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 6, 1998 (63 FR 53679), FDA announced that a food additive petition (FAP 8B4626) had been filed by BASF Corp., 3000 Continental Dr. North, Mt. Olive, NJ 07828–1234. The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of anthra(2,1,9-def:6,5,10-d′e′f′)diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29) as a colorant for polymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive as a colorant for all polymers intended for use in contact with food is safe and that the additive will have the intended technical effect. Therefore, the regulations in § 178.3297 should be amended as set forth below.

In accordance with § 171.1(h) (21CFR 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 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 June 17, 1999 file with the Dockets Management Branch (address above) a written objection 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 objection 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 178.3297 is amended in the table in paragraph (e), by alphabetically adding an entry for anthra(2,1,9-def:6,5,10-d′e′f′)diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29) under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
Anthra(2,1,9-def:6,5,10-d′e′f′)diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29; CAS Reg. No. 81–33–4)	For use at levels not to exceed 1% by weight of polymers. The finished articles are to contact food only under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: May 5, 1999.

L. Robert Lake,

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

[FR Doc. 99–12396 Filed 5–17–99 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 92F–0285]

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 bis(*p*-ethylbenzylidene) sorbitol as a clarifying agent for polypropylene articles intended for use in contact with food. This action responds to a petition filed by Mitsui Toatsu Chemicals, Inc. (now Mitsui Chemicals, Inc.).

DATES: Effective May 18, 1999; written objections and requests for a hearing by June 17, 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–216), 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 August 10, 1992 (57 FR 35595), FDA announced that a food additive petition (FMY 2B4330) had been filed by Mitsui Toatsu Chemicals, Inc., c/o 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) to provide for the expanded safe use of bis(*p*-ethylbenzylidene) sorbitol as a clarifying agent for polypropylene articles intended for use in contact with food. Subsequent to the filing of the petition, Mitsui Toatsu Chemicals, Inc., merged with Mitsui Chemicals, Inc. Therefore, the current name of the petitioner is Mitsui Chemicals, Inc.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and that therefore the regulations in § 178.3295 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.

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 June 17, 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 178.3295 is amended in the table by revising the entry for ''Bis(*p*-ethylbenzylidene) sorbitol'' to read as follows:

§ 178.3295 Clarifying agents for polymers.

* * * * *

Substances	Limitations
Bis(*p*-ethylbenzylidene) sorbitol (CAS Reg. No. 79072–96–1).	For use only as a clarifying agent at a level not to exceed 0.35 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1a, 1.1b, 3.1a, 3.2a, or 3.2b, where the copolymers complying with items 3.1a, 3.2a, or 3.2b contain not less than 85 weight percent of polymer units derived from propylene.
* * * * * * *	

Dated: May 3, 1999.

L. Robert Lake,

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

[FR Doc. 99–12394 Filed 5–17–99; 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; Fenbendazole

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 Hoechst Roussel Vet. The supplemental NADA provides for revised feeding instructions for using fenbendazole in Type C medicated swine feeds to allow for restricted feeding of sows.

EFFECTIVE DATE: May 18, 1999.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed supplemental NADA 131–675 for fenbendazole Type C medicated swine feeds. The supplemental NADA provides for increasing the concentration of fenbendazole in Type C medicated swine feeds from 10 to 80 grams per ton (g/t) to 10 to 300 g/t to be fed at 9 milligrams per kilogram (mg/kg) (4.08 mg per pound (lb)) over a 3- to 12-day period. The supplement is approved as of April 16, 1999, and the regulations in 21 CFR 558.258(c)(1)(i) are amended to reflect that fenbendazole Type C medicated swine feeds contain 10 to 300 g/t fenbendazole and are fed at 9 mg/kg body weight (4.08 mg/lb) over a 3- to 12-day period.

The supplemental NADA approval provides for clarification of the amount of drug fed to the animals for treatment. No additional safety or effectiveness data were required. Therefore, a freedom of information summary is not 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.

§ 558.258 [Amended]

2. Section 558.258 *Fenbendazole* is amended in paragraph (c)(1)(i) introductory text by removing ''10 to 80'' and adding in its place ''10 to 300''.

Dated: May 4, 1999.

Margaret Ann Miller,

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

[FR Doc. 99–12395 Filed 5–17–99; 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; Lasalocid and Bacitracin Zinc

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 new animal drug application (NADA) filed by Roche Vitamins, Inc. The NADA provides for the use of approved lasalocid Type A medicated articles and bacitracin zinc Type A medicated articles in making Type C medicated feed used for the prevention of coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis,* and *E. adenoeides,* and for increased rate of weight gain and improved feed efficiency in growing turkeys.

EFFECTIVE DATE: May 18, 1999.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298, is the sponsor of NADA 141–109 that provides for the use of 20 percent of lasalocid Type A medicated articles and bacitracin zinc Type A medicated articles containing 50 grams (g) per pound bacitracin activity in making Type C medicated feed containing 68 to 113 g/ton (t) lasalocid and 4 to 50 g/t bacitracin zinc used for the prevention of coccidiosis caused by *Eimeria meleagrimitis, E. gallopavonis,* and *E. adenoeides* and for increased rate of weight gain and improved feed efficiency in growing turkeys. The NADA is approved as of April 15, 1999, and the regulations are amended in 21 CFR 558.78 and 558.311 to reflect the approval. The basis for 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)(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.

2. Section 558.78 is amended by revising paragraph (d)(3)(xii) to read as follows:

§ 558.78 Bacitracin zinc.

* * * * *

(d) * * *

(3) * * *

(xii) Lasalocid sodium alone or with roxarsone as in § 558.311.

* * * * *

3. Section 558.311 is amended in the table by revising paragraph (e)(1)(xiv) to read as follows:

§ 558.311 Lasalocid.

* * * * *