animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for over-the-counter (OTC) marketing status for oral use of oxfendazole suspension in cattle.

DATES: This rule is effective March 9, 2007.

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: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 140–854 for SYNANTHIC (oxfendazole) Bovine Dewormer Suspension, approved for oral use in cattle for the removal of various internal parasites. The supplemental NADA provides for OTC marketing status. The supplemental application is approved as of January 29, 2007, and the regulations are amended in 21 CFR 520.1630 to reflect the approval and a current format. 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.

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 Parts 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. Amend § 520.1630 as follows:

■ a. Redesignate paragraph (d) as paragraph (e);

■ b. Add new paragraph (d);

■ c. Revise the introductory text in newly redesignated paragraphs (e)(1) and (e)(2); and

■ d. Revise paragraph (a) and newly redesignated paragraphs (e)(1)(i), (e)(1)(iii), (e)(2)(i), and (e)(2)(iii).

The redesignation, addition, and revisions read as follows:

§ 520.1630 Oxfendazole suspension.

(a) *Specifications*. Each milliliter of suspension contains:

(1) 90.6 milligrams (mg) oxfendazole (9.06 percent).

(2) 225.0 mg oxfendazole (22.5 percent).

* * * * *

(d) *Special considerations*. See § 500.25 of this chapter. If labeled for administration by stomach tube: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses*. Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount*. 10 mg per kilogram (/kg) of body weight by stomach tube or dose syringe. Horses maintained on premises where reinfection is likely to occur should be retreated in 6 to 8 weeks.

* * * * *

(iii) *Limitations*. Withholding feed or water prior to use is unnecessary. Administer drug with caution to sick or debilitated horses. Do not use in horses intended for human consumption.

(2) *Cattle*. Use the products described in paragraphs (a)(1) and (a)(2) of this section as follows:

(i) *Amount*. 4.5 mg/kg of body weight by dose syringe. Treatment may be repeated in 4 to 6 weeks.

* * * * *

(iii) *Limitations*. Cattle must not be slaughtered until 7 days after treatment. Do not use in lactating dairy cattle.

Dated: February 21, 2007.

Steven D. Vaughn,

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

[FR Doc. E7–4205 Filed 3–8–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Enrofloxacin

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 Bayer HealthCare LLC. The supplemental NADA provides for changing scientific nomenclature for a bovine respiratory pathogen on labeling for enrofloxacin injectable solution.

DATES: This rule is effective March 9, 2007.

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: *joan.gotthardt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 141 068 for BAYTRIL 100 (enrofloxacin) Injectable Solution used for the treatment of bovine respiratory disease associated with several bacterial pathogens. The supplemental NADA provides for changing a pathogen name from *Pasteurella haemolytica* to *Mannheimia haemolytica* on product labeling. The supplemental NADA is approved as of February 15, 2007, and the regulations in 21 CFR 522.812 are amended to reflect the approval and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33 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 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. Revise § 522.812 to read as follows:

§ 522.812 Enrofloxacin.

(a) *Specifications*. Each milliliter (mL) of solution contains:

(1) 22.7 milligrams (mg) enrofloxacin or

(2) 100 mg enrofloxacin.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerance*. See § 556.228 of this chapter.

(d) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

(e) *Conditions of use*—(1) *Dogs*. Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount*. 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days.

(ii) *Indications for use*. For the management of diseases associated with bacteria susceptible to enrofloxacin.

(2) *Cattle*. Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amount*. Single-dose therapy: 7.5 to 12.5 mg/kg of body weight (3.4 to 5.7 mL per 100 pounds) by subcutaneous injection. Multiple-day therapy: 2.5 to 5.0 mg/kg of body weight (1.1 to 2.3 mL per 100 pounds) by subcutaneous injection once daily for 3 to 5 days.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*.

(iii) *Limitations*. Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been establishedfor this product in pre-ruminating calves. Do not use in calves to be processed for veal. The effect of enrofloxacin on bovine reproductive performance, pregnancy, and lactation have not been determined.

Dated: February 28, 2007.

Steven D. Vaughn,

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

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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; Imidacloprid and 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 two new animal drug applications (NADAs) filed by Bayer HealthCare LLC. The NADAs provide for the topical use by veterinary prescription of topical solutions containing imidacloprid and two strengths of moxidectin, one for use on dogs and the other for use on cats, for the prevention of heartworm disease, the treatment of flea infestations, and the treatment and control of several internal parasites.

DATES: This rule is effective March 9, 2007.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; tel: 301–827–7540; e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 141–251 that provides for veterinary prescription use of ADVANTAGE MULTI (imidacloprid 10% and moxidectin 2.5%) for Dogs, a topical solution used for the prevention of heartworm disease, the treatment of flea infestations, and the treatment and control of several internal parasites. Bayer HealthCare LLC also filed NADA 141–254 that provides for veterinary prescription use of ADVANTAGE MULTI (imidacloprid 10% and moxidectin 1%) for Cats, a topical solution used for the prevention of heartworm disease, the treatment of flea infestations, and the treatment and control of ear mites and several internal parasites. NADA 141–251 is approved as of December 20, 2006, and NADA 141–254 is approved as of January 19, 2007. Accordingly, the regulations are amended in part 524 (21 CFR part 524) by adding § 524.1146 to reflect these approvals.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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 under NADA 141–251 qualifies for 3 years of marketing exclusivity beginning December 20, 2006, and this approval under NADA 141–254 qualifies for 3 years of marketing exclusivity beginning January 19, 2007.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do 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. Add § 524.1146 to read as follows: