

in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 522 and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. Section 522.468 is added to read as follows:

§ 522.468 Colistimethate sodium powder for injection.

(a) *Specifications.* Each vial contains colistimethate sodium equivalent to 10 grams colistin activity and mannitol to be reconstituted with 62.5 milliliters sterile saline or sterile water for injection. The resulting solution contains colistimethate sodium equivalent to 133 milligrams per milliliter colistin activity.

(b) *Sponsor.* See 046573 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) 1- to 3-day-old chickens.

(i) *Dosage.* 0.2 milligram colistin activity per chicken.

(ii) *Indications for use.* Control of early mortality associated with *Escherichia coli* organisms susceptible to colistin.

(iii) *Limitations.* For subcutaneous injection in the neck of 1- to 3-day-old chickens. Not for use in laying hens producing eggs for human consumption. Do not use in turkeys. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.167 is added to read as follows:

§ 556.167 Colistimethate.

A tolerance for residues of colistimethate in the edible tissues of chickens is not required.

Dated: February 22, 1998.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 98-6909 Filed 3-17-98; 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; Narasin, Bambermycins, and Roxarsone

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 Hoechst Roussel Vet. The NADA provides for using approved single ingredient Type A medicated articles to make Type C medicated broiler feeds containing narasin, bambermycins, and roxarsone.

EFFECTIVE DATE: March 18, 1998.

FOR FURTHER INFORMATION CONTACT:

Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2604.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed NADA 140-843 that provides for using approved single ingredient Type A medicated articles, Monteban® (45 grams (g) narasin activity per pound (/lb)), Flavomycin® (4 and 10 g bambermycins activity/lb), and 3-Nitro® (45.4, 90, and 227 g roxarsone/lb), to make Type C medicated broiler feeds containing 54 to 72 g narasin, 1 to 2 g bambermycins, and 22.7 to 45.4 g roxarsone/ton of feed. The Type C medicated broiler feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. mivati*, *E. acervulina*, *E. maxima*, and *E. brunetti*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens. NADA 140-843 is approved as of March 18, 1998.

Accordingly §§ 558.363 and 558.366 (21 CFR 558.363 and 558.366) are amended to reflect the approval. The

basis for approval is discussed in the freedom of information summary. In addition, 21 CFR 558.95(d)(5) is amended by adding new paragraph (d)(5)(iii) to provide a cross-reference to the 3-way combination drug Type C medicated feed.

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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. to 4 p.m., Monday through Friday.

This approval is for use of approved Type A medicated articles to make combination Type C medicated feeds. One ingredient, roxarsone, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required for making a Type B or Type C medicated feed as in this application. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of narasin, bambermycins, and roxarsone Type A medicated articles to make Type C medicated feeds as provided in NADA 140-843 requires a feed mill license rather than an approved FDA Form 1900.

Under section 512(c)(2)(F)(ii) of the act, this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning March 18, 1998 because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval and conducted or sponsored by the applicant.

FDA 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 558.95 is amended by adding paragraph (d)(5)(iii) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(5) * * *

(iii) Narasin and roxarsone as in § 558.363.

3. Section 558.363 is amended by revising paragraph (a), redesignating paragraph (c) as paragraph (d) and reserving paragraph (c), and by adding paragraph (d)(1)(vii), to read as follows:

§ 558.363 Narasin.

(a) *Approvals.* Type A medicated articles containing specified levels of narasin approved for sponsors identified in § 510.600(c) of this chapter for use as in paragraph (d) of this section are as follows:

(1) To 000986: 36, 45, 54, 72, and 90 grams per pound, paragraph (d)(1)(i) of this section.

(2) To 000986: 36, 45, 54, 72, and 90 grams per pound, with 10, 20, 50, and 80 percent roxarsone, paragraph (d)(1)(ii) of this section.

(3) To 000986: 36 grams per pound, with 36 grams per pound nicarbazin, paragraph (d)(1)(iii) of this section.

