## 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 178.3725 is amended in the table by alphabetically adding an entry under the headings ''Substances'' and ''Limitations'' to read as follows:

**§ 178.3725 Pigment dispersants.**

* * * * *

| Substances | Limitations |
|---|---|
| Dimethylolpropionic acid (CAS Reg. No. 4767–03–7). ..... | For use only at levels not to exceed 0.45 percent by weight of the pigment. The pigmented articles may contact all foods under conditions of use A through H as described in Table 2 of § 176.170(c) of this chapter. |
| * * * * * * * | |

Dated: August 26, 1999.

**L. Robert Lake,**

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

[FR Doc. 99–23001 Filed 9–2–99; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 178

**[Docket No. 98F–0893]**

### 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 siloxanes and silicones, methyl hydrogen, reaction products with 2,2,6,6-tetramethyl-4-(2-propenyloxy)piperidine as an ultraviolet (UV) stabilizer for polypropylene intended for use in contact with food. This action responds to a petition filed by Great Lakes Chemical Corp.

**DATES:** This regulation is effective September 3, 1999. Submit written objections and requests for a hearing by October 4, 1999.

**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 October 21, 1998 (63 FR 56197), FDA announced that a food additive petition (FAP 8B4633) had been filed by Great Lakes Chemical Corp., 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 siloxanes and silicones, methyl hydrogen, reaction products with 2,2,6,6-tetramethyl-4-(2-propenyloxy)piperidine as a UV stabilizer for high density polyethylene and polypropylene intended for use in contact with food.

The petition was subsequently amended to request the use of the additive only in polypropylene, at a maximum level of use of 0.33 percent by weight of the polymer. Because the request to amend the petition is for a use that is within the scope of the filing notice of October 21, 1998, the agency determined that an amended filing notice was not required. Accordingly, the regulation in this document provides for the amended clearance sought by the petitioner.

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) 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 8B4633 (63 FR 56197). 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 collection 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 on or before October 4, 1999, 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:** 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.**

* * * * *

(b) * * *

| Substances | Limitations |
|---|---|
| * * * | * * * * |
| Siloxanes and silicones, methyl hydrogen, reaction products with 2,2,6,6-tetramethyl-4-(2-propenyloxy)piperidine (CAS Reg. No. 182635–99–0). | For use as an ultraviolet (UV) stabilizer only at levels not to exceed 0.33 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1a, 1.1b, 1.2, and 1.3, under conditions of use D, E, F, and G, as described in Table 2 of § 176.170 of this chapter. |
| * * * | * * * * |

Dated: August 26, 1999.

**L. Robert Lake,**

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

[FR Doc. 99–23000 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 510 and 522

### Implantation or Injectable Dosage Form New Animal Drugs; Estradiol and Testosterone, Progesterone and Estradiol, Trenbolone, and Trenbolone and Estradiol, With Tylosin

**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 four supplemental applications filed by Ivy Laboratories, Div. of Ivy Animal Health, Inc., two supplemental new animal drug applications (NADA's) and two supplemental abbreviated new animal drug applications (ANADA's). The supplemental applications provide for addition of tylosin as a local antibacterial to estradiol/testosterone, progesterone/estradiol, trenbolone, and trenbolone/estradiol cattle ear implants. The products are subcutaneous implants for cattle for weight gain and/or feed efficiency.

**EFFECTIVE DATE: SEPTEMBER 3, 1999.**

**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 the following applications:

Supplemental NADA 110–315 for Component® E–S with Tylan® implant (200 milligrams (mg) progesterone and 20 mg estradiol benzoate in eight pellets with 29 mg tylosin tartrate in one pellet) for increased rate of weight gain and improved feed efficiency in steers weighing 400 pounds (lb) or more, and Component E–C® with Tylan® implant (100 mg progesterone and 10 mg estradiol benzoate in four pellets with 29 mg tylosin tartrate in one pellet) for increased rate of weight gain in suckling beef calves up to 400 lb of body weight.

Supplemental NADA 135–906 for Component® E–H with Tylan® implant (20 mg estradiol benzoate and 200 mg testosterone propionate in eight pellets with 29 mg tylosin tartrate in one pellet) for growth promotion and improved feed efficiency in heifers weighing 400 lb or more.

Supplemental ANADA 200–221 for Component® TE–S with Tylan® implant (120 mg trenbolone acetate and 24 mg estradiol in six pellets with 29 mg tylosin tartrate in one pellet) for increased rate of weight gain and improved feed efficiency in feedlot steers.

Supplemental ANADA 200–224 for Component® T–S with Tylan® implant and Component® T–H with Tylan® implant. Component® T–S with Tylan® implant contains 140 mg trenbolone acetate in seven pellets and 29 mg tylosin tartrate in one pellet. It is used for improved feed efficiency in growing-finishing feedlot steers. It should be reimplanted once after 63 days. Component® T–H with Tylan® implant contains 200 mg trenbolone acetate in 10 pellets and 29 mg tylosin tartrate in 1 pellet. It is used for increased rate of weight gain and improved feed efficiency in growing-finishing feedlot heifers. It should be used in feedlot heifers only, during approximately the last 63 days prior to slaughter.

The supplements are approved as of July 20, 1999, and the regulations are amended in § 522.842 (21 CFR 522.842) and 21 CFR 522.1940, 522.2476, and 522.2477 to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

Also, § 522.842 is amended to remove several outdated paragraphs.

In addition, the sponsor has informed FDA of the change of corporate name to Ivy Laboratories, Div. of Ivy Animal Health, Inc. FDA is amending 21 CFR 510.600(c) to reflect the new name.

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 each supplement 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.