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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 luminal 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

(oan), Eleventh Coast Guard District, Bridge Section, Building 50-3, Coast Guard Island, Alameda, CA 94501-5100 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays. The Bridge Section, Eleventh Coast Guard District, maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT:

David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District, telephone (510) 437-3516.

SUPPLEMENTARY INFORMATION:

Regulatory History

On November 25, 2003, the notice of proposed rulemaking (NPRM), entitled Drawbridge Operation Regulations; Mare Island Strait, Napa River, Vallejo, CA, was published in the **Federal Register**. We received one letter and one telephone call commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

To reduce drawbridge operating costs, The City of Vallejo requested an increase in rush hour closure periods. However, reduced traffic, following Navy closure of the Mare Island Naval Shipyard in the 1990's, no longer justifies rush hour closure periods. The City of Vallejo also requested an increase in hours when vessels provide advance notice for drawspan operation. Drawbridge operation logs justify the increased advance notice hours, as these hours coincide with periods when vessels have not historically requested an opening. The changes made by this rule are expected to reduce bridge operating costs while continuing to meet the reasonable needs of waterway traffic.

Discussion of Comments and Changes

The single letter received during the comment period indicated misinterpretation of the word "normal," when referring to operational periods of the drawspan. The expressed concern was the possibility for navigational delays to slower vessels, enroute between the Napa River and Sacramento and San Joaquin Delta destinations, eight to ten hours away. The desire was not to have to wait until 9 a.m. for a bridge opening, so as not to make an already long trip longer, and necessitate completing the voyage during hours of darkness. The use of the word normal, concerning drawbridge operating times, has been removed from the regulation.

Since the two-hour advance notice requirement presently does not affect vessel transit times, no change is expected to result from the adjusted advance notice times. The two-hour

advance notice request period does not preclude the ability of the drawbridge to open promptly and fully for the passage of vessels when they arrive at the drawbridge for a pre-arranged opening, and no delays in arrival at a destination should result from the rulemaking.

The telephone conversation with the City of Vallejo provided a 24-hour telephone number for communicating bridge opening requirements to the bridge. The city preferred to not direct mariners to contact the Police Department Dispatcher, due to possible conflicts with established dispatcher duties, and the reference has been removed from the regulation. During the time when a drawbridge operator is present, the phone rings at the bridge. During advance notice periods, the phone rings at the appropriate City of Vallejo office to arrange for drawspan operation. The regulatory text has been amended to include the 24-hour telephone number provided by the City of Vallejo.

Since all drawbridges are subject to emergency operation in compliance with 33 CFR 117.31, including public vessels of the United States, the individual emergency operation text has been removed from the regulation.

The City of Vallejo requested consideration for future review of rush hour closure periods at this drawbridge. Nothing in this rule prevents future review of drawbridge operating regulations at this drawbridge.

There are no drawbridges under Coast Guard jurisdiction on the tributaries to Napa River and Mare Island Strait. Therefore, the reference to "tributaries" has been removed from the regulation.

The Mare Island Drawbridge is no longer owned or operated by the U.S. Navy, and the drawbridge structure does not meet the definition of a "causeway." Therefore, references to the U.S. Navy and Mare Island Causeway have been removed from the regulation.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

The rulemaking will not result in significant negative impacts to the waterway users, while reducing drawbridge operating costs for the City of Vallejo.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this rule under Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (32)(e) of the Instruction, from further environmental documentation.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

■ 2. In § 117.169a revise the section heading and paragraph to read as follows:

§ 117.169 Mare Island Strait and The Napa River.

(a) The draw of the Mare Island Drawbridge, mile 2.8, at Vallejo shall open on signal between the hours of 9 a.m. and 7 p.m. daily, and upon two hours advance notice all other times. When the drawbridge operator is present, mariners may contact the drawbridge via marine radio or telephone at (707) 648–4313 for drawspan operation. When the drawbridge operator is not present, mariners may contact the City of Vallejo via the same telephone number to schedule drawspan operation.

* * * * *

Dated: April 12, 2004.

Kevin J. Eldridge

Rear Admiral, U.S. Coast Guard, Commander, Eleventh Coast Guard District.

[FR Doc. 04–9196 Filed 4–22–04; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141, 142 and 143

[FRL–7652–8]

Lead and Copper Rule; Expert Panel Workshops on Simultaneous Compliance and Monitoring Protocols

AGENCY: Environmental Protection Agency.

ACTION: Notice of public meetings.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is convening two expert panel workshops to discuss issues associated with the Lead and Copper Rule (LCR). The first of these workshops, Simultaneous Compliance and the Lead and Copper Rule, will discuss how utilities manage treatment decisions to ensure simultaneous compliance with the LCR and National

Primary Drinking Water Regulations. The second workshop, LCR Monitoring Protocols, will examine and discuss potential issues associated with the current LCR sampling and monitoring requirements for lead, copper, and water quality parameters.

DATES: The first workshop, Simultaneous Compliance and the Lead and Copper Rule, will be held on Tuesday, May 11, 2004, 8 a.m. to 5 p.m. (CDT) and Wednesday, May 12, 2004, 8 a.m. to 12 p.m. (CDT). The second workshop, LCR Monitoring Protocols, will be held Wednesday, May 12, 2004, 1 p.m. to 5 p.m. (CDT) and Thursday, May 13, 2004, 8 a.m. to 5 p.m. (CDT).

ADDRESSES: The workshops will be held at the St. Louis Airport Marriott, I–70 at Lambert Airport, St. Louis, MO 63134.

FOR FURTHER INFORMATION CONTACT: To attend this workshop as an observer, please contact the Safe Drinking Water Hotline at 1–800–426–4791 or 703–285–1093 between 9 a.m. and 5:30 p.m. (EDT) or by e-mail: hotline-sdwa@epa.gov. There is no charge for attending this workshop as an observer, but seats are limited, so register as soon as possible. Any person needing special accommodations at any of these meetings, including wheelchair access, should make this known at the time of registration. For administrative meeting information, call Brian Murphy, Economic and Engineering Services, Inc., at 425–452–8100 or by e-mail Murphy@ees-1.com. For technical information, contact Patricia Moe, Office of Water, Office of Ground Water and Drinking Water, U.S. EPA, 1200 Pennsylvania Ave., NW., (MC 4607M), Washington, D.C., 20460 at 202–564–1436 or by e-mail at moe.patricia@epa.gov.

SUPPLEMENTARY INFORMATION: Members of the public may attend as observers at the workshop and provide comments during 30-minute periods each on Tuesday, Wednesday, and Thursday. Individual comments should be limited to no more than 5 minutes.

Dated: April 19, 2004.

Cynthia C. Dougherty,

Director, Office of Ground Water and Drinking Water.

[FR Doc. 04–9265 Filed 4–22–04; 8:45 am]

BILLING CODE 6560–50–P