## 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

Manufacturers'' (CP 7382.830). This draft document provides guidance to the FDA field staff for the enforcement of the quality system regulation (part 820 (21 CFR part 820)). This draft is a revision to the document first made available in May 1995, in accordance with the amendments to part 820, effective June 1, 1997.

This guidance document represents the agency's current thinking on inspection of medical device manufacturers. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

## II. Electronic Access

In order to receive the ''Draft Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers'' (CP 7382.830) via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (487) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes the ''Draft Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers'' (CP 7382.830), device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The ''Draft Compliance Program Guidance Manual: Inspection of Medical Device Manufacturers'' (CP 7382.830) will be available at ''http://www.fda.gov/cdrh/ochome.html''.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

## II. Comments

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by October 28, 1998, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for examination in the the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 17, 1998.

**D.B. Burlington,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. 98–20305 Filed 7–29–98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98D–0566]**

### International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH); Draft Guidance on Stability Testing of New Animal Drug Substances and Products (#73), Stability Testing for New Dosage Forms of New Animal Drugs (#74), and Stability Testing: Photostability Testing of New Animal Drug Substances and Products (#75); Availability; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for comment of three draft guidance for industry documents entitled ''Stability Testing of New Animal Drug Substances and Products,'' ''Stability Testing for New Drug Dosage Forms of New Animal Drugs,''and ''Stability Testing: Photostability Testing of New Animal Drug Substances and Products.'' These related draft guidance documents have been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from guidelines that were adopted by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance is intended to provide guidance on stability testing of new drug substances and products and new dosage forms included as part of registration applications for approval of veterinary medicinal products submitted to the European Union, Japan, and the United States.

**DATES:** Written comments should be submitted by August 31, 1998.

**Note:** FDA will accept comments after the deadline, but to assure consideration at the next VICH Committee meeting, we must receive them by August 31, 1998.

**ADDRESSES:** Submit written requests for single copies of these draft guidance documents to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments to the Dockets Management Branch (HFA–