protective order—(1) *Persons who must file an application for release under protective order.* To be permitted access to proprietary information in the administrative record of a determination under panel review, all persons described in paragraphs (b)(1), (2), (4), (5), (6), or (c)(5)(i) of this section shall file an application for a protective order.

(2) * * *

(ii) Such forms shall require the applicant to submit a personal sworn statement that, in addition to such other conditions as the Commission Secretary may require, the applicant will:

(A) Not disclose any proprietary information obtained under protective order and not otherwise available to any person other than:

(*1*) Personnel of the Commission involved in the particular panel review in which the proprietary information is part of the administrative record,

(*2*) The person from whom the information was obtained,

(*3*) A person who is authorized to have access to the same proprietary information pursuant to a Commission protective order, and

(*4*) A clerical person retained or employed by and under the direction and control of a person described in paragraph (b)(1), (2), (5), or (6) of this section who has been issued a protective order, if such clerical person has signed and dated an agreement, provided to the Commission Secretary upon request, to be bound by the terms set forth in the application for a protective order of the person who retains or employs him or her (the authorized applicant shall be responsible for retention and accuracy of such forms and shall be deemed responsible for such persons' compliance with the administrative protective order);

(B) Not use any of the proprietary information released under protective order and not otherwise available for purposes other than the particular proceedings under Article 1904 of the Agreement;

(C) Upon completion of panel review, or at such other date as may be determined by the Commission Secretary, return to the Commission, or certify to the Commission Secretary the destruction of, all documents released under the protective order and all other material (such as briefs, notes, or charts), containing the proprietary information released under the protective order, except that those described in paragraph (b)(1) of this section may return such documents and other materials to the United States Secretary. The United States Secretary may retain a single file copy of each document for the official file.

(D) Update information in the application for protective order as required by the protective order; and

(E) Acknowledge that the person becomes subject to the provisions of 19 U.S.C. 1677f(f) and to this subpart, as well as corresponding provisions of Canadian and Mexican law on disclosure undertakings concerning proprietary information.

(3) *Timing of applications.* An application for any person described in paragraph (b)(1) or (b)(2) of this section may be filed after a notice of request for panel review has been filed with the Secretariat. A person described in paragraph (b)(4) of this section shall file an application immediately upon assuming official responsibilities in the United States, Canadian or Mexican Secretariat. An application for any person described in paragraph (b)(5) or (b)(6) of this section may be filed at any time after the United States Trade Representative, the Canadian Minister of Trade, or the Mexican Secretary of Economia, as the case may be, has notified the Commission Secretary that such person requires access.

(4) * * *

(ii) *Applications of persons described in paragraph (b)(2) of this section*—(A) *Filing.* A person described in paragraph (b)(2) of this section, concurrent with the filing of a complaint or notice of appearance in the panel review on behalf of the participant represented by such person, shall file the completed original of the form (NAFTA APO Form C) and three (3) copies with the Commission Secretary, and four (4) copies with the United States Secretary.

* * * * *

(5) *Persons who retain access to proprietary information under a protective order issued during the administrative proceedings.* (i) If counsel or a professional has been granted access in an administrative proceeding to proprietary information under a protective order that contains a provision governing continued access to that information during panel review, and that counsel or professional retains the proprietary information more than fifteen (15) days after a First Request for Panel Review is filed with the Secretariat, that counsel or professional, and such clerical persons with access on or after that date, become immediately subject to the terms and conditions of NAFTA APO Form C maintained by the Commission Secretary on that date including provisions regarding sanctions for violations thereof.

(ii) Any person described in paragraph (c)(5)(i) of this section, concurrent with the filing of a complaint or notice of appearance in the panel review on behalf of the participant represented by such person, shall:

(A) File the completed original of the form (NAFTA APO Form C) and three (3) copies with the Commission Secretary; and

(B) File four (4) copies of the completed NAFTA APO Form C with the United States Secretary.

