amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 99–SW–72–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have a substantial direct effect 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701.

### § 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

**AD 99–26–04 Kaman Aerospace Corporation:** Amendment 39–11523. Docket No. 99–SW–72–AD.

Applicability: Model K–1200 helicopters, with clutch assembly, part number (P/N) K974002–701, installed, certificated in any category.

**Note 1:** This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required before the first flight of each day.

To prevent failure of the engine adapter flange, loss of power to the main rotors, and a subsequent forced landing, accomplish the following:

(a) Inspect the integrity of the clutch assembly, in a location where background noise would not hinder evaluation, by firmly and uniformly rotating the Kaflex shaft in the anti-rotating direction (counter-clockwise looking forward) while maintaining hand contact. The anti-rotation speed should be approximately one-fourth to one-half revolution per second. An unairworthy clutch will feel rough with a continuous dry ''raspy'' feel and sound, or it may feel as though the clutch has heavy detents or ''catches'' on the interior surface that impede the free rotary motion.

(b) Remove any unairworthy clutch assembly, P/N K974002–701, before further flight and replace with an airworthy clutch assembly.

**Note 2:** Kaman K–1200 K–MAX Maintenance Manual Temporary Revision (TR) No. 284, dated November 5, 1999, which revises the procedures for engine area daily inspections and TR No. 289, dated November 12, 1999, which describes the method of inspecting the transmission assembly, pertain to the subject of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Boston Aircraft Certification Office, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Boston Aircraft Certification Office.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Boston Aircraft Certification Office.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(e) This amendment becomes effective on February 8, 2000, to all persons except those persons to whom it was made immediately effective by Emergency Priority Letter AD 99–26–04, issued December 8, 1999, which contained the requirements of this amendment.

Issued in Fort Worth, Texas, on January 13, 2000.

**Eric Bries,**

*Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 00–1642 Filed 1–21–00; 8:45 am]

**BILLING CODE 4910–13–U**

## 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 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:** The rule is effective June 7, 2000. Submit written comments on or before

April 10, 2000. 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 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 June 7, 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:** 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 and 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 January 24, 2000. 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 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.

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 June 7, 2000.

## 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 April 10, 2000, 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)' '' and by adding in its place ''(ASTM) D 3492–96, 'Standard Specification for Rubber Contraceptives (Male Condoms)' ''; and by revising the footnote to read ''Copies of the standard are available from the American Society for Testing and 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: December 29, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 00–1404 Filed 1–21–00; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF THE TREASURY

## Internal Revenue Service

## 26 CFR Parts 1 and 602

**[TD 8863]**

**RIN 1545–AX64**

## Stock Transfer Rules: Supplemental Rules

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Temporary regulations.

**SUMMARY:** This document contains temporary regulations that provide an election for certain taxpayers engaged in certain exchanges described in section 367(b). These regulations provide guidance for taxpayers that make the specified election in order to determine the extent to which income must be included and certain corresponding adjustments must be made. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the **Federal Register**.

**DATES:** *Effective Date.* These regulations are effective as of February 23, 2000.

*Applicability Date.* These regulations apply to section 367(b) exchanges that occur on or after February 23, 2000.

**FOR FURTHER INFORMATION CONTACT:** Mark D. Harris, (202) 622–3860 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

### Paperwork Reduction Act

These regulations are being issued without prior notice and public procedure pursuant to the