

SUMMARY: This notice confirms the effective date of a direct final rule which revises the Class E Airspace at Carrizo Springs, Glass Ranch, TX.

EFFECTIVE DATE: The direct final rule published at 65 FR 21301 is effective 0901 UTC, August 10, 2000.

FOR FURTHER INFORMATION CONTACT: Donald J. Day, Airspace Branch, Air Traffic Division, Southwest Region, Federal Aviation Administration, Fort Worth, TX 76193-0520, telephone: 817-222-5593.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on April 21, 2000, (65 FR 21301). The FAA uses the direct final rulemaking procedure for a noncontroversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on August 10, 2000. No adverse comments were received, and, thus, this action confirms that this direct final rule will be effective on that date.

Issued in Fort Worth, TX, on June 30, 2000.

Robert N. Stevens,

*Acting Manager, Air Traffic Division,
Southwest Region.*

[FR Doc. 00-18134 Filed 7-17-00; 8:45 am]

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 4

Vessels in Foreign and Domestic Trades

CFR Correction

In Title 19 of the Code of Federal Regulations, Parts 1 to 140, revised as of April 1, 2000, on page 64, in § 4.95, the third sentence is removed.

[FR Doc. 00-55512 Filed 7-17-00; 8:45 am]

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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; Confirmation in Part and Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation in part and technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is confirming, in part, the direct final rule 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. In addition, FDA is correcting errors made in the direct final rule regarding ASTM's address and an FDA zip code.

DATES: The direct final rule published on January 24, 2000 (65 FR 3627), as amended by this rule, is effective June 7, 2000.

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: In the **Federal Register** of January 24, 2000 (65 FR 3627), FDA published a direct final rule and a companion proposed rule to amend various medical device regulations. The amendments would update references in those regulations to various standards issued by the American Society for Testing and Materials (ASTM). The preamble to the direct final rule and the companion proposed rule explained 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. 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.

Based on information received from ASTM, FDA, through the direct final rule and companion proposed rule, identified several device regulations

that contained obsolete or withdrawn ASTM standards. The medical device regulations and the ASTM standards at issue are:

- 21 CFR 801.410 *Use of impact-resistant lenses in eyeglasses and sunglasses*—The agency proposed to amend paragraph (d)(2) by replacing “ASTM Method D 1415-68 ‘Test for International Hardness of Vulcanized Rubber,’” with “ASTM Method D 1415-88, ‘Standard Test Method for Rubber Property—International Hardness,’” and also replace “ASTM Method D 412-68 ‘Tension Test of Vulcanized Rubber’” with “ASTM Method D 412-97, ‘Standard Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension’”.

- 21 CFR 801.430 *User labeling for menstrual tampons*—The agency sought to amend paragraph (f)(2) by replacing “(ASTM) D 3492-83, ‘Standard Specification for Rubber Contraceptives (Male Condoms)’” with “(ASTM) D 3492-96, ‘Standard Specification for Rubber Contraceptives (Male Condoms)’”.

FDA received one comment. The comment, submitted by ASTM, pointed out that because ASTM had revised two of the cited ASTM references again, the two references in the direct final rule were now obsolete. ASTM recommended changing D412-97 to D412-98A and D3492-96 to D3492-97 to reflect the current ASTM cites. ASTM's comment explained how the standards had changed and provided detailed descriptions of the changes in its comment. In general, the changes were not significant; some changes involved removing terms that were not commonly used or defined, deleting redundant wording, adding metric measurements, and changing measurement methods to improve accuracy or clarity.

Because these changes are not significant and ASTM has already made these changes to its standards, FDA finds for good cause that notice and public comment on the latest ASTM standards citation revisions is unnecessary.

Therefore, FDA is confirming, in part, the direct final rule insofar as it pertains to § 801.410 and its reference to ASTM Method D 1415-88, “Standard Test Method for Rubber Property—International Hardness” and the addresses where the standards may be found or inspected. Similarly, FDA is confirming the addresses in § 801.430 where the standards may be found or inspected, although it is correcting errors that were made in the direct final rule regarding the ASTM's address.

