DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0593]

Dover Chemical Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Dover Chemical Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 3,9-bis[2,4-bis(1-methyl-1-phenylethyl)phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane, which may contain not more than 2 percent by weight of triisopropanolamine, as an antioxidant and/or stabilizer for polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215),Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 8B4614) has been filed by Dover Chemical Corp., 3676 Davis Rd. NW., Dover, OH 44622. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 3,9-bis[2,4-bis(1-methyl-1-phenylethyl)phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane, which may contain not more than 2 percent by weight of triisopropanolamine, as an antioxidant and/or stabilizer for polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 11, 1998.

George H. Pauli,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–20359 Filed 7–29–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 83F–0089]

National Starch and Chemical Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 3B3696) proposing that the food additive regulations be amended to provide for the safe use of the partial sodium salt of a copolymer of dimethyldiallylammonium chloride with acrylamide and acrylic acid as a component of paper and paperboard for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3084.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 22, 1983 (48 FR 17390), FDA announced that a food additive petition (FAP 3B3696) had been filed by National Starch and Chemical Corp., P.O. Box 6500, Bridgewater, NJ 08807–0500. The petition proposed to amend the food additive regulations in § 176.170 Components of paper and paperboard in contact with aqueous and fatty foods (21 CFR 176.170) to provide for the safe use of the partial sodium salt of a copolymer of dimethyldiallylammonium chloride with acrylamide and acrylic acid as a component of paper and paperboard for use in contact with food. National Starch and Chemical Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: July 2, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–20304 Filed 7–29–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0449]

''Draft Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Draft Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers.'' This draft guidance provides guidance to the FDA field staff for the enforcement of the requirements of the quality system regulation, and it includes guidance on the amendments to the quality system regulation, which became effective June 1, 1997. This draft guidance is intended to represent the agency's current thinking on inspection of medical device manufacturers, and it is not final nor is it in effect at this time.

DATES: Written comments may be provided at any time, however, comments should be submitted by October 28, 1998.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance document entitled ''Draft Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Wes W. Morgenstern, Center for Devices and Radiological Health (HFZ–305), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–4699.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Draft Compliance Program Guidance Manual: Inspection of Medical Device