PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.2620 [Amended]

4. Section 524.2620 *Liquid crystalline trypsin, Peru balsam, castor oil* is amended in paragraph (a)(2) by removing ''000514'' and adding in its place ''062794''.

Dated: August 23, 2001.

Claire M. Lathers,

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

[FR Doc. 01–22198 Filed 9–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Marbofloxacin Tablets

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 the use of marbofloxacin tablets in cats for the treatment of infections associated with bacteria susceptible to marbofloxacin.

DATES: This rule is effective September 5, 2001.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, is the sponsor of NADA 141–151 that provides for use of Zeniquin™ (marbofloxacin) Tablets for the treatment of infections in dogs associated with bacteria susceptible to marbofloxacin. Pfizer, Inc., filed a supplemental NADA which provides for the addition of cats to product indications. The supplemental NADA is approved as of August 1, 2001, and the regulations in 21 CFR 520.1310 are amended 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 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for non-food-producing animals qualifies for 3 years of marketing exclusivity beginning August 1, 2001, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(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 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

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

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

2. Section 520.1310 is amended by revising paragraphs (a) and (d) to read as follows:

§ 520.1310 Marbofloxacin tablets.

(a) *Specifications.* Each tablet contains 25, 50, 100, or 200 milligrams (mg) marbofloxacin.

* * * * *

(d) *Conditions of use*—(1) *Amount.* 1.25 mg per pound (/lb) of body weight once daily, but may be increased to 2.5 mg/lb of body weight once daily.

(2) *Indications for use.* For the treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

Dated: August 21, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–22165 Filed 9–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Moxidectin

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 Fort Dodge Animal Health. The supplemental NADA provides for topical use of a 0.5 percent moxidectin solution on cattle for treatment and control of infections of additional life stages and species of gastrointestinal roundworms.

DATES: This rule is effective September 5, 2001.

FOR FURTHER INFORMATION CONTACT: Janis Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Div. of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501, filed supplemental NADA 141–099 that provides for use of Cydectin® (moxidectin) 0.5% Pour-On for Beef and Dairy Cattle at 500 micrograms moxidectin per kilogram of body weight for treatment and control of infections of additional life stages and species of gastrointestinal roundworms. The supplemental NADA is approved as of June 18, 2001, and the regulations are amended in 21 CFR 524.1451 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 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.

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 June 18, 2001, because the supplemental 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 of the application and conducted or sponsored by the applicant.

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 impact on 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 the 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 524.1451 is amended by redesignating paragraph (d) as paragraph (e), by removing the last sentence of newly redesignated paragraph (e)(3), by adding new paragraph (d), and by revising newly redesignated paragraph (e)(2) to read as follows.

§ 524.1451 Moxidectin.

* * * * *

(d) *Special considerations.* See § 500.25 of this chapter.

(e) * * *

(2) *Indications for use.* Beef and dairy cattle: For treatment and control of internal and external parasites: gastrointestinal roundworms (*Ostertagia ostertagi* (adult and L4, including inhibited larvae), *Haemonchus placei* (adult and L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *Cooperia oncophora* (adult and L4), *C. pectinata* (adult), *C. punctata* (adult and L4), *C. spatulata* (adult), *C. surnabada* (adult and L4), *Bunostomum phlebotomum* (adult), *Oesophagostomum radiatum* (adult and L4), *Nematodirus helvetianus* (adult and L4)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (H*ypoderma bovis*, *H. lineatum*); mites (*Chorioptes bovis*, *Psoroptes ovis* (*P. communis* var. *bovis*)); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Bovicola*(*Damalinia*) *bovis*); and horn flies (*Haematobia irritans*). To control infections and to protect from reinfection with *H. placei* for 14 days after treatment, *O. radiatum* and *O. ostertagi* for 28 days after treatment, and *D. viviparus* for 42 days after treatment.

* * * * *

Dated: August 24, 2001.

Claire M. Lathers,

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

[FR Doc. 01–22200 Filed 9–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Oxytetracycline; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the tolerance for the sum of residues of the tetracyclines in milk previously established but inadvertently removed in a subsequent amendment and to reflect the correct tolerance of 0.3 part per million oxytetracycline in milk. This action is being taken to improve the accuracy of the agency's regulations.

DATES: This rule is effective September 5, 2001.

FOR FURTHER INFORMATION CONTACT: Lynn G. Friedlander, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6985.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations in § 556.500 (21 CFR 556.500) to reflect the tolerance for the sum of residues of the tetracyclines in milk, which had been established in a final rule published in the **Federal Register** of September 30, 1998 (63 FR 52157 at 52158), but removed in a subsequent amendment to § 556.500 in a final rule published in the **Federal Register** of October 27, 1998 (63 FR 57245 at 57246). At this time, § 556.500 is being amended to reflect the correct tolerance of 0.3 part per million for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline in milk.

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. Publication of this document constitutes final action on this changes under the Administrative Procedure Act (5 U.S.C. 553).

List of Subjects in 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 part 556 is amended as follows:

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

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

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

2. Section 556.500 is amended by revising paragraph (b) to read as follows:

§ 556.500 Oxytetracycline.

* * * * *

(b) *Beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobster, and salmonids.* Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk as follows:

(1) 2 parts per million (ppm) in muscle.

(2) 6 ppm in liver.

(3) 12 ppm in fat and kidney.