order for documents to be timely received and accepted. You can obtain paper copies of the EDGAR Filer Manual from the following address: Public Reference Room, U.S. Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0102 or by calling Thomson Financial Inc at (800) 638–8241. Electronic format copies are available on the Commission's Web site. The address for the Filer Manual is <*http://www.sec.gov/info/edgar.shtml*>. You can also photocopy the document at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC.

Dated: April 19, 2004.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 04–9273 Filed 4–20–04; 2:01 pm]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Moxidectin and Praziquantel Gel

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 Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for oral use of a moxidectin and praziquantel gel in horses and ponies for the treatment and control of an additional species of small strongyles.

DATES: This rule is effective April 23, 2004.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *mberson@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW, Fort Dodge, IA 50501, filed a supplement to NADA 141–216 for QUEST PLUS (moxidectin 2.0%/praziquantel 12.5%) Gel, used for the treatment and control of various species of internal parasites in horses and ponies. The supplement provides for the speciation of adult small strongyles in product labeling. The supplemental NADA is approved as of March 17, 2004, and 21 CFR 520.1453 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(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. Section 520.1453 is amended by revising paragraph (d)(2) to read as follows:

§ 520.1453 Moxidectin and praziquantel gel.

* * * * *

(d) * * *

(2) *Indications for use.* For the treatment and control of large strongyles: *Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), and *T. serratus* (adults); small strongyles (adults): (*Cyathostomum* spp., including *C. catinatum* and *C. pateratum*; *Cylicocyclus* spp., including *C. insigne*, *C. leptostomum*, and *C. nassatus*; *Cylicostephanus* spp., including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; *Coronocyclus* spp., including *C. coronatus*, *C. labiatus*, and *C. labratus*; and *Gyalocephalus capitatus*; small strongyles: undifferentiated lumenal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids: *Parascaris equorum* (adults and L4 larval stages); pinworms: *Oxyuris equi* (adults and L4 larval stages); hairworms: *Trichostrongylus axei* (adults); large-mouth stomach worms: *Habronema muscae* (adults); horse stomach bots: *Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars); and tapeworms: *Anoplocephala perfoliata* (adults). One dose also suppresses strongyle egg production for 84 days.

* * * * *

Dated: April 2, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–9182 Filed 4–22–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD11–03–006]

RIN 1625–AA09

Drawbridge Operation Regulation; Mare Island Strait, Napa River, Vallejo, CA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulation governing the operation of the Mare Island Drawbridge, spanning the Napa River between the City of Vallejo and Mare Island, CA, by eliminating the rush hour closure periods when the drawspan need not open for vessels, and by increasing the hours when vessels provide advance notice for drawspan operation. The action is to reduce bridge operating costs without reducing the ability of vessels to transit the drawbridge, thereby continuing to meet the reasonable needs of waterway traffic.

DATES: This rule is effective May 24, 2004.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD11–03–006 and are available for inspection or copying at Commander