control number was not available when the final rule was published, thus necessitating publication of this notice. The FAA request was approved by OMB without change and expires on April 30, 2010.

Title 49 U.S.C. 106(g), 40113, 40119, 41706, 44101, 44701–44702, 44705, 44709–44711, 44713, 44716–44717, 44722, 46105, grants authority to the Administrator to publish this notice. The final rule (71 FR 75616) became effective on February 13, 2007 and the compliance date for information collection requirements in §§ 460.5, 460.7, 460.9, 460.19, 460.45, and 460.49 is May 17, 2007.

Issued in Washington, DC on May 8, 2007.

Pamela Hamilton-Powell,

Director, Office of Rulemaking Aviation Safety.

[FR Doc. E7–9480 Filed 5–16–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Pimobendan

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 Boehringer Ingelheim Vetmedica, Inc. The NADA provides for the veterinary prescription use of pimobendan chewable tablets in dogs for the management of the signs of congestive heart failure.

DATES: This rule is effective May 17, 2007.

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.hhs.gov*.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 N. Belt Hwy., St. Joseph, MO 64506–2002, filed NADA 141–273 that provides for the veterinary prescription use of VETMEDIN (pimobendan) Chewable Tablets in dogs for the management of the signs of mild, moderate, or severe (modified New York Heart Association Class II, III, or IV) congestive heart failure due to atrioventricular valvular insufficiency or dilated cardiomyopathy; for use with concurrent therapy for congestive heart failure as appropriate on a case-by-case basis. The NADA is approved as of April 30, 2007, and the regulations in 21 CFR part 520 are amended by adding § 520.1780 to reflect the approval.

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)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of the approval.

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. Add § 520.1780 to read as follows:

§ 520.1780 Pimobendan.

(a) *Specifications.* Each chewable tablet contains 1.25, 2.5, or 5 milligrams (mg) pimobendan.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally at a total daily dose of 0.23 mg per pound (0.5 mg per kilogram) body weight, using a suitable combination of whole or half tablets. The total daily dose should be divided into two portions administered approximately 12 hours apart.

(2) *Indications for use.* For the management of the signs of mild, moderate, or severe (modified New York Heart Association Class II, III, or IV) congestive heart failure due to atrioventricular valvular insufficiency or dilated cardiomyopathy; for use with concurrent therapy for congestive heart failure as appropriate on a case-by-case basis.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: May 7, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–9516 Filed 5–16–07; 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; Ivermectin and Clorsulon

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 an abbreviated new animal drug application (ANADA) filed by Norbrook Laboratories, Ltd. The ANADA provides for the use of an ivermectin and clorsulon solution by subcutaneous injection in cattle for control of various internal and external parasites.

DATES: This rule is effective May 17, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed ANADA 200–436 that provides for use of NOROMECTIN Plus (ivermectin and clorsulon) Injection for Cattle by subcutaneous injection in cattle for control of various internal and external parasites. Norbrook Laboratories, Ltd.'s NOROMECTIN Plus Injection for Cattle

is approved as a generic copy of Merial, Ltd.'s IVOMEC Plus Injection for Cattle, approved under NADA 140–833. The ANADA is approved as of April 23, 2007, and the regulations are amended in 21 CFR 522.1193 to reflect the approval.

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.

FDA 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 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. Amend § 522.1193 as follows:

a. Revise the section heading and paragraphs (a) and (b);

b. Redesignate paragraph (d) as paragraph (e);

c. Add new paragraph (d); and

d. Revise newly redesignated paragraph (e).

The revisions, redesignation, and addition read as follows:

§ 522.1193 Ivermectin and clorsulon.

(a) *Specifications.* Each milliliter (mL) of solution contains 10 milligrams (mg) (1 percent) ivermectin and 100 mg (10 percent) clorsulon.

(b) *Sponsors.* See Nos. 050604 and 055529 in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

* * * * *

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

(e) *Conditions of use in cattle*—(1) *Amount.* Administer 1 mL (10 mg ivermectin and 100 mg clorsulon) per 50 kilograms (110 pounds) by subcutaneous injection.

(2) *Indications for use.* For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei, Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*; lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); liver flukes (adults only) (*Fasciola hepatica*); grubs (parasitic stages) (*Hypoderma bovis, H. lineatum*); lice (*Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*); and for control of infections of *D. viviparus* and *O. radiatum* for 28 days afer treatment; *O. ostertagi, T. axei*, and *C. punctata* for 21 days after treatment; and *H. placei and C. oncophora* for 14 days after treatment.

(3) *Limitations.* For subcutaneous use only. Not for intravenous or intramuscular use. Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Do not use in other animal species because severe adverse reactions, including fatalities in dogs, may result. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: May 7, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–9517 Filed 5–16–07; 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; Ivermectin

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 an abbreviated new animal drug application (ANADA) filed by Norbrook Laboratories, Ltd. The ANADA provides for use of a one percent ivermectin solution by subcutaneous injection in cattle, swine, reindeer, and American bison for the treatment and control of various internal and external parasites.

DATES: This rule is effective May 17, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed supplemental ANADA 200–437 that provides for use of NOROMECTIN (ivermectin) Injection for Cattle and Swine by subcutaneous injection in cattle, swine, reindeer, and American bison for the treatment and control of various internal and external parasites. Norbrook Laboratories, Ltd.'s NOROMECTIN Injection for Cattle and Swine is approved as a generic copy of Merial, Ltd.'s IVOMEC Injection for Cattle and Swine approved under NADA 128–409. The ANADA is approved as of April 20, 2007, and the regulations are amended in 21 CFR 522.1192 to reflect the approval and a current format.

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.

FDA 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.