

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.

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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