(4) To 012799: 36, 45, 54, 72, and 90 grams per pound, with 2 and 10 grams per pound bambermycins, paragraph (d)(1)(iv) of this section.

(5) To 012799: 45 grams per pound, with 4 and 10 grams per pound bambermycins, and 45.4, 90, and 227 grams per pound roxarsone, paragraph (d)(1)(vii) of this section.

* * * * *

(d) * * *

(1) * * *

(vii) *Amount per ton.* Narasin 54 to 72 grams, bambermycins 1 to 2 grams, and roxarsone 22.7 to 45.4 grams.

(A) *Indications for use.* For prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. mivati*, *E. acervulina*, *E. maxima*, and *E. brunetti*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys or horses or other equines

access to formulations containing narasin. Ingestion of narasin by these animals has been fatal. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of water intake may result in leg weakness or paralysis. Withdraw 5 days before slaughter. Narasin as provided by 000986 in § 510.600(c) of this chapter, bambermycins by 012799, and roxarsone by 046573.

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§ 558.366 [Amended]

4. Section 558.366 *Nicarbazin* is amended, in paragraph (c) in the table in the first entry, under the column "Limitations" by removing "558.363(c)(1)(iii)" and by adding in its place "558.363(d)(1)(iii)."

Dated: February 22, 1998.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 98-6905 Filed 3-17-98; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 8739]

RIN 1545-AV09

IRS Adoption Taxpayer Identification Numbers; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final and temporary regulations.

SUMMARY: This document contains corrections to Treasury Decision 8739, which was published in the **Federal Register** on Monday, November 24, 1997 (62 FR 62518) relating to taxpayer identifying numbers.

DATES: This correction is effective November 24, 1997.

FOR FURTHER INFORMATION CONTACT: Michael L. Gompertz, (202) 622-4910 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of these corrections are under section 6109 of the Internal Revenue Code.

Need for Correction

As published, TD 8739 contains errors which may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final and temporary regulations (TD 8739), which was the subject of FR Doc. 97-30550, is corrected as follows:

§ 301.6109-1 [Corrected]

1. On page 62520, column 2, § 301.6109-1(h)(2)(iii), line 1, the language "(iii) Paragraphs (a)(1)(i), (a)(1)(ii)(A)," is corrected to read "(iii) Paragraphs (a)(1)(i), (a)(1)(ii) introductory text, (a)(1)(ii)(A).". On the last two lines of the paragraph, the language "(a)(1)(ii) introductory text, and (a)(1)(ii)(A) and (B).". is corrected to read "(a)(1)(ii) introductory text, (a)(1)(ii)(A) and (a)(1)(ii)(B).".

§ 301.6109-1T [Corrected]

2. On page 62520, column 3, § 301.6109-1T(h), the last three lines of the paragraph, the language "further guidance prior to November 24, 1997, see § 301.6109-1(a)(1)(i), (a)(1)(ii)(A) and (a)(1)(ii)(B).". is corrected to read "guidance applicable prior to November 25, 1997, see § 301.6109-1(a)(1)(i), (a)(1)(ii) introductory text, (a)(1)(ii)(A) and (a)(1)(ii)(B).".

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 98-6927 Filed 3-17-98; 8:45 am]

BILLING CODE 4830-01-U

POSTAL SERVICE

39 CFR Part 20

Implementation of New Market Opportunities Program

AGENCY: Postal Service.

ACTION: Interim rule.

SUMMARY: The Postal Service proposes to adopt, as an interim rule, new rates and conditions of mailing for the New Market Opportunities Program. This program is designed to meet the needs of direct mail and mail order companies seeking to easily and cost effectively enter the international marketplace. It is available for companies who wish to test sending catalogs and merchandise to any or all of the following markets: Brazil, Canada, Chile, China, France, Germany, Hong Kong, Japan, Mexico, Singapore, and the United Kingdom. A mailer will send catalogs using International Surface Air Lift or VALUEPOST™/CANADA service and merchandise using Global Package Link. To assist the mailers' tests in these markets, the Postal Service includes other services as part of the program, including translation of order form and