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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 Materials Citations; Companion Document to Direct Final Rule**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend certain references in various medical device regulations. The amendments would update the references in those regulations to various standards of the American Society for Testing and Materials (ASTM) to reflect the current standards designations. 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 by [*insert date 75 days after date of publication in the Federal Register*]. If FDA receives no significant adverse comment on these various medical devices regulations within the specified comment period, the agency intends to publish in the **Federal Register** a document confirming the effective date of the final rule 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*]. 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 and will proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule comment period.

**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 proposing to revise 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 rule is proposing to amend §§ 801.410(d)(2) and 801.430(f)(2) (21 CFR 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 proposal would amend 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 proposal would amend 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

This proposed rule is a companion to the direct final rule published in the final rule section of this issue of the **Federal Register**. This companion proposed rule is substantially identical to the direct final rule. 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 in the **Federal Register** a confirmation 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 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 and will proceed to respond to all of the comments under this companion proposed 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 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 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. For example, a comment recommending a rule change in addition 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 <sup>an amendment, paragraph, a section of this rule and that provision</sup> ~~part of the rule, and the part~~ can be severed from the remainder of the rule, FDA may adopt as final those <sup>provisions</sup> ~~parts~~ of the rule that are not the subject of a significant adverse comment.

### 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 proposed 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 impact on those who use the standard. Thus, the proposal is not a significant regulatory action as defined in Executive Order 12866, 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 economic impact of a rule on small entities. The proposed rule, if finalized, would simply update ASTM citations used in various device regulations. The updated citations are the result of periodic re-approvals of long-standing ASTM test methods or standards and will have no significant adverse impact on those who use the ASTM standards. Under the Regulatory Flexibility Act, FDA certifies that the proposed rule will not impose any additional regulatory burdens on small entities.

#### **V. Paperwork Reduction Act of 1995**

FDA tentatively concludes that this proposed 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 proposal. 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.

### **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:

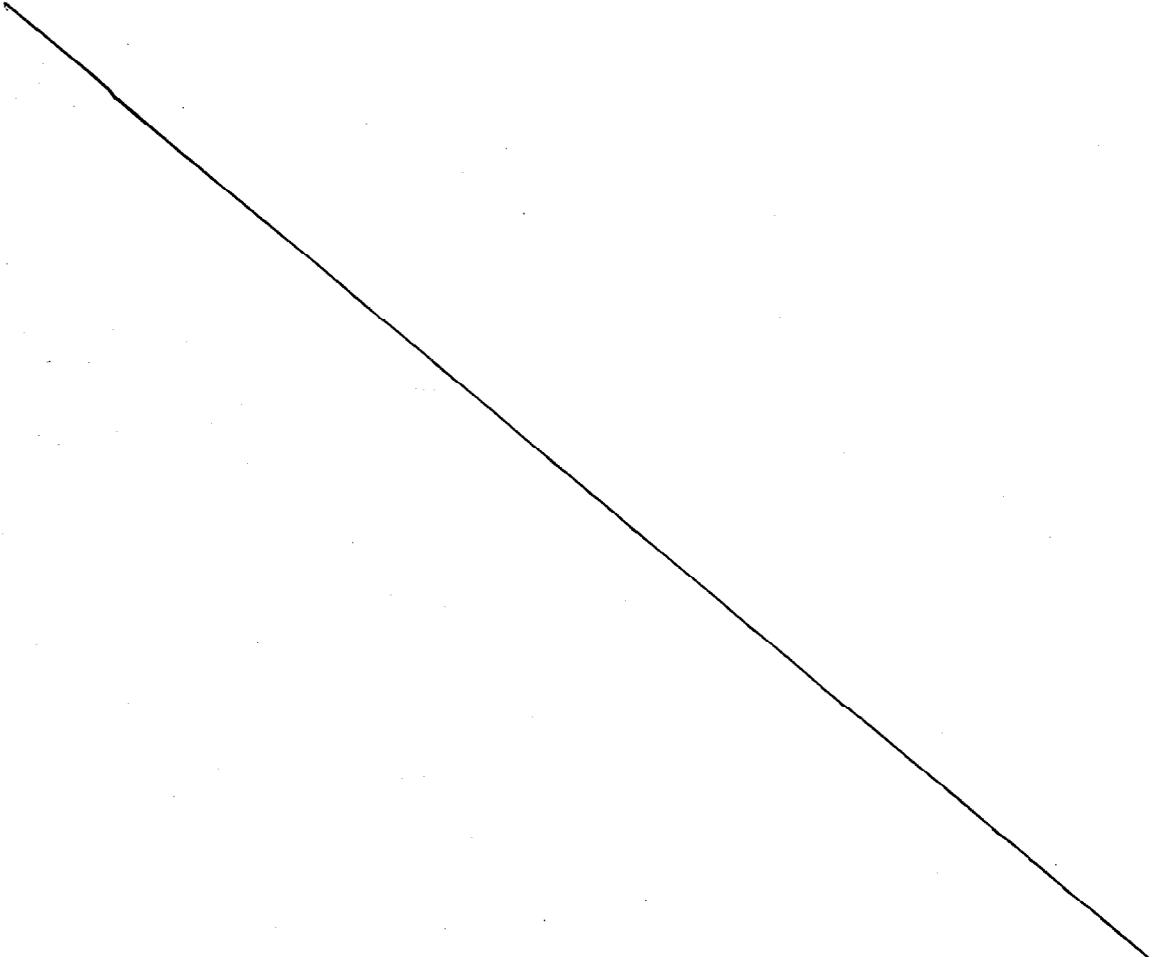
**Authority:** 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

#### **§ 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.”

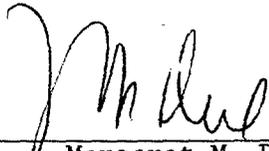
**§ 801.430 [Amended]**

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)’<sup>1</sup>” and by adding in its place “(ASTM) D 3492–96, ‘Standard Specification for Rubber Contraceptives (Male Condoms)’<sup>1</sup>”; 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

  
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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

LC [FR Doc. <sup>66</sup>99-???? Filed ??-??-<sup>60</sup>99; 8:45 am]

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