

approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of ASTM Standard D5489-96c Guide to Care Symbols for Care Instructions on Consumer Textile Products may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428, or may be inspected at the Federal Trade Commission, room 130, 600 Pennsylvania Avenue, NW., Washington, DC, or at the Office of the Federal Register, suite 700, 800 North Capitol Street, NW., Washington, DC.

**Authority:** 15 U.S.C. 41-58.

By direction of the Commission.

**Donald S. Clark,**

Secretary.

[FR Doc. 97-13869 Filed 5-28-97; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 178**

[Docket No. 96F-0370]

**Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers**

**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 3,9-bis[2,4-bis(1-methyl-1-phenylethyl)phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food. This action is in response to a petition filed by Dover Chemical Corp.

**DATES:** Effective May 29, 1997; written objections and requests for a hearing by June 30, 1997.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, 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 October 15, 1996 (61 FR 53748), FDA announced that a food additive petition (FAP 6B4521) had been filed by Dover Chemical Corp., 3676 Davis Rd. NW., Dover, OH 44622. The petition proposed 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 as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that: (1) The proposed use of the additive is safe, (2) the food additive will have the intended technical effect, and (3) the regulations in § 178.2010 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.

Any person who will be adversely affected by this regulation may at any time on or before June 30, 1997, 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 178**

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 178 is amended as follows:

**PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS**

1. The authority citation for 21 CFR part 178 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).

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry for 3,9-bis[2,4-bis(1-methyl-1-phenylethyl)phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane to read as follows:

**§ 178.2010 Antioxidants and/or stabilizers for polymers.**

\* \* \* \* \*

(b) \* \* \*

Substances	Limitations
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3,9-bis[2,4-bis(1-methyl-1-phenylethyl)phenoxy]-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane (CAS Reg. No. 154862-43-8).	For use only: 1. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, and items 2.1, 2.2, 2.3, 3.1, or 3.2 (where density of each of these polymers is greater than 0.94 gram per cubic centimeter) and under conditions of use C, D, E, F, and G as described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.06 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, item 3.1 or 3.2, having a density less than 0.94 gram per cubic centimeter and under conditions of use C, D, E, F, and G as described in Table 2 of § 176.170(c) of this chapter.
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Dated: May 15, 1997.  
**Fred R. Shank,**  
 Director, Center for Food Safety and Applied Nutrition.  
 [FR Doc. 97-14105 Filed 5-28-97; 8:45 am]  
 BILLING CODE 4160-01-F

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510 and 558**

**Animal Drugs, Feeds, and Related Products; Change of Sponsor**

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for five new animal drug applications (NADA's) from Merck

Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065 to Koffolk, Inc.

**EFFECTIVE DATE:** May 29, 1997.

**FOR FURTHER INFORMATION CONTACT:** Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

**SUPPLEMENTARY INFORMATION:** Merck Research Laboratories, Division of Merck & Co., Inc., Rahway, NJ 07065, has informed FDA that it has transferred ownership of, and all rights and interests in, the following NADA's to Koffolk, Inc., One Parker Plaza, Fort Lee, NJ 07024:

NADA No.	Ingredient
9-476 .....	NICARB 25%
98-378 .....	Nicarbazin-Bacitracin Methylene Disalicylate
107-997 .....	Nicarbazin-Roxarsone-Lincomycin Medicated Feed
108-115 .....	Nicarbazin-Roxarsone
108-116 .....	Nicarbazin-Lincomycin

Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by alphabetically adding a new listing for Koffolk, Inc. The agency is also amending § 558.366 to reflect the transfer of ownership.

**List of Subjects**

*21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*21 CFR Part 558*

Animal drugs, animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "Koffolk, Inc.," and in the table in paragraph (c)(2) by numerically adding a new entry for "063271" to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

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(c) \* \* \*

(1) \* \* \*