§ 812.47 Emergency research under § 50.24 of this chapter.

* * * * *

(b) * * * The sponsor promptly shall provide this information in writing to FDA, investigators who are asked to participate in this or a substantially equivalent clinical investigation, and other IRB's that are asked to review this or a substantially equivalent investigation.

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5522 Filed 3–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 97F–0412]

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/propylene copolymers that contain up to 20 mole-percent of polymer units derived from propylene, with the remainder of the polymer consisting of ethylene, and having a minimum viscosity-average molecular weight of 95,000 and a minimum Mooney viscosity of 13, at up to 30 percent in blends with regulated polyolefins intended for contact with foods. This action responds to a petition filed by Mitsui Petrochemical Industries, Ltd.

DATES: The regulation is effective March 8, 1999; written objections and requests for a hearing by April 7, 1999.

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: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 6, 1997 (62 FR 52136), FDA announced that a food additive petition (FAP 7B4549) had been filed by Mitsui Petrochemical Industries, Ltd., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 177.1520 *Olefin polymers* (21 CFR 177.1520) to provide for the safe use of ethylene/propylene copolymers that contain up to 20 mole-percent of polymer units derived from propylene, with the remainder of the polymer consisting of ethylene, and having a minimum viscosity-average molecular weight of 95,000 and a minimum Mooney viscosity of 13, at up to 30 percent of other regulated polymer blends 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 therefore, (3) the regulations in § 177.1520 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 on or before April 7, 1999, file with the Dockets Management Branch (address above) written objections thereto. 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 shall be submitted and shall 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.

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 177.1520 is amended in the table in paragraph (c) by adding an item 3.7 to read as follows:

§ 177.1520 Olefin polymers.

* * * * *

(c)* * *

Olefin polymers	Density	Melting Point (MP) or softening point (SP) (*Degrees Centigrade*)	Maximum extractable fraction (expressed as percent by weight of the polymer) in *N*-hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
*	*	*	*	*
3.7 Ethylene/propylene copolymers, meeting the identity described in paragraph (a)(3)(i) of this section, containing not less than 80 mole-percent of polymer units derived from ethylene and having a minimum viscosity average molecular weight of 95,000 as determined by the method described in paragraph (d)(5) of this section, and a minimum Mooney viscosity of 13 as determined by the method described in paragraph (d)(6) of this section. Ethylene/propylene copolymers described in this item 3.7 are to be used only in blends with other olefin polymers complying with this section, at levels not to exceed 30 percent by weight of the total polymer blend, and in contact with food only of types identified in § 176.170(c) of this chapter, Table 1, under Types I, II, III, IV–B, VI, VII, VIII, and IX. Additionally, optional adjuvants permitted for use in olefin copolymers complying with item 3.4 of this table may be used in the production of this copolymer.	Not less than 0.86			
*	*	*	*	*

* * * * *

Dated: February 23, 1999.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–5520 Filed 3–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. 98N–0655]

List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to include a list of drug products that may not be used for pharmacy compounding under the exemptions under section 503A of the Federal Food, Drug, and Cosmetic Act (the act) because they have had their approval withdrawn or were removed from the market because the drug product or its components have been found to be unsafe or not effective. The list has been compiled under the new statutory requirements of the Food and Drug Administration Modernization Act of 1997 (Modernization Act).

DATES: This rule is effective on April 7, 1999.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers