FDA 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 Subject in 21 CFR Part 522

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 522 is 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 522.810 is added to read as follows:

§ 522.810 Embutramide, chloroquine, and lidocaine solution.

(a) *Specifications*. Each milliliter (mL) of solution contains 135 milligrams (mg) embutramide; 45 mg chloroquine phosphate, U.S.P.; and 1.9 mg lidocaine, U.S.P.

(b) *Sponsor*. See No. 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. One mL per 5 pounds of body weight.

(2) *Indications for use*. For euthanasia.

(3) *Limitations*. Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: June 10, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–12422 Filed 6–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

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 new animal drug application (NADA) filed by Fort Dodge Animal Health. The NADA provides for use of an injectable moxidectin solution for the treatment and control of various internal and external parasites of cattle.

DATES: This rule is effective June 23, 2005.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571, e-mail: *jgotthar@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed NADA 141–220 that provides for use of CYDECTIN (moxidectin) Injectable Solution for Beef and Nonlactating Dairy Cattle for the treatment and control of various internal and external parasites. The NADA is approved as of May 20, 2005, and the regulations are amended in part 522 (21 CFR part 522) by adding § 522.1450 and in part 556 (21 CFR part 556) by revising § 556.426 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 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 Division of Dockets Management (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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning May 20, 2005.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

■ 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 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 522.1450 is added to read as follows:

§ 522.1450 Moxidectin solution.

(a) *Specifications*. Each milliliter of solution contains 10 milligrams (mg) moxidectin.

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.426 of this chapter.

(d) *Conditions of use in beef and nonlactating dairy cattle.*—(1) *Amount*. 0.2 mg/kilogram body weight (0.2 mg/2.2 pound) as a single subcutaneous injection.

(2) *Indications for use*. For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults and inhibited fourth-stage larvae), *Haemonchus placei* (adults), *Trichostrongylus axei* (adults), *T. colubriformis* (fourth-stage larvae), *Cooperia oncophora* (adults), *C. punctata* (adults and fourth-stage larvae), *C. surnabada* (adults and fourth-stage larvae), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); grubs: *Hypoderma bovis* and *H. lineatum*; mites: *Psoroptes ovis* (*P. communis* var. *bovis*); lice: *Linognathus vituli* and *Solenopotes capillatus*; for protection of cattle from reinfection with *D. viviparus* and *O. radiatum* for 42 days after treatment, with *H. placei* for 35 days after treatment, and with *O. ostertagi* and *T. axei* for 14 days after treatment.

(3) *Limitations*. Do not slaughter cattle within 21 days of treatment. Because a withholding time for milk has not been established, do not use in female dairy

cattle of breeding age. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

§ 522.1451 [Amended]

■ 3. Section 522.1451 is amended by revising the section heading to read ''Moxidectin for suspension.''

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

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

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

■ 5. Section 556.426 is amended by redesignating paragraphs (b)(1)(i) through (b)(1)(iii) as paragraphs (b)(1)(ii) through (b)(1)(iv); by revising newly redesignated paragraphs (b)(1)(ii) and (b)(1)(iv); and by adding new paragraphs (b)(1)(i) and (c) to read as follows:

§ 556.426 Moxidectin.

* * * * *

(b) * * *

(1) * * *

(i) *Fat* (*the target tissue*). The tolerance for parent moxidectin (the marker residue) is 900 parts per billion (ppb).

(ii) *Liver*. The tolerance for parent moxidectin (the marker residue) is 200 ppb.

(iii) * * *

(iv) *Milk*. The tolerance for parent moxidectin (the marker residue) is 40 ppb.

* * * * *

(c) *Related conditions of use*. See § 522.1451 of this chapter.

Dated: June 10, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–12421 Filed 6–22–05; 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; Gentamicin Sulfate, Mometasone Furoate, Clotrimazole Otic Suspension; 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 approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for a new container size, a 7.5-gram dropper bottle, from which gentamicin sulfate, mometasone furoate, clotrimazole otic suspension may be administered for the treatment of otitis externa in dogs. The regulations are also being amended to correct the description of a previously approved container size. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective June 23, 2005.

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, e-mail: *melanie.berson@fda.gov*.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 141–177 for use of MOMETAMAX (gentamicin sulfate, U.S.P.; mometasone furoate monohydrate; and clotrimazole, U.S.P.) Otic Suspension for the treatment of otitis externa in dogs. The supplement provides for a new container size, a 7.5-gram dropper bottle. The supplemental NADA is approved as of June 1, 2005, and the regulations are amended in 21 CFR 524.1044h to reflect the approval.

The regulations are also being amended to correct the description of a previously approved container size. This action is being taken to improve the accuracy of the regulations.

The agency has determined under 21 CFR 25.33(a)(4) 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 Subject 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 524.1044h is amended by revising paragraphs (b) and (c)(1) to read as follows:

§ 524.1044h Gentamicin sulfate, mometasone furoate, clotrimazole otic suspension.

* * * * *

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. For dogs weighing less than 30 pounds (lb), instill 4 drops from the 7.5-, 15-, or 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 7.5-, 15-, or 30-g bottle into the ear canal (4 drops from the 215-g bottle), once or twice daily for 7 days.

* * * * *

Dated: June 15, 2005.

Steven D. Vaugh,

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

[FR Doc. 05–12402 Filed 6–22–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1306

[Docket No. DEA–202F]

RIN 1117–AA68

Authority for Practitioners To Dispense or Prescribe Approved Narcotic Controlled Substances for Maintenance or Detoxification Treatment

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is amending its regulations to allow qualified practitioners not otherwise registered as a narcotic treatment program to dispense and prescribe to narcotic dependent persons Schedule III, IV, and V narcotic controlled drugs approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment. This Final Rule is in response to amendments to the Controlled Substances Act by the Drug Addiction Treatment Act of 2000 (DATA) that are designed to expand and