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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]

**BILLING CODE 4910-13-M**

## 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journals is outdated and because  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]

**BILLING CODE 4160-01-F**

## 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.

\* \* \* \* \*

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.