DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Milbemycin Oxime

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 Ciba-Geigy Animal Health, Ciba-Geigy Corp. The supplemental NADA provides for expanding the indications for use of milbemycin oxime tablets in dogs and puppies to include removal and control of adult roundworm infections caused by *Toxascaris leonina*.

EFFECTIVE DATE: August 26, 1996.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Ciba-Geigy Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419–8300, is the sponsor of NADA 140–915, which covers Interceptor® (milbemycin oxime) tablets. The product is currently approved for the prevention of heartworm disease caused by *Dirofilaria immitis*, control of hookworm infections caused by *Ancylostoma caninum*, and removal and control of adult roundworm infections caused by *Toxocara canis* and whipworm infections caused by *Trichuris vulpis* in dogs and in puppies 4 weeks of age or greater and 2 pounds of body weight or greater. The supplemental NADA provides for expanding the indications for use in both dogs and puppies by adding removal and control of the adult roundworm *T. leonina*. The drug is available by veterinary prescription.

The supplemental NADA 140–915 is approved as of July 9, 1996, and the regulations are amended in 21 CFR 520.1445(c)(2) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity for the new indications beginning on July 9,1996, because the application includes reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted by the sponsor.

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.

List of Subjects in 21 CFR Part 520

Animal drugs.

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.1445 [Amended]

2. Section 520.1445 *Milbemycin oxime tablets* is amended in paragraph (c)(2) by adding the phrase ''and *Toxascaris leonina*'' after ''*Toxocara canis*''.

Dated: August 14, 1996.

Robert C. Livingston,

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

[FR Doc. 96–21728 Filed 8–23–96; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Bambermycins

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 Agri-Vet Co. The supplemental NADA provides for using bambermycins Type A medicated articles to make a bambermycins free-choice Type C medicated loose mineral feed for pasture cattle (slaughter, stocker, and feeder) for increased rate of weight gain.

EFFECTIVE DATE: August 26, 1996.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Hoechst-Roussel Agri-Vet Co., Rt. 202–206, P.O. Box 2500, Somerville, NJ 08876–1258, filed supplemental NADA 141–034, which provides for using 10-grams per pound (g/lb) Flavomycin® (bambermycins) Type A medicated articles to make free-choice Type C medicated loose mineral feeds containing 120 g/ton bambermycins for pasture cattle (slaughter, stocker, and feeder). The Type C feeds are fed at 10- to 20-milligrams (mg) bambermycins per head per day for increased rate of weight gain. The supplemental NADA is approved as of August 26, 1996, and the regulations are amended in 21 CFR 558.95(b)(4)(iii) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

As required by 21 CFR 510.455, use of a Type A medicated article to make a free-choice Type C medicated feed/medicated loose mineral feed requires an approved Form FDA 1900.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning August 26, 1996, because it contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant. Marketing exclusivity applies only to the new use.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.95 is amended by adding new paragraph (b)(4)(iii) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(b) * * *

(4) * * *

(iii) Used as a free-choice Type C medicated loose mineral feed for pasture cattle (slaughter, stocker, and feeder) as follows:

(*a*) *Specifications.*

Ingredient	International Feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6–01–080	42.50
Sodium chloride (salt)	6–04–152	20.10
Calcium carbonate (38% calcium)	6–01–069	15.24
Corn distillers dried grains w/solubles	5–28–236	9.57
Magnesium oxide	6–02–756	5.15
Vitamin and trace mineral premix *	.....	3.72
Mineral oil	.....	1.00
Yeast (primary dehydrated yeast)	7–05–533	0.75
Bambermycins Type A article (10 g/lb)	.....	0.60
Iron oxide	6–02–431	0.50
Magnesium sulfate (67%)	6–02–758	0.32
Selenium premix (270 mg/lb) *	.....	0.21
Copper sulfate	6–01–720	0.18
Potassium sulfate (0.33%)	6–06–098	0.16

*Content of vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(*b*) *Amount per ton.* 120 grams.

(*c*) *Indications for use.* For increased rate of weight gain.

(*d*) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder). Feed a nonmedicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 5.33 ounces per head per day. Feed continuously to provide 10- to 20-milligrams bambermycins per head per day. Not for use in animals intended for breeding. Each use of this free-choice Type C medicated feed must be the subject of an approved Form FDA 1900 as required by 21 CFR 510.455.

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Dated: August 16, 1996.

Robert C. Livingston,

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

[FR Doc. 96–21654 Filed 8–23–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 26

[TD 8644]

RIN 1545–AJ11; 1545–AL75; 1545–AO89

Generation-Skipping Transfer Tax; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations (TD 8644) which were published in the Federal Register for Wednesday, December 27, 1995 (60 FR 66898), as corrected on June 12, 1996 (61 FR 29653). The final regulations relate to generation-skipping transfer tax.

EFFECTIVE DATE: December 27, 1995.

FOR FURTHER INFORMATION CONTACT: Jim Hogan (202) 622–3090 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are subject to these corrections are under chapter 13 of the Internal Revenue Code.

Need for Correction

As published, TD 8644, as corrected, contains errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 26

Estate taxes, Reporting and recordkeeping requirements.

Accordingly, 26 CFR part 26 is corrected by making the following correcting amendments:

PART 26—GENERATION-SKIPPING TRANSFER TAX REGULATIONS UNDER THE TAX REFORM ACT OF 1986

Paragraph 1. The authority citation for part 26 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 26.2601–1 [Corrected]

Par. 2. In § 26.2601–1, paragraph (b)(3)(iii)(B) is amended by revising ''(b)(3)(iii)(A), (B), and (C)'' to read ''(b)(3)(iii)(A)(*1*), (*2*), and (*3*)''.

§ 26.2642–5 [Corrected]

Par. 3. Section 26.2642–5 is amended by removing the punctuation '';'' following the word ''ratio'' in the first sentence of paragraph (b)(1).

§ 26.2654–1 [Corrected]

Par. 4. Section 26.2654–1 is amended by revising paragraph (a)(1)(ii)(B) to read as follows:

§ 26.2654–1 Certain trusts treated as separate trusts.

(a) * * * (1) * * *

(ii) * * *

(B) If the pecuniary amount is payable in kind on the basis of value other than the date of distribution value of the assets, the trustee is required to allocate assets to the pecuniary payment in a manner that fairly reflects net appreciation or depreciation in the value of the assets in the fund available to pay the pecuniary amount measured from the valuation date to the date of payment.

* * * * *

Michael L. Slaughter,

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

[FR Doc. 96–21598 Filed 8–23–96; 8:45 am]

BILLING CODE 4830–01–U

Fiscal Service

31 CFR Part 214

RIN 1510–AA54

Depositaries for Federal Taxes

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: This action removes Part 214 from Title 31 of the Code of Federal Regulations. Part 214 governed the designation of financial institutions as depositaries for Federal taxes and the handling of deposits of Federal taxes by such depositaries and by Federal Reserve Banks. A Notice of Proposed Rule Making published October 27, 1992, proposed to combine portions of this part with 31 CFR Part 203 ''Treasury Tax and Loan Depositaries'' and to eliminate Part 214. Regulations published on July 1, 1993, incorporated the relevant provisions of Part 214 into Part 203. Part 214 should have been removed at that time. This action corrects that oversight.

EFFECTIVE DATE: September 25, 1996.

ADDRESS: Cash Management Policy and Planning Division, Financial Management Service, U.S. Department of the Treasury, Room 420, Liberty Center, 401 14th Street, S.W., Washington, DC 20227.

FOR FURTHER INFORMATION CONTACT: Donald E. Clark (202) 874–7106 (Financial Program Specialist).

SUPPLEMENTARY INFORMATION:

Background

On October 27, 1992, the Fiscal Service published a Notice of Proposed Rule Making to remove Part 214 and to revise sections of Part 203 of Title 31 of the Code of Federal Regulations. No comments on the proposed rule were received. Accordingly, on July 1, 1993, portions of this regulation were incorporated into Part 203 ''Treasury Tax and Loan Depositaries.'' (58 FR 35395). Part 214 should have been removed at that time. This action rectifies that oversight.

Rulemaking Analysis

Treasury has determined that this regulation is not a significant regulatory action as defined in Executive Order 12866. Accordingly, a regulatory assessment is not required. It is hereby certified that this revision will not have a significant economic impact on a substantial number of small entities. Because the provisions of Part 214, here being eliminated, are duplicative of those contained in Part 203, there will not be a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required.

List of Subjects in 31 CFR Part 214

Banks, Banking, Taxes.

For the reasons set out in the preamble and under the authority of 31 U.S.C. 321, 31 CFR Part 214 is removed.