DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 96F–0051]

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 expand the safe use of oxidized bis(hydrogenated tallow alkyl) amines as a process stabilizer for polypropylene homo- and copolymers and high-density polyethylene homo- and copolymers intended for use in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective July 23, 1997; written objections and requests for a hearing by August 22, 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: Mark A. Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 23, 1996 (61 FR 7005), FDA announced that a food additive petition (FAP 6B4491) had been filed by Ciba-Geigy Corp., 540 White Plains Rd., P.O. Box 2005, Tarrytown, NY 10591–9005 (zip code was incorrectly identified as 10591–4311). The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to expand the safe use of oxidized bis(hydrogenated tallow alkyl) amines as a process stabilizer for polypropylene homo- and copolymers and high-density polyethylene homo- and copolymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive as a process stabilizer for polypropylene homo- and copolymers and high-density polyethylene homo- and copolymers is safe and that the additive will have the 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 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. No comments were received during the 30-day comment period specified in the filing notice for comments on the environmental assessment submitted with the petition.

Any person who will be adversely affected by this regulation may at any time on or before August 22, 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 revising ''Limitations'' for the entry ''Oxidized bis(hydrogenated tallow alkyl) amines'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
Oxidized bis (hydrogenated tallow alkyl) amines	For use only: 1. At levels not to exceed 0.1 percent by weight of polypropylene polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, 1.3, 3.1a (density not less than 0.85 gram per cubic centimeter and less than 0.91 gram per cubic centimeter), 3.2b, 3.4, and 3.5. The finished polymers may be used in contact with food types I, II, IV–B, VII–B and VIII described in Table 1 of § 176.170(c) of this chapter, under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter and with food types III, IV–A, V, VI, VII–A, and IX described in Table 1 of § 176.170(c) of this chapter, under conditions of use D through H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.075 percent by weight of high-density polyethylene polymers complying with § 177.1520(c) of this chapter, item 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.6 (density not less than 0.94 gram per cubic centimeter), and 5. The finished polymers may be used in contact with food types I, II, IV–B, VII–B and VIII described in Table 1 of § 176.170(c) of this chapter, under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, and with food types III, IV–A, V, VI, VII–A and IX described in Table 1 of § 176.170(c) of this chapter, under conditions of use D through H described in Table 2 of § 176.170(c) of this chapter.
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Dated: July 3, 1997.

Janice F. Oliver,

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

[FR Doc. 97–19250 Filed 7–22–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor Address

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 address for Hoechst Roussel Vet.

EFFECTIVE DATE: July 23, 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: Hoechst Roussel Vet, Rt. 202–206, P.O. Box 2500, Somerville, NJ 08876–1258, has informed FDA of a change of sponsor address to Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor address.

List of Subjects in 21 CFR Part 510

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

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 part 510 is 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 revising the entry for ''Hoechst Roussel Vet'' and in the table in paragraph (c)(2) in the entry for ''012799'' by revising the sponsor address to read as follows:

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

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * *	* * *
Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059.	012799
* * *	* * * *

(2) * * *