FDA is amending § 801.410 by replacing “ASTM Method D 412–97” with “ASTM Method D 412–98A” and using the current title for ASTM method D 412.98A. FDA is also amending § 801.430(f)(2) by replacing “(ASTM), D 3492–96,” with “(ASTM) D 3492–97.”

List of Subjects 21 CFR Part 801

Hearing aids, Medical devices, Professional and patient labeling.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, the direct final rule published on January 24, 2000 (65 FR 3627), is confirmed as effective June 7, 2000, with the following changes:

PART 801—LABELING

1. The authority citation for 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 412–97, Standard Test Methods for Vulcanized Rubber and Thermoplastic Rubbers and Thermoplastic Elastomers—Tension,” and by adding in its place “ASTM Method D 412–98A, ‘Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension,’” and by removing “10850” and by adding in its place “20850”.

§ 801.430 [Amended]

3. Section 801.430 “*User labeling for menstrual tampons*” is amended in paragraph (f)(2) by removing “(ASTM) D 3492–96, ‘Standard Specification for Rubber Contraceptives (Male Condoms)’” and by adding in its place “(ASTM) D 3492–97, ‘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 20850, or at the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC.”

Dated: June 28, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–18082 Filed 7–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8893]

RIN 1545–AW52

Retention of Income Tax Return Preparers’ Signatures

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide income tax return preparers with two alternative means of meeting the requirement that a preparer retain the copy of the return or claim manually signed by the preparer. The regulations are necessary to inform preparers about the two alternatives and to provide them with the guidance needed to comply with the alternatives.

DATES: *Effective Date:* These regulations are effective July 18, 2000.

Applicability Date: For dates of applicability, see § 1.6695–1(g) of these regulations.

FOR FURTHER INFORMATION CONTACT: Beverly A. Baughman (202) 622–4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) relating to the penalty for failure to sign an income tax return under section 6695(b) of the Internal Revenue Code.

On December 31, 1998, final and temporary regulations (TD 8803, 1999–12 I.R.B. 15) under section 6695 were published in the **Federal Register** (63 FR 72182). A notice of proposed rulemaking (REG–106386–98, 1999–12 I.R.B. 31) cross-referencing the temporary regulations was published in the **Federal Register** (63 FR 72218) on the same date. Although written or electronic comments and requests for a public hearing were solicited, no comments were received and no public hearing was requested or held. The proposed regulations under section 6695 are adopted by this Treasury decision and the corresponding temporary regulations are removed.

Section 6695(b) provides that any person who is an income tax return preparer with respect to a return or claim for refund, who is required by regulations prescribed by the Secretary to sign the return or claim, and who fails to comply with those regulations,

must pay a penalty of \$50 for such failure, unless it is shown that the failure is due to reasonable cause and not willful neglect. The maximum penalty imposed with respect to documents filed during a calendar year will not exceed \$25,000.

Section 7701(a)(36)(A) provides that, in general, the term *income tax return preparer* means any person who prepares for compensation, or who employs one or more persons to prepare for compensation, any return of tax or claim for refund imposed by subtitle A. For purposes of the preceding sentence, the preparation of a substantial portion of a return or claim is treated as if it were the preparation of such return or claim.

Section 1.6695–1(b)(1) generally provides that an income tax return preparer, with respect to a return or claim for refund, must manually sign the return or claim (which may be a photocopy) in the appropriate space provided on the return or claim after it is completed and before it is presented to the taxpayer (or nontaxable entity) for signature.

Explanation of Provisions

The final regulations provide that the employer of the preparer or the partnership in which the preparer is a partner, or the preparer (if not employed or engaged by a preparer and not a partner of a partnership which is a preparer), must retain the manually signed copy of the return or claim. In the alternative, the person required to retain the manually signed copy of the return or claim may either retain a photocopy of that manually signed copy or use an electronic storage system meeting the requirements of section 4 of Rev. Proc. 97–22 (1997–1 C.B. 652), or procedures subsequently prescribed by the Commissioner, to store and produce a copy of the return or claim manually signed by the preparer.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking that preceded these regulations was submitted to the Chief Counsel for