(iii) Any person described in paragraph (c)(5)(i) of this section must submit a new application for a protective order at the commencement of a panel review.

* * * * *

(e) *Retention of protective orders; service list.* The Commission Secretary shall retain, in a public file, copies of applications granted, including any updates thereto, and protective orders issued under this section, including protective orders filed in accordance with paragraph (b)(6)(ii) of this section. The Secretary shall establish a list of persons authorized to receive proprietary information in a review, including parties whose applications have been granted.

* * * * *

By Order of the Commission.

Issued: February 16, 2005.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–3292 Filed 2–18–05; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Paste

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 Cross Vetpharm Group Ltd. The ANADA provides for oral use of ivermectin paste in horses for treatment and control of various internal parasites or parasitic conditions.

DATES: This rule is effective February 22, 2005.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary

Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lonnie.luther@fda.gov*.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–326 for BIMECTIN (ivermectin) Paste 1.87%. The application provides for oral use of 1.87 percent ivermectin paste in horses for the treatment and control of various species of internal parasites or parasitic conditions. Cross Vetpharm Group's BIMECTIN Paste 1.87% is approved as a generic copy of Merial Limited's EQVALAN Paste, approved under NADA 134–314. ANADA 200–326 is approved as of January 19, 2005, and 21 CFR 520.1192 is 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 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 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 520.1192 is amended by adding paragraphs (b)(3) and (e)(1)(ii)(C) to read as follows:

§ 520.1192 Ivermectin paste.

* * * * *

(b) * * *

(3) No. 061623 for use of a 1.87 percent paste for use as in paragraph (e)(1)(i), (e)(1)(ii)(C), and (e)(1)(iii) of this section.

* * * * *

(e) * * *

(1) * * *

(ii) * * *

* * * * *

(C) Large strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, and *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., and *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth-stage larvae)—*Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum*; Hairworms (adults)—*Trichostrongylus axei*; Large-mouth Stomach Worms (adults)—*Habronema muscae*; Bots (oral and gastric stages)—*Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi*; Intestinal Threadworms (adults)—*Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

* * * * *

Dated: February 8, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–3280 Filed 2–18–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–05–013]

Drawbridge Operation Regulations: Raritan River, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the New Jersey Transit Rail Operations (NJTRO) Bridge, at mile 0.5, across the Raritan River, at Perth Amboy, New Jersey. Under this temporary deviation the bridge may remain in the closed position beginning at 11 p.m. on Friday through 6 p.m. on Saturday for four weekends between March 18 and May 14, 2005. This temporary deviation is necessary to facilitate scheduled maintenance at the bridge.

DATES: This deviation is effective from March 18, 2005 through May 14, 2005.

FOR FURTHER INFORMATION CONTACT: Joe Arca, Project Officer, First Coast Guard District, at (212) 668–7165.

SUPPLEMENTARY INFORMATION: The NJTRO Bridge has a vertical clearance in the closed position of 8 feet at mean high water and 13 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.747.

The bridge owner, New Jersey Transit Rail Operations (NJTRO), requested a temporary deviation from the drawbridge operation regulations to facilitate necessary scheduled bridge maintenance, replacement of miter rails, at the bridge. The bridge must remain in the closed position during the performance of these repairs.

Under this temporary deviation the NJTRO Bridge may remain in the closed position beginning at 11 p.m. on Friday through 6 p.m. on Saturday for four weekends as follows: March 18 through March 19; April 1 through April 2; April 15 through April 16; and April 29 through April 30, 2005. Two alternate weekend closure dates, May 6 through May 7, and May 13 through May 14, 2005, have been authorized in the event that inclement weather requires cancellation of any of the above dates.

This deviation from the operating regulations is authorized under 33 CFR 117.35, and will be performed with all due speed in order to return the bridge to normal operation as soon as possible.

Dated: February 11, 2005.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 05–3255 Filed 2–18–05; 8:45 am]

BILLING CODE 4910–15–P