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]

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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; 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]

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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; 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.

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