| Substances | Limitations |
|---|---|
| * * * | * * * * |
| Tris(2,4-di-*tert*-butylphenyl)phosphite. (CAS Reg. No. 31570–04–4). | For use only:<br>* * *<br>6. At levels not to exceed 0.2 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1(a), 3.1(b), 3.1(c), 3.2(a), or 3.2(b). The finished polymers complying with items 2.1, 2.2, or 2.3 having a density less than 0.94 gram per cubic centimeter and a thickness greater than 0.051 millimeter (0.002 inch), either shall have a level of tris(2,4-di-*tert*-butylphenyl)phosphite that shall not exceed 0.062 milligram per square inch of food-contact surface or shall contact all food types identified in Table 1 of § 176.170(c) of this chapter only under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter. |
| * * * | * * * * |

Dated: June 23, 1998.

**L. Robert Lake,**

*Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.*

[FR Doc. 98–17545 Filed 7–1–98; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 178

**[Docket No. 97F–0469]**

### 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 expanded safe use of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, which may contain up to 1 percent by weight of triisopropanolamine, as an antioxidant and/or stabilizer in high-density polyethylene and high-density olefin copolymers intended for use in contact with food. This action is in response to a petition filed by General Electric Co.

**DATES:** This regulation is effective July 2, 1998. Written objections and requests for a hearing by August 3, 1998.

**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:** 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:** In a notice published in the **Federal Register** of November 20, 1997 (62 FR 62062), FDA announced that a food additive petition (FAP 8B4567) had been filed by General Electric Co., One Lexan Lane, Mt. Vernon, IN 47620–9364. 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 expanded safe use of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, which may contain up to 1 percent by weight of triisopropanolamine, as an antioxidant and/or stabilizer in high-density polyethylene and high-density olefin copolymers (more appropriately identified as high-density polyethylene homopolymers and copolymers) intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe and that the additive will achieve its intended technical effect. Therefore, 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 previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4567 (62 FR 62062). FDA has concluded that the action is of the type that does not individually or cumulatively have a significant effect on the human environment, and that therefore, neither an environmental assessment nor an environmental impact statement is required.

Any person who will be adversely affected by this regulation may at any time on or before August 3, 1998, 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 objection 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.

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.

**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**: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by revising the entry for ''Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester'' by adding item ''4.'' under the heading ''Limitations'' to read as follows:

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

* * * * *

(b) * * *

| Substances | Limitations |
|---|---|
| * * * | * * * * |
| Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester (CAS Reg. No. 161717–32–4), which may contain not more than 1 percent by weight of triisopropanolamine (CAS Reg. No. 122–20–3). | For use only:<br>* * *<br>4. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1(a), 3.1(b), 3.1(c), 3.2 (a), or 3.2(b), having a density not less than 0.94 grams per cubic centimeter, in contact with foods only of types III, IV, V, VI–A, VI–C, VII, VIII, and IX identified in Table 1 of § 176.170(c) of this chapter, and under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter; provided that the food-contact surface does not exceed 0.003 inch (0.076 mm) in thickness. |
| * * * | * * * * |

Dated: June 23, 1998.

**L. Robert Lake,**

*Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.*

[FR Doc. 98–17544 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 510 and 520

### 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 the change of sponsor for two approved new animal drug applications (NADA's) from Danbury Pharmacal, Inc., to Phoenix Scientific, Inc.

**EFFECTIVE DATE:** July 2, 1998.

**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:** Danbury Pharmacal, Inc., 131 West St., Danbury, CT 06810, has informed FDA that it has transferred the ownership of and all rights and interests in the approved NADA's 91–818 and 94–170 (phenylbutazone tablets) to Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457. The agency is amending 21 CFR 510.600(c)(1) and (c)(2) to remove the sponsor name for Danbury Pharmacal, Inc., because the firm no longer is the holder of any approved NADA's. The agency also is amending 21 CFR 520.1720a to reflect the change of sponsor.

**List of Subjects**

*21 CFR Part 510*

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

*21 CFR Parts 520*

Animal drugs.

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 520 are amended as follows:

## PART 510—NEW ANIMAL DRUGS

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

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

**§ 510.600 [Amended]**

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Danbury Pharmacal, Inc.''; and in the table in paragraph (c)(2) by removing the entry for ''000591''.

## PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

**§ 520.1720a [Amended]**

4. Section 520.1720a *Phenylbutazone tablets and boluses* is amended in paragraph (b)(3) by removing the numbers ''000591, 000856, 000864, and 015579'' and adding in their place the numbers ''000856, 000864, 015579, and 059130''.