Bulletin DC9–53–278, dated November 4, 1996, and McDonnell Douglas Service Bulletin DC9–53–278, Revision 01, dated April 29, 1999. This incorporation by reference was approved previously by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 as of August 18, 1999 (64 FR 37838, July 14, 1999). Copies may be obtained from The Boeing Company, Douglas Products Division, P.O. Box 1771, Long Beach, California 90846–1771, Attention: Business Unit Manager, Contract Data Management, C1–255 (35–22). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(i) The effective date of this amendment remains August 18, 1999.

Issued in Renton, Washington, on September 3, 1999.

Dorenda D. Baker,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–23472 Filed 9–9–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Doramectin

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 Pfizer, Inc. The supplemental NADA provides for further use of doramectin in cattle for treatment and control of the gastrointestinal roundworm *Trichostrongylus axei* L4 and for control of and protection from reinfection with *Haemonchus placei* for 35 days after treatment.

EFFECTIVE DATE: September 10, 1999.

FOR FURTHER INFORMATION CONTACT: Thomas Letonja, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7576.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed supplemental NADA 141–095 that provides for topical use of Dectomax® (doramectin) pour-on solution for further use on cattle for treatment and control of *T. axei* L4 and for control of and protection from reinfection with *H. placei* for 35 days after treatment. The supplemental NADA is approved as of August 10, 1999, and the regulations are amended in 21 CFR 524.770(d)(2) to reflect this approval. The basis of 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 supplemental 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.

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 supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning August 10, 1999, because the supplement 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 of the supplement and conducted or sponsored by the applicant. Exclusivity applies only to the added indication for use of doramectin topical in cattle for treatment and control of *T. axei* L4 and for control of and protection from reinfection with *H. placei* for 35 days after treatment.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

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

2. Section 524.770 is amended by revising paragraph (d)(2) to read as follows:

§ 524.770 Doramectin.

* * * * *

(d) * * *

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, *Ostertagia ostertagi*, *C. punctata*, and *Oesophagostomum radiatum* for 28 days, and *Haemonchus placei* for 35 days after treatment.

* * * * *

Dated: August 27, 1999.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation.

[FR Doc. 99–23466 Filed 9–9–99; 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 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 new animal drug application (NADA) filed by Hoechst Roussel Vet. The NADA provides for combining approved single ingredient lasalocid and bambermycins Type A medicated articles to make Type C medicated broiler feeds to be used for prevention of certain forms of coccidiosis and for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: September 10, 1999.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–28), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed NADA 141–129 that provides for combining approved single ingredient Avatec® (lasalocid) and Flavomycin® (bambermycins) Type A medicated articles to make Type C medicated broiler feeds containing 68 to 113 grams per ton (g/t) lasalocid and 1 to 2 g/t bambermycins. The Type C medicated broiler feeds are used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency in broiler chickens. The NADA is approved as of August 6, 1999, and the regulations are amended in 21 CFR 558.95 by adding paragraph (d)(1)(xiv) and in 21 CFR 558.311 by adding paragraph (e)(4)(ii) to reflect the approval.

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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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)(1)(xiv) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(1) * * *

(xiv) *Amount per ton*. Bambermycins 1 to 2 grams, plus lasalocid 68 to 113 grams.

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

(*b*) *Limitations*. For broiler chickens only. Feed continuously as sole ration. Lasalocid as provided by No. 063238 in § 510.600(c) of this chapter.

* * * * *

3. Section 558.311 is amended by adding paragraph (e)(4)(ii) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

(4) * * *

(ii) Bambermycins as in § 558.95 of this chapter.

Dated: August 30, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–23467 Filed 9–9–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 200

[T.D. ATF–414]

RIN 1512–AB91

Rules of Practice in Permit Proceedings; Technical Amendments

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: This Treasury decision amends the provisions of its rules of practice in permit proceedings to change the title designation ''District Director'' to ''Director of Industry Operations (DIO)'' wherever it appears, and to make other necessary conforming amendments. All such changes are to provide clarity and uniformity throughout Title 27 Code of Federal Regulations.

EFFECTIVE DATE: September 10, 1999.

FOR FURTHER INFORMATION CONTACT: Nancy M. Kern, Regulations Division, 650 Massachusetts Avenue, NW, Washington, DC 20226, (202–927–8210).

SUPPLEMENTARY INFORMATION:

Background

The Bureau of Alcohol, Tobacco and Firearms (ATF) administers regulations published in Chapter I of Title 27 Code of Federal Regulations. ATF determined that the regulations in part 200 should be revised to reflect the current ATF field structure reorganization, which established the positions of ''Director of Industry Operations'' for the respective ATF operating Field Divisions, and eliminated the positions of ''District Directors'' (formerly Regional Directors) for such districts.

These amendments do not make any substantive changes and are only intended to improve the clarity of Title 27.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR part 1320, do not apply to this final rule because there are no recordkeeping or reporting requirements.

Regulatory Flexibility Act

Because no notice of proposed rulemaking is required for this rule, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

Executive Order 12866

This final rule is not subject to the requirements of Executive Order 12866 because the regulations make nonsubstantive technical amendments to previously published regulations.

Administrative Procedure Act

Because this final rule merely makes technical amendments and conforming changes to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b), or with the 30-day delayed effective date under 5 U.S.C. 553(b).

Drafting Information

The principal author of this document is Nancy M. Kern, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR 200

Administrative practice and procedure, Authority delegations.

Authority and Issuance

Title 27, Code of Federal Regulations is amended as follows: