rule as making noncontroversial amendments to existing regulations, i.e., adopting revised ASTM methods for certain medical device regulations, and FDA anticipates no significant adverse comments. Consistent with FDA’s procedures on direct final rulemaking, elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule to amend the relevant medical device regulations. The companion proposed rule is substantially identical to the 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 comments. The comment period for the direct final rule runs

concurrently with the comment period of the companion proposed rule. Any comments received under the companion proposed rule will be considered as comments regarding the direct final rule.

FDA is providing a comment period on the direct final rule of 75 days after [insert date of publication in the Federal Register]. If the agency receives any significant adverse comments, FDA intends to withdraw this final rule by publication in the **Federal Register** of a document 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 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 significant or adverse under this procedure.

In addition, if a significant adverse comment applies to ~~part of the rule, and the part can be severed~~ ^{an amendment, paragraph, or section of this rule and that} from the remainder of the rule, FDA may adopt as final those ~~parts~~ ^{provisions} of the rule that are not the subject of a significant adverse comment. ^{provision}

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If FDA withdraws 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 Administrative Procedure Act (5 U.S.C. 552 *et seq.*). If FDA receives no significant adverse comments during the specified comment period, FDA intends to publish a confirmation notice in the **Federal Register** within 30 days after the comment period ends. FDA intends to make the direct final rule effective ~~30 days after the date the confirmation notice is published~~ ^[insert date 135 days after date of publication] in the **Federal Register**.

III. Environmental Impact

The agency has determined, under 21 CFR 25.30(i) 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 impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. The revised ASTM standard citations that FDA is adopting in the medical device regulations reflect minor changes to the currently listed methods in those regulations. The updated citations are the result of periodic reapprovals of long-standing test methods or standards and should have no significant adverse impact on those who use the standard. Thus, the rule is not a significant regulatory action as defined in Executive Order 12866, and so is not subject to review under the Executive Order.

Under section 603(a) of the Regulatory Flexibility Act (RFA), for any proposed rule for which the agency is required by section 553 of the Administrative Procedure Act or any other law to publish a general notice of proposed rulemaking, the agency is required to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. The agency has published, in the companion proposed rule published elsewhere in this **Federal Register**, an initial regulatory flexibility analysis. Because the companion proposed rule is a proposed rule for which a general notice of proposed rulemaking is required, and therefore is subject to the RFA, the agency will consider any comments it receives on the initial regulatory flexibility analysis in the companion proposed rule when deciding whether to withdraw this direct final rule.

V. Paperwork Reduction Act of 1995

This direct 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.

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 final rule. The comment period runs concurrently with the comment period for the companion proposed 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 brackets in the heading of this document. 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 proposed rule and this direct final rule. In the event that the direct final rule is withdrawn, all comments received regarding the companion proposed rule and the direct final rule will be considered as comments on the 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, 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.

§ 801.410 [Amended]

2. Section 801.410 *Use of impact-resistant lenses in eyeglasses and sunglasses* is amended in paragraph (d)(2) by removing “ASTM Method D 1415–68 ‘Test for International Hardness of Vulcanized Rubber,’” and by adding in its place “ASTM Method D 1415–88, Standard Test

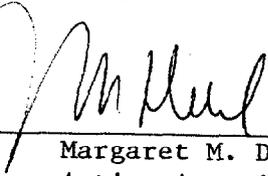
Method for Rubber Property—International Hardness,”; by removing “ASTM Method D 412–68 ‘Tension Test of Vulcanized Rubber,’” and by adding in its place “ASTM Method D 412–97, Standard Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension,”; and by removing “1916 Race St., Philadelphia, PA 19103, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.” and by adding in its place “100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428, or available for inspection at the Center for Devices and Radiological Health’s Library, 9200 Corporate Blvd., Rockville, MD 10850, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.”

§ 801.430 [Amended]

3. Section 801.430 *User labeling for menstrual tampons* is amended in paragraph (f)(2) by removing “(ASTM), D 3492–83, ‘Standard Specification for Rubber Contraceptives (Condoms)’¹” and by adding in its place “(ASTM) D 3492–96, ‘Standard Specification for Rubber Contraceptives (Male Condoms)’¹”; and by revising the footnote to read “Copies of the standard are available from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, PA

19428, or available for inspection at the Center for Devices and Radiological Health's Library, 9200 Corporate Blvd., Rockville, MD 10850, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC."

Dated: 12/29/99
December 29, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

LDC [FR Doc. ⁰⁰99-???? Filed ??-??-⁰⁰99; 8:45 am]

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