Filed - Regulations - Registration

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 85C-0532]

Confirmation of Effective Date for Iron Oxides, Chromium Oxide Greens, and Titanium Dioxide; Listing of Color Additives for Coloring Contact Lenses

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of August 9, 1986, for the final rule that amended the color additive regulations to provide for the safe use of iron oxides, chromium oxide greens, and titanium dioxide as color additives in contact lenses. This action responds to a petition filed by Wesley-Jessen.

DATE: Effective date confirmed: August 9, 1986.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 9, 1986 (51 FR 24815), FDA amended the color additive regulations to provide for the safe use of iron oxides, chromium oxide greens, and titanium dioxide as color additives in contact lenses.

FDA gave interested persons until August 8, 1986, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA has concluded that the final rule published in the Federal Register of July 9, 1986, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additive, Cosmetics, Drugs, Medical devices.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 (21 U.S.C. 371, 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections and requests for a hearing were filed in response to the July 9, 1986, final rule. Accordingly, the amendments promulgated thereby became effective August 9, 1986.

Dated: September 12, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86-21086 Filed 9-17-86; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 807

[Docket No. 85N-0470]

Medical Device Registration; Recordkeeping Reduction

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to reduce the number of years that owners or operators of registered medical device establishments are required to keep a historical file of the labeling and advertisements for discontinued devices. The reduction is in response to Office of Management and Budget (OMB) guidelines. FDA is also revising and correcting the authority citation for its device registration regulations.

EFFECTIVE DATE: November 17, 1986.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION: Section 807.31 (21 CFR 807.31) requires owners or operators of medical device establishments to maintain a historical file of certain labeling and advertisements for their medical devices for (1) 5 years after the date the owner or operator made the last shipment of a discontinued device or (2) the anticipated useful life of the device (approved by OMB under control number 0910-0057).

OMB's rule (5 CFR Part 1320) implementing the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96-511) (44 U.S.C. 3501-3520) establishes policies and procedures for controlling paperwork burdens imposed by Federal agencies on the public. Section 1320.6(f) of OMB's rule sets forth general information collection guidelines which provide that an agency should not require persons to retain records, other than health, medical or tax records, for more than 3 years, unless the agency demonstrates that the requirement is necessary to satisfy a statutory requirement or is justified by some other substantial need.

Based on its experience, and in consideration of OMB's guidelines, FDA believes that it is not necessary for the protection of the public health that the records required by § 807.31(c) be retained for 5 years.

Therefore, in the Federal Register of February 19, 1986 (51 FR 6008), FDA published a proposed rule to reduce the retention period applicable to labeling and advertising of discontinued devices to 3 years. The notice also proposed to revise the authority citation for 21 CFR Part 807 because reference to section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) was inadvertently omitted at the time Part 807 was originally promulgated.

The agency received two comments in response to the proposal. One comment was from a trade association; the other was from a manufacturer. Both comments supported the proposal.

Therefore, FDA is adopting the proposed rule as published in the Federal Register to reduce the retention period of labeling and advertising of discontinued devices to 3 years.

FDA has examined the consequences of this final rule in accordance with Executive Order 12291 and found that the rule is not a major rule as specified in the order. Therefore, a regulatory impact analysis is not required. FDA certifies, under the Regulatory Flexibility Act, that the rule will not have a significant economic impact on a substantial number of small entities because it does not impose any new requirements on any person. Therefore, a regulatory flexibility analysis is not required.

The agency has determined under 21 CFR 25.24(a)(8) 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.

List of Subjects in 21 CFR Part 807

Confidential business information, 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, Part 807 is amended as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS OF DEVICES

1. The authority citation for 21 CFR Part 807 is revised to read as follows:

Authority: Secs. 301(p) 501, 502, 510, 513, 701(a), 52 Stat. 1049-1051 as amended, 1055, 76 Stat. 794-795 as amended, 86 Stat. 462 as

amended, 90 Stat. 540–546 (21 U.S.C. 331(p), 351, 352, 360, 360c, 371(a)); 21 CFR 5.10.

2. In § 807.31 by revising paragraph (c) to read as follows:

§ 807.31 Additional listing information.

* * * * *

(c) Each owner or operator may discard labeling and advertisements from the historical file 3 years after the date of the last shipment of a discountinued device by an owner or operator.

