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Issued in College Park, Georgia, on March 20, 2000.

Nancy B. Shelton,

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

[FR Doc. 00-7959 Filed 3-30-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 10, 12, and 510

[Docket No. 99N-4957]

Removal of Designated Journals; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of April 24, 2000 for the final rule that appeared in the **Federal Register** of December 10, 1999 (64 FR 69188). The direct final rule amends the regulation that lists the veterinary and scientific journals available in FDA's library. The purpose of the list is to allow individuals to reference articles from listed journals in new animal drug application documents submitted to Dockets Management Branch, and objections and requests for hearing on a regulation or order instead of submitting a copy or reprint of the article. FDA is taking this action because this list of journals is outdated and because individuals rarely use the regulation. This document confirms the effective date of the direct final rule.

DATES: Effective date confirmed: April 24, 2000.

FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0205.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 10, 1999 (64 FR 69188), FDA solicited comments concerning the direct final rule for a 75-day period ending February 23, 2000. FDA stated that the effective date of the direct final rule would be on April 24, 2000, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did

not receive any significant adverse comments.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the amendments issued thereby will go into effect on April 24, 2000.

Dated: March 24, 2000.

William K. Hubbard,

*Senior Associate Commissioner for Policy,
Planning, and Legislation.*

[FR Doc. 00-7936 Filed 3-30-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 94F-0246]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethylene-vinyl acetate-vinyl alcohol copolymers with revised specifications that provide for a decreased minimum acceptable ethylene content and an increased maximum permitted level of migration of ethylene-vinyl acetate-vinyl alcohol oligomers for use as articles or components of articles intended for contact with food. This action responds to a petition filed by Kuraray Co., Ltd.

DATES: This rule is effective March 31, 2000. Submit written objections and requests for a hearing by May 1, 2000. 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 a certain publication in 21 CFR 177.1360(d), as of March 31, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3083.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of August 17, 1994 (59 FR 42277), FDA announced that a food additive petition

(FAP 4B4421) had been filed by Kuraray Co., Ltd., c/o 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend § 177.1360 *Ethylene-vinyl acetate-vinyl alcohol copolymers* (21 CFR 177.1360) of the food additive regulations to provide for the safe use of ethylene-vinyl acetate-vinyl alcohol copolymers with revised specifications that provide for a decreased minimum acceptable ethylene content and an increased maximum permitted level of migration of ethylene-vinyl acetate-vinyl alcohol oligomers for use as articles or components of articles intended for contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and (3) the regulations in § 177.1360 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This 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.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by May 1, 2000. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so

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.

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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.