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.

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 § 522.1192 to read as follows:

§ 522.1192 Ivermectin.

(a) *Specifications*—(1) Each milliliter (mL) of solution contains 20 milligrams (mg) ivermectin.

(2) Each mL of solution contains 10 mg ivermectin.

(3) Each mL of solution contains 2.7 mg ivermectin.

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

(1) No. 050604 for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; the product described in paragraph (a)(2) of this section as in paragraphs (e)(2)(i), (e)(2)(ii)(A), (e)(2)(ii)(C), (e)(2)(iii), (e)(3), (e)(4) and (e)(5) of this section; and the product described in paragraph (a)(3) of this section as in paragraphs (e)(3) and (e)(6) of this section.

(2) Nos. 059130 and 055529 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2)(i), (e)(2)(ii)(A), (e)(2)(ii)(B), (e)(2)(iii), (e)(3), (e)(4), and (e)(5) of this section.

(c) *Related tolerances.* See § 556.344 of this chapter.

(d) *Special considerations*—(1) See § 500.25 of this chapter.

(2) Labeling shall bear the following precaution: ''This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.''

(e) *Conditions of use*—(1) *Horses*—(i) *Amount.* 200 micrograms per kilogram (µg/kg) of body weight by intramuscular injection.

(ii) *Indications for use.* For the treatment and control of large strongyles (adult) (*Strongylus vulgaris*, *S. edentatus*, *Triodontophorus* spp.), small strongyles (adult and fourth stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (adult and fourth-stage larvae) (*Oxyuris equi*), large roundworms (adult) (*Parascaris equorum*), hairworms (adult) (*Trichostrongylus axei*), large mouth stomach worms (adult) (*Habronema muscae*), neck threadworms (microfilariae) (*Onchocerca* spp.), and stomach bots (*Gastrophilus* spp.).

(iii) *Limitations.* Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* 200 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use*—(A) For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *T. 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*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (scabies) (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*).

(B) For control of infections of *D. viviparus* for 28 days after treatment, and *O. ostertagi* for 21 days after treatment, and *H. placei*, *T. axei*, *C. punctata*, *C. oncophora*, and *O. radiatum* for 14 days after treatment.

(C) For control of infections and to protect from reinfection with *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; *H. placei* and *C. oncophora* for 14 days after treatment.

(iii) *Limitations.* Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(3) *Swine*—(i) *Amount.* 300 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use.* For the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (large roundworm, *Ascaris suum*; red stomach worm, *Hyostrongylus rubidus*; nodular worm, *Oesophagostomum* spp.; threadworm, *Strongyloides ransomi* (adults only)); somatic roundworm larvae (threadworm, *S. ransomi* (somatic larvae)); lungworms (*Metastrongylus* spp. (adults only)); lice (*H. suis*); and mites (*S. scabiei* var. *suis*).

(iii) *Limitations.* Do not treat swine within 18 days of slaughter.

(4) *American bison*—(i) *Amount.* 200 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use.* For the treatment and control of grubs (*H. bovis*).

(iii) *Limitations.* Do not slaughter within 56 days of last treatment.

(5) *Reindeer*—(i) *Amount.* 200 µg/kg of body weight by subcutaneous injection.

(ii) *Indications for use.* For the treatment and control of warbles (*Oedemagena tarandi*).

(iii) *Limitations.* Do not treat reindeer within 56 days of slaughter.

(6) *Ranch-raised foxes*—(i) *Amount.* 200 µg/kg of body weight by subcutaneous injection. Repeat in 3 weeks.

(ii) *Indications for use.* For treatment and control of ear mites (*Otodectes cynotis*).

Dated: May 7, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–9515 Filed 5–16–07; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD13–07–013]

RIN 1625–AA00

Special local regulation: ULHRA Hydroplane Races, Howard Amon Park, Richland, WA

AGENCY: Coast Guard, DHS.

ACTION: Special local regulation temporary final rule.

SUMMARY: The Coast Guard is undertaking two actions with regard to the above captioned regulation. The first is to withdraw the temporary final rule previously published on April 23, 2007 because it erroneously described the race area. The second is to correct the previous error by establishing a temporary special local regulation for the ULHRA National Series Hydroplane Race to be held on the waters of the Columbia River in the vicinity of Howard Amon Park, Richland, WA. These special local regulations limit the movement of non-participating vessels in the regulated race area. This