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. Section 522.1193 is amended by revising paragraphs (d)(2) and (d)(3) to read as follows:

§ 522.1193 Ivermectin and clorsulon injection.

* * * * *

(d) * * *

(2) *Indications for use.* It is used in cattle 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*). It is also used to control infections of *D. viviparus* and *O. radiatum* for 28 days after 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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. 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 19, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–12717 Filed 6–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–04–027]

RIN 1625–AA09

Drawbridge Operation Regulations: Chelsea River, MA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary final rule governing the operation of the P.J. McArdle Bridge, mile 0.3, across the Chelsea River between East Boston and Chelsea, Massachusetts. This final rule will allow the bridge to remain in the closed position from 10 a.m. to 5 p.m. on June 5, 2004, to facilitate the First Annual Chelsea River Revel 5K Road Race. Vessels that can pass under the bridge without a bridge opening may do so at all times.

DATES: This rule is effective only on June 5, 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 [CGD01–04–027] and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, One South Street, New York, New York, 10004, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (212) 668–7165. The First Coast Guard District, Bridge Branch, maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: Mr. Joe Arca, Project Officer, First Coast Guard District, (212) 668–7069.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 27, 2004, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Chelsea River, Massachusetts, in the **Federal Register** (69 FR 22749). We received no comment letters in response to the notice of proposed rulemaking. No public hearing was requested and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**.

The Coast Guard did not receive the bridge owner's request to close the bridge until March 16, 2004; therefore, taking into consideration the time for the NPRM, it is necessary to make this rule effective in less than 30 days in order to allow the event to take place as scheduled on June 5, 2004. The Coast Guard believes this is reasonable because the bridge must remain closed during the running of the First Annual Chelsea River Revel 5K Road Race in the interest of public safety.

Background and Purpose

The P.J. McArdle Bridge has a vertical clearance of 21 feet at mean high water and 30 feet at mean low water in the closed position. The existing drawbridge operation regulations listed at 33 CFR § 117.593 require the bridge to open on signal at all times.

The owner of the bridge, the City of Boston, requested a temporary change to the drawbridge operation regulations to allow the bridge to remain in the closed position from 10 a.m. to 5 p.m. on June 5, 2004, to facilitate the running of the First Annual Chelsea River Revel 5K Road Race. Vessels that can pass under the bridge without a bridge opening may do so at all times.

The Chelsea River is predominantly transited by commercial tugs, barges, and oil tankers. The Coast Guard coordinated this closure with the mariners that normally use this waterway and no objections were received.

The Coast Guard did not receive the request to keep the bridge closed to facilitate the scheduled road race until March 16, 2004. A shortened comment period was necessary, due the short notice given to the Coast Guard, to allow this final rule to become effective in time for the start of First Annual Chelsea River Revel 5K Road Race on June 5, 2004.

The Coast Guard believes this final rule is needed in order to provide for public safety and the safety of the race participants.

Discussion of Comments and Changes

The Coast Guard received no comments in response to our notice of proposed rulemaking. No changes have been made to this final rule.

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).

This conclusion is based on the fact that the bridge closure is only 7 hours in duration.

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 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.

This conclusion is based on the fact that the bridge closure is only 7 hours in duration.

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.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

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 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 effect 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 does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This final rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

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. The Administrator of the Office of Information and Regulatory Affairs has designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this final rule under Commandant Instruction M16475.1D, 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. It has been determined that this final rule does not significantly impact the environment.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

■ For the reasons set out 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. On June 5, 2004 only, § 117.593 is suspended and a new § 117.T594 is added to read as follows:

§ 117.T594 Chelsea River.

(a) All drawbridges across the Chelsea River shall open on signal; except that, the P.J. McArdle Bridge, mile 0.3, need

not open for the passage of vessel traffic from 10 a.m. to 5 p.m. on June 5, 2004.

(b) The opening signal for each drawbridge is two prolonged blasts followed by two short blasts and one prolonged blast. The acknowledging signal is three prolonged blasts when the draw can be opened immediately and two prolonged blasts when the draw cannot be opened or is open and must be closed.

Dated: May, 25, 2004.

John L. Grenier,

Captain, U.S. Coast Guard, Acting Commander, First Coast Guard District.

[FR Doc. 04–12824 Filed 6–4–04; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 03–026]

RIN 1625–AA00

Security Zone; San Francisco Bay, Oakland Estuary, Alameda, CA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a security zone extending approximately 150 feet into the navigable waters of the Oakland Estuary, Alameda, California, surrounding the United States Coast Guard Island Pier. This action is necessary to provide for the security of the military service members on board vessels moored at the pier and the government property associated with these valuable national assets. This security zone prohibits all persons and vessels from entering, transiting through or, anchoring within a portion of the Oakland Estuary surrounding the Coast Guard Island Pier unless authorized by the Captain of the Port (COTP) or his designated representative.

DATES: This rule is effective July 7, 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 COTP 03–026 and are available for inspection or copying at the Waterways Branch of the Marine Safety Office San Francisco Bay, Coast Guard Island, Alameda, California, 94501, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Doug Ebbers, U.S. Coast Guard Marine Safety Office San Francisco Bay, at (510) 437–3073.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On January 29, 2004, we published a notice of proposed rulemaking (NPRM) entitled ''Security Zone; San Francisco Bay, Oakland Estuary, Alameda, CA'' in the **Federal Register** (69 FR 4267) proposing to establish a permanent security zone extending approximately 150 feet into the navigable waters of the Oakland Estuary surrounding the United States Coast Guard Island Pier. We received one letter commenting on the proposed rule. No public hearing was requested, and none was held.

Penalties for Violating Security Zone

Vessels or persons violating this security zone will be subject to the penalties set forth in 33 U.S.C. 1232 and 50 U.S.C. 192. Pursuant to 33 U.S.C. 1232, any violation of the security zone described herein, is punishable by civil penalties (not to exceed $32,500 per violation, where each day of a continuing violation is a separate violation), criminal penalties (imprisonment up to 6 years and a maximum fine of $250,000), and in rem liability against the offending vessel. Any person who violates this section, using a dangerous weapon, or who engages in conduct that causes bodily injury or fear of imminent bodily injury to any officer authorized to enforce this regulation, also faces imprisonment up to 12 years. Vessels or persons violating this section are also subject to the penalties set forth in 50 U.S.C. 192: seizure and forfeiture of the vessel to the United States, a maximum criminal fine of $10,000, and imprisonment up to 10 years.

The Captain of the Port will enforce this zone and may enlist the aid and cooperation of any Federal, State, county, municipal, or private agency to assist in the enforcement of the regulation.

Background and Purpose

Since the September 11, 2001 terrorist attacks on the World Trade Center in New York, the Pentagon in Arlington, Virginia and Flight 93, the Federal Bureau of Investigation (FBI) has issued several warnings concerning the potential for additional terrorist attacks within the United States. In addition, the ongoing hostilities in Afghanistan and the conflict in Iraq have made it prudent for U.S. ports to be on a higher state of alert because Al-Qaeda and other organizations have declared an ongoing intention to conduct armed attacks on U.S. interests worldwide.

The threat of maritime attacks is real as evidenced by the attack on the USS Cole and the subsequent attack in October 2002 against a tank vessel off the coast of Yemen. These threats manifest a continuing threat to U.S. assets as described in the President's finding in Executive Order 13273 of August 21, 2002 (67 FR 56215, September 3, 2002) that the security of the U.S. is endangered by the