* * * * *

Dated: August 14, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–21087 Filed 9–17–86; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 8098]

Income Taxes; Returns Relating to Cash Payments in Excess of $10,000 Received in a Trade or Business

Correction

In FR Doc. 86–19939 beginning on page 31610 in the issue of Thursday, September 4, 1986, make the following corrections:

§ 1.60501–1 [Corrected]

1. On page 31612, in the second column, in § 1.60501–1(d)(2)(ii), third line, "many" should read "may"; and

2. On the same page, in the third column, in § 1.60501–1(d)(2)(iv), *Example*, twelfth line, "of" should read "at".

BILLING CODE 1505–01–M

26 CFR Part 1

[T.D. 8092]

Income Taxes; Temporary Regulations on Allocation of Basis to New Target's Assets.

Correction

In FR Doc. 86–14839 beginning on page 23737 in the issue of Tuesday, July 1, 1986, make the following corrections:

§ 1.338–4T [Corrected]

1. On page 23741, in the third column, in § 1.338–4T, in the line below *Answer 3, "Example:* (1)" should read "*Example:* (i)";

§ 1.338(b)–2T [Corrected]

2. On page 23742, in the second column, in § 1.338(b)–2T(a)(3), second line, "election" should read "allocation"; and

§ 1.338(b)–4T [Corrected]

3. On the same page, same column, in § 1.338(b)–4T(a)(3), second line, "§ 1338–4T(b)(1)" should read "§ 1.338–4T(b)(1)".

BILLING CODE 1505–01–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

Commercial Diving Standard

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule; technical amendments.

SUMMARY: This document amends paragraph (e)(1) of the section on equipment in the commercial diving standard, 29 CFR 1910.430, by correcting a reference to the OSHA standards on compressed gas cylinders and equipment to read "§§ 1910.101 and 1910.169–171," instead of "§§ 1910.166–19171." Sections 1910.166–168 were deleted in 1984 (49 FR 5318) because they repeated provisions also found in § 1910.101.

DATE: This amendment is effective September 18, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, U.S. Department of Labor, Occupational Safety and Health Administration, Room N3637, 200 Constitution Avenue, NW., Washington, DC 20210, (202) 523–8151.

SUPPLEMENTARY INFORMATION: On February 10, 1984, OSHA published a final rule (49 FR 5318) revoking advisory and repetitive standards contained in OSHA's General Industry Standards (29 CFR Part 1910). Among the standards revoked by this action were those contained in §§ 1910.166 through 1910.168. These sections repeated requirements concerning compressed gas cylinders and compressed gas equipment which are also found in § 1910.101. As noted in the final rule, the removal of §§ 1910.166 through 1910.168 was not intended to lessen employee protection in any way.

However, 29 CFR Part 1910, Subpart T, Commercial Diving Operations, contains a provision, § 1910.430(e)(1), which requires that compressed gas cylinders be designed, constructed and maintained in accordance with the applicable provisions of 29 CFR 1910.166 through 1910.171. Because §§ 1910.166 through 1910.168 have been revoked, with their coverage being continued in § 1910.101, it is necessary to correct § 1910.430(e)(1) to reference § 1910.101 instead of §§ 1910.166 through 1910.168. Pursuant to 29 CFR 1911.5 and 5 U.S.C. 553(b), the Assistant Secretary has determined that notice and public procedure on this amendment are unnecessary. This is a minor amendment which corrects an inaccurate reference in the diving standard, and makes no substantive change in the requirements of that standard. For the same reason, pursuant to 5 U.S.C. 553(d), this amendment is made effective immediately upon publication.

This document was prepared under the direction of John A. Pendergrass, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Accordingly, pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653 655, 657), section 107, Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333), section 41, Longshoremen's and Harbor Workers' Compensation Act (33 U.S.C. 941), 5 U.S.C. 553, Secretary of Labor's Order No. 9–83 (48 FR 35736) and 29 CFR Part 1911, 29 CFR Part 1910, is amended as set forth below.

Signed at Washington, DC, this 11th day of September 1986.

John A. Pendergrass,

Assistant Secretary of Labor.

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

1. The Authority Citation for Subpart T of 29 CFR Part 1910 is revised to read as follows:

Authority: Secs. 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Sec. 107, Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 333); Sec. 41, Longshoremen's and Harbor Workers' Compensation Act (33 U.S.C. 941); Secretary of Labor's Order No. 8–76 (41 FR 25059) or 9–83 (48 FR 35736), as applicable; 29 CFR Part 1911. Section 1910.430(e)(1) also issued under 5 U.S.C. 553.

2. Paragraph (e)(1) of § 1910.430 is revised to read as follows:

§ 1910.430 Equipment.

* * * * *

(e) * * *

(1) Be designed, constructed and maintained in accordance with the