state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1360 is amended by revising paragraphs (a)(3) and (d) to read as follows:

§ 177.1360 Ethylene-vinyl acetate-vinyl alcohol copolymers.

* * * * *

(a) * * *

(3) Those copolymers containing 17 to 40 percent ethylene and 60 to 83 percent vinyl alcohol units by weight may be used in contact with foods as described in paragraph (d) of this section.

* * * * *

(d) The finished food-contact article shall not exceed 0.018 centimeter (0.007 inch) thickness and may contact all foods, except those containing more than 8 percent alcohol, under conditions of use B through H described in table 2 of § 176.170(c) of this chapter. Film samples of 0.018 centimeter (0.007 inch) thickness representing the finished articles shall meet the following extractive limitation when tested by ASTM method F34–76 (Reapproved 1980), ''Standard Test Methods for Liquid Extraction of Flexible Barrier Materials,'' which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (b) of this section. The film when extracted with distilled water at 100 °C (212 °F) for 30 minutes yields ethylene-vinyl acetate-vinyl alcohol oligomers not to exceed 0.093 milligram per square centimeter (0.6 milligram per square inch) of food contact surface as determined by a method entitled ''Analytical Method of Determining the Amount of EVOH in the Extractives Residue of EVOH Film,'' dated March 23, 1987, as developed by the Kuraray Co., Ltd., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

* * * * *

Dated: March 20, 2000.

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–8037 Filed 3–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 807, 820, and 897

[Docket No. 95N–0253]

RIN 0910–AA48

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Revocation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its regulations governing access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents. This action is being taken in response to the Supreme Court decision of March 21, 2000 in which the court held that Congress has not given FDA the authority to regulate tobacco products as customarily marketed. This action will result in the removal of the regulations.

DATES: This rule is effective March 31, 2000.

FOR FURTHER INFORMATION CONTACT: Anne Kirchner, Office of the Commissioner (HF–13), 5600 Fishers Lane, Rockville, MD 20857, 301–827–0585.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 11, 1995 (60 FR 41314), We (FDA) issued proposed regulations to restrict the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. In addition, we issued a jurisdictional determination that cigarettes and smokeless tobacco products are combination products consisting of a drug (nicotine) and device components intended to deliver nicotine to the body. We issued final regulations based on this proposal in the **Federal Register** of August 28, 1996 (61 FR 44398).

On March 21, 2000, in *Food and Drug Administration* vs. *Brown & Williamson Tobacco Corp., et al.*, the Supreme Court ruled that Congress has not granted FDA jurisdiction to regulate tobacco products as customarily marketed. In accordance with this ruling, we are hereby removing our regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)). We are also addressing the additional steps necessitated by the courts ruling, such as termination of state contracts to help enforce the age and photo identification requirements of the regulations.

List of Subjects

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 897

Advertising, Cigarettes, Labeling, Sale and distribution, Smokeless tobacco.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 801, 803, 807, and 820 are amended and part 897 is removed 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.

§ 801.126 [Removed]

2. Remove § 801.126.

PART 803—MEDICAL DEVICE REPORTING

3. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

4. Amend § 803.19 by removing paragraphs (f) and (g).

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

5. The authority citation for 21 CFR part 807 continues to read as follows:

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

6. Amend § 807.65 by removing paragraph (j).

PART 820—QUALITY SYSTEM REGULATION

7. The authority citation for 21 CFR part 820 continues to read as follows:

Authority: 351, 352, 360, 360c, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383.

8. Amend § 820.1 by removing paragraphs (e) and (f).

PART 897—[REMOVED]

9. Remove part 897.

Dated: March 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–7960 Filed 3–30–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803, 807, 812, 814, 860, 1005, 1010, 1020, and 1040

[Docket No. 00N–0784]

Medical Devices; Information Processing Procedures; Obtaining, Submitting, Executing, and Filing of Forms: Change of Addresses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending procedural regulations that pertain to obtaining, submitting, executing, and filing certain documents to reflect new addresses in the agency. All filings and other documents subject to these regulations must be directed to the new address. This action is being taken to ensure the accuracy of FDA's regulations.

DATES: This rule is effective March 31, 2000.

FOR FURTHER INFORMATION CONTACT: Domini H. Cassis, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2964.

SUPPLEMENTARY INFORMATION: This rule reflects the relocation of certain component offices within the agency that are responsible for processing documents relating to medical devices. This administrative action is limited to changing specific addresses for obtaining, submitting, executing, and filing certain documents, but it makes no other changes in filing requirements.

This document is published as a final rule with the effective date shown above. Because the final rule is an administrative action to update addresses for certain agency offices, FDA has determined that it has no substantive impact on the public. It imposes no costs, and merely updates a list of addresses included in the Code of Federal Regulations (CFR) for the convenience of the public. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary and that this rule may take effect upon publication.

List of Subjects

21 CFR Part 803

Imports, Medical devices, Recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

21 CFR Part 1005

Administrative practice and procedure, Electronic products, Imports, Radiation protection, Surety bonds.

21 CFR Part 1010

Administrative practice and procedure, Electronic products, Exports, Radiation protection.

21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

21 CFR 1040

Electronic products, Labeling, Lasers, Medical devices, Radiation protection, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 803, 807, 812, 814, 860, 1005, 1010, 1020, and 1040 are amended as follows:

PART 803—MEDICAL DEVICE REPORTING

1. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

2. Section 803.11 is revised to read as follows:

§ 803.11 Obtaining the forms.

User facilities and manufacturers must submit all reports of individual adverse events on FDA Form 3500A (MEDWATCH form) or in an electronic equivalent as approved under § 803.14. This form and all other forms referenced in this section can also be obtained from the Consolidated Forms and Publications Office, Washington