

employees, officers or directors generally, if the operation of the plan, contract or arrangement uses the same method to allocate benefits to management and nonmanagement participants; and

(v) Any compensatory plan, contract or arrangement if you are furnishing compensation information on an aggregate basis as permitted by Item 6.B.

If you are filing compensatory plans, contracts or arrangements, only file copies of the plans and not copies of each individual's personal agreement under the plans, unless there are particular provisions in a personal agreement that should be filed as an exhibit so investors will understand that individual's compensation under the plan.

5. A list showing the number and a brief identification of each material foreign patent for an invention not covered by a United States patent, but only if we request you to file the list.

6. A statement explaining in reasonable detail how earnings per share information was calculated, unless the computation is clear from material contained in the registration statement or report.

7. A statement explaining in reasonable detail how any ratio of earnings to fixed charges, any ratio of earnings to combined fixed charges and preferred stock dividends or any other ratios in the registration statement or report were calculated.

8. A list of all your subsidiaries, their jurisdiction of incorporation and the names under which they do business. You may omit the names of subsidiaries that, in the aggregate, would not be a "significant subsidiary" as defined in rule 1-02(w) of Regulation S-X as of the end of the year covered by the report. You may omit the names of multiple wholly owned subsidiaries carrying on the same line of business, such as chain stores or service stations, if you give the name of the immediate parent company, the line of business and the number of omitted subsidiaries broken down by U.S. and foreign operations.

9. Statement pursuant to the instructions to Item 8.A.4, regarding the financial statements filed in registration statements for initial public offerings of securities.

10. (a) Any additional exhibits you wish to file as part of the registration statement or report, clearly marked to indicate their subject matter, and (b) any document or part of a document incorporated by reference in this filing if it is not otherwise required to be filed or is not a Commission filed document incorporated in a Securities Act registration statement.

* * * * *

PART 260—GENERAL RULES AND REGULATIONS, TRUST INDENTURE ACT OF 1939

51. The authority citation for part 260 continues to read as follows:

Authority: 15 U.S.C. 77eee, 77ggg, 77nnn, 78sss, 78ll(d), 80b-3, 80b-4, and 80b-11.

§ 260.0-11 [Amended]

51. Amend § 260.0-11 by removing in paragraph (b)(2) the words "Item 9 of Form 20-F (§ 249.220f of this chapter), management's discussion and analysis

of financial condition and results of operations," and adding, in their place, the words "Item 5 of Form 20-F (§ 249.220f of this chapter), "Operating and Financial Review and Prospects,""; and by removing in paragraph (c)(3) the words "Item 9 of Form 20-F" and adding, in their place, the words "Item 5 of Form 20-F".

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 99-25699 Filed 10-4-99; 8:45 am]

BILLING CODE 8010-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 99F-1422]

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 2,4-di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate as an antioxidant and/or stabilizer for polypropylene, polystyrene, rubber-modified polystyrene, and styrene block copolymers intended for use in contact with food. This action responds to a petition filed by Sumitomo Chemical Co., Ltd.

DATES: This regulation is effective October 5, 1999. Submit written objections and requests for a hearing by November 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 May 26, 1999 (64 FR 28501), FDA announced that a food additive petition (FAP 9B4661) had been filed by Sumitomo Chemical Co., Ltd., 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 expanded safe use of 2,4-di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate as an antioxidant and/or stabilizer for polypropylene, polystyrene, rubber-modified polystyrene, and styrene block copolymers 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) 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 9B4661 (64 FR 28501). 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 November 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 revising the entry for “2,4-Di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate” to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

| Substances | Limitations |
|---|---|
| * * * | * * * |
| 2,4-Di- <i>tert</i> -pentyl-6-[1-(3,5-di- <i>tert</i> -pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate (CAS Reg. No. 123968-25-2). | For use only: 1. At levels not to exceed 0.2 percent by weight of polypropylene complying with § 177.1520 of this chapter in contact with food under conditions of use D through G as described in Table 2 of § 176.170(c) of this chapter, except that polypropylene containing the additive at levels not to exceed 0.075 percent by weight may contact food under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 1.0 percent by weight of styrene block polymers complying with § 177.1810 of this chapter. The additive is used under conditions of use D through G as described in Table 2 of § 176.170(c) of this chapter. 3. At levels not to exceed 1.0 percent by weight of polystyrene and rubber modified polystyrene complying with § 177.1640 of this chapter in contact with food under conditions of use D through G as described in Table 2 of § 176.170(c) of this chapter. |
| * * * | * * * |

Dated: September 21, 1999.

L. Robert Lake,

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

[FR Doc. 99-25790 Filed 10-4-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Pyrantel Tartrate

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 Pfizer, Inc. The supplemental NADA provides

for revised feeding instructions for use of pyrantel tartrate Type A medicated articles to make Type C medicated horse feeds.

EFFECTIVE DATE: October 5, 1999.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed supplemental NADA 140-819 that provides for revised feeding instructions for use of Pfizer's pyrantel tartrate Type A medicated articles (Strongid® 48 (48 grams of pyrantel tartrate per pound (g/lb))) to make Type C medicated horse feeds (Strongid® C (4.8 g/lb) and Strongid® C2x (9.6 g/lb)) used for the prevention of *Strongylus vulgaris* larval infections, and control of several types of adult and 4th stage larval large and small strongyle, pinworm, and ascarid infections. The supplement provides for use of a top-dressed Type C feed

containing up to 20,000 g of pyrantel tartrate per ton to be fed at the currently approved rate of 1.2 milligrams per pound of body weight daily. The supplemental NADA is approved as of August 24, 1999, and § 558.485 (21 CFR 558.485) is amended to reflect the approval.

Also, § 558.485(e)(2)(i)(A) is amended to reflect that the organism *Triodontophorus* is now classified as a small strongyle.

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)(3) that this action is of a type that does not individually or cumulatively have a significant effect on