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Dated: April 28, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–11478 Filed 5–8–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F–1910]

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 2-[4,6-bis(2,4-dimethylphenyl)-1,3,5-triazin-2-yl]-5-(octyloxy)phenol as a stabilizer for olefin polymers intended for use in contact with food. This action is in response to a petition filed by Cytec Industries, Inc.

DATES: This rule is effective May 9, 2000. Submit written objections and requests for a hearing by June 8, 2000.

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 June 22, 1999 (64 FR 33306), FDA announced that a food additive petition (FAP 9B4675) had been filed by Cytec Industries, Inc., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington DC 20001. 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 2-[4,6-bis(2,4-dimethylphenyl)-1,3,5-triazin-2-yl]-5-(octyloxy)phenol as a stabilizer for olefin polymers intended for use in contact with food.

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) that 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 21 CFR 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 9B4675. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

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.

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by June 8, 2000. 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 are to be submitted and are to 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: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by alphabetically adding an entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

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(b) * * *

Substances	Limitations
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2-[4,6-Bis(2,4-dimethylphenyl)-1,3,5-triazin-2-yl]-5-(octyloxy)phenol (CAS Reg. No. 2725–22–6).	For use only: 1. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter in contact with food types I, II, IV–B, VI, VII–B, and VIII described in § 176.170(c) of this chapter, table 1, under conditions of use D through G as described in § 176.170(c), table 2, of this chapter. 2. At levels not to exceed 0.1 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1a, 1.2, and 1.3 in contact with food under conditions of use A through H as described in § 176.170(c), table 2, of this chapter. 3. At levels not to exceed 0.04 percent by weight of polyethylene and olefin copolymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.1c, 3.2a, and 3.2b having a minimum density of 0.94 gram per cubic centimeter, in contact with food under conditions of use A through H as described in § 176.170, table 2, of this chapter provided that the finished articles used in contact with fatty food types III, IV–A, V, VII–A, and IX as described in table 1 of § 176.170(c) of this chapter hold a minimum of 2 gallons (7.6 liters) of food. 4. At levels not to exceed 0.4 percent by weight of ethylene copolymers complying with § 177.1520(c) of this chapter, items 3.1a, 3.1b, 3.1c, 3.2a, and 3.2b, having a density of less than 0.94 gram per cubic centimeter, in contact with food under conditions of use B through H, as described in § 176.170(c), table 2, of this chapter provided that the finished articles used in contact with fatty food types III, IV–A, V, VII–A, and IX hold a minimum of 5 gallons (18.9 liters) of food. 5. At levels not to exceed 0.04 percent by weight of polyethylene having a density of less than 0.94 gram per cubic centimeter, and olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.3a, 3.3b, 3.4, 3.5, 3.6, 4, 5, and 6, in contact with food under conditions of use D through G as described in § 176.170(c) of this chapter, table 2, provided that the finished articles used in contact with fatty food types III, IV–A, V, VII–A, and IX hold a minimum of 5 gallons (18.9 liters) of food.
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Dated: April 27, 2000

L. Robert Lake,

Director of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–11479 Filed 5–8–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Div. of Ivy Animal Health, Inc. The supplemental ANADA provides for subcutaneous use of a cattle ear implant containing trenbolone and estradiol for pasture cattle for increased rate of weight gain. Technical changes are also made.

DATES: This rule is effective May 9, 2000.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed supplemental ANADA 200–221 for use of Component® TE–G (40 milligrams (mg) trenbolone acetate and 8 mg estradiol, in 2 pellets, each pellet containing 20 mg of trenbolone acetate and 4 mg of estradiol) for increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers). The supplemental ANADA is approved as of March 6, 2000, and the regulations in 21 CFR 522.2477 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because