

under the Advisers Act, or any part of such books and records which may be specified in any such demand.

(i) Notwithstanding anything in the foregoing, in any case in which the Director of the OCIE believes it appropriate, the Director may submit the matter to the Commission.

By the Commission.

Dated: July 28, 1995.

Margaret H. McFarland,

Deputy Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 94F-0090]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide broadened specifications for congealing point and oil content for synthetic paraffinic waxes produced by the Fischer-Tropsch process so that the specifications for synthetic paraffin waxes more closely resemble specifications for other synthetic waxes permitted for use in food packaging under other regulations. This action is in response to a petition filed by Shell Oil Co.

DATES: Effective August 3, 1995; written objections and requests for a hearing September 5, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 18, 1994 (59 FR 18412), FDA announced that a food additive petition (FAP 4B4416) had been filed by Shell Oil Co., One Shell Plaza, P.O. Box 4320, Houston, TX 77210. The petition proposed to amend the food additive regulations in § 175.250 *Paraffin*

(*synthetic*) (21 CFR 175.250) to incorporate broadened specifications for congealing point and oil content for synthetic paraffinic waxes produced by the Fischer-Tropsch process, so that the specifications for synthetic paraffin waxes more closely resemble specifications for other synthetic paraffin waxes permitted for use in food packaging under other regulations.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe and that § 175.250 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 21 CFR 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.

Any person who will be adversely affected by this regulation may at any time on or before September 5, 1995, 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 175

Adhesives, 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 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

§ 175.250 [Amended]

2. Section 175.250 *Paraffin (synthetic)* is amended in paragraph (a) in the third sentence by adding the words "may be" after the word "and", in paragraph (b)(1) in the first sentence by removing "93 °C" and adding in its place "50 °C", and in paragraph (b)(2) in the first sentence by removing "0.5 percent" and adding in its place "2.5 percent."

Dated: July 22, 1995.

Janice F. Oliver,

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

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21 CFR Part 176

[Docket No. 92F-0504]

Indirect Food Additives: Paper and Paperboard Components

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 perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[(γ , ω -perfluoroC₄₋₂₀alkylthio)methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide as an oil and water repellent for paper and