

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 meleagridis*, *E. gallopavonis*, and *E. adenoides*, 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 meleagridis*, *E. gallopavonis*, and *E. adenoides* 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.

* * * * *

(e)(1) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* * *	* * *	* * *	* * *	* * *
(xiv) 68 (0.0075 pct) to 113 (0.0125 pct)	Bacitracin 4 to 50	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagritidis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> .	Feed continuously as sole ration	000004
		Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagritidis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> ; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration	063238
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Dated: April 30, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99-12393 Filed 5-17-99; 8:45 am]

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DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[TD 8820]

RIN 1545-AU11

Section 467 Rental Agreements; Treatment of Rent and Interest Under Certain Agreements for the Lease of Tangible Property**AGENCY:** Internal Revenue Service (IRS), Treasury.**ACTION:** Final regulations.

SUMMARY: This document contains final regulations relating to the treatment of rent and interest under certain agreements for the lease of tangible property. The regulations apply to certain rental agreements that provide increasing or decreasing rents, or deferred or prepaid rent, and provide guidance for lessees and lessors of tangible property.

DATES: Effective Date: These regulations are effective on May 18, 1999.

Applicability Date: For dates of applicability of these regulations, see Effective Dates under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Forest Boone of the Office of Assistant Chief Counsel (Income Tax and

Accounting) at (202) 622-4960 (not a toll-free number).

SUPPLEMENTARY INFORMATION:**Background**

Section 467 was added to the Internal Revenue Code by section 92(a) of the Tax Reform Act of 1984 (Pub. L. 98-369 (98 Stat. 609)). On June 3, 1996, the IRS and Treasury Department issued a notice of proposed rulemaking (61 FR 27834 [IA-292-84, 1996-2 C.B. 462]) relating to section 467. The proposed regulations provide guidance regarding the applicability of section 467, and the amount of rent and interest required to be accrued under section 467.

Comments responding to the notice were received, and a public hearing was held on September 25, 1996.

The IRS and Treasury Department issued interim guidance in Notice 97-72 (1997-2 C.B. 334), which informed taxpayers of certain conditions under which a refinancing of indebtedness incurred by a lessor to acquire property that is the subject of a rental agreement will not be considered a substantial modification of that agreement for purposes of section 467. After considering the comments that were received in response to the notice of proposed rulemaking and the statements made at the public hearing, the proposed regulations are adopted as revised by this Treasury decision. The significant comments and revisions are discussed below.

Explanation of Provisions**1. Section 467 Rental Agreements**

Under the proposed and final regulations, section 467 applies to any rental agreement with increasing or decreasing rent and aggregate rental

payments or other consideration of more than \$250,000. A rental agreement has increasing or decreasing rents if the annualized fixed rent allocated to any rental period exceeds the annualized fixed rent allocated to any other rental period in the lease term.

In determining whether a rental agreement has increasing or decreasing rent, the proposed regulations provide that a rent holiday at the beginning of the lease term is disregarded if the rent holiday period is three months or less. Several commentators requested that the rent holiday period be lengthened, arguing that it should be the same as the rent holiday period permitted for determining whether a leaseback or long-term agreement has tax-motivated increasing rents (the lesser of 24 months or 10 percent of the lease term). The final regulations do not adopt this suggestion.

Section 467(d)(1)(B) provides that a rental agreement will be treated as a section 467 rental agreement if there are increases in the amount to be paid as rent under the agreement. Except for the \$250,000 de minimis exception set forth in section 467(d)(2), section 467 does not contain any exceptions to the rule that rental agreements with increasing rent are section 467 rental agreements. The three-month rent holiday exception was added in the proposed regulations to prevent relatively insubstantial rent holidays from causing a rental agreement to be treated as a section 467 rental agreement. Accordingly, the three-month rent holiday exception is intended merely as a de minimis exception and a rule of administrative convenience. In contrast, Congress specifically directed that a rent holiday safe harbor should be provided for