

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F-0421]

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 di-*tert*-butyl-*m*-cresyl phosphonite condensation product with biphenyl for use as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food. This action responds to a petition filed by Yoshitomi Fine Chemicals, Ltd.

DATES: The regulation is effective January 19, 1999. Submit written objections and requests for a hearing by February 18, 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: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 17, 1997 (62 FR 54117), FDA announced that a food additive petition (FAP 7B4557) had been filed by Yoshitomi Fine Chemicals, Ltd., 6-9 Hiranomachi 2-chome, Chuo-ku, Osaka 541, Japan. 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 di-*tert*-butylcresyl phosphonite condensation product with biphenyl, produced by the condensation of 2,4-di-*tert*-butylcresol with the Friedel-Crafts addition product of phosphorus trichloride and biphenyl, for use as an

antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

The agency notes that the petitioner later requested that the term meta (*m*) be placed between butyl and cresyl in the name of the subject additive and between butyl and cresol in the name of one of the starting materials in order to provide more accurate and descriptive names. FDA agrees that this nomenclature provides a more accurate description of the additive and its starting materials. Therefore, FDA uses this nomenclature in the final rule.

FDA has evaluated 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 carefully considered the potential environmental effects of this rule as announced in the notice of filing for the petition. 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 on or before February 18, 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 |
|--|--|
| <p>Di-<i>tert</i>-butyl-<i>m</i>-cresyl phosphonite condensation product with biphenyl (CAS Reg. No. 178358-58-2) produced by the condensation of 2,4-di-<i>tert</i>-butyl-<i>m</i>-cresol with the Friedel-Crafts addition product (phosphorus trichloride and biphenyl) so that the food additive has a minimum phosphorus content of 5.0 percent.</p> | <p>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, 2.1, 2.2, 3.1(a), 3.1(b), 3.2(a), or 3.2(b).</p> |

Dated: January 6, 1999.

L. Robert Lake,

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

[FR Doc. 99-1032 Filed 1-15-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin and 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 a supplemental new animal drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly and Co. The supplemental NADA provides for use of monensin and tylosin Type A medicated articles for making Type B and C cattle feeds, the Type C cattle feed to be fed at a range of 60 to 90 milligrams of tylosin per head per day (mg/hd/day) rather than the currently approved 90 mg/hd/day.

EFFECTIVE DATE: January 19, 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: Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 104-646 that provides for combining Rumensin® (80 grams per pound (g/lb) monensin sodium) and Tylan® (40 or 100 g/lb tylosin phosphate) Type A medicated articles to make Type B and C medicated cattle feeds. The Type C medicated cattle feeds are to be fed to

cattle fed in confinement for slaughter at 50 to 360 mg/hd/day monensin and 60 to 90 mg/hd/day tylosin for improved feed efficiency and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces pyogenes*. The tylosin feeding level is the same as currently approved under 21 CFR 558.625(f)(1)(i)(c) for use of tylosin Type C cattle feeds. The supplemental NADA is approved as of November 19, 1998, and the regulations are amended in 21 CFR 558.355(f)(3)(ii)(b) to reflect the approval.

A summary of data and information submitted to support approval of this supplemental 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)(2) 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.

List of Subjects in 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 part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in paragraph (f)(3)(ii)(b) by removing “90” and adding in its place “60 to 90.”

Dated: December 17, 1998.

Andrew J. Beaulieu,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99-1037 Filed 1-15-99; 8:45 am]

BILLING CODE 4160-01-F

POSTAL SERVICE

39 CFR Part 20

Global Direct—Canada Admail Service

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service published an interim rule and request for comment on a new service, Global Direct—Canada Admail, in the **Federal Register** on August 21, 1998, (63 FR 44789). The Postal Service hereby gives notice that it is adopting the interim rule.

EFFECTIVE DATE: January 19, 1999.

FOR FURTHER INFORMATION CONTACT: Walter J. Grandjean, (202) 314-7256.

SUPPLEMENTARY INFORMATION: In cooperation with Canada Post Corporation (CPC), the Postal Service introduced, on an interim basis, Global Direct—Canada Admail. This international mail service is primarily intended for major printing firms, direct marketers, mail order companies, and other high-volume mailers seeking easier access to the Canadian domestic postal system. It is intended to provide mail delivery in an average of 5 to 10 business days in major urban areas throughout Canada. Ancillary services for local business reply and the return of undeliverable mail are also introduced for use with Global Direct—Canada Admail.

On August 21, 1998, the Postal Service published in the **Federal Register** (63 FR 44789) an interim rule and request for comment on this new service, Global Direct—Canada Admail. Comments were requested on or before September 21, 1998.

The Postal Service did not receive any written comments on the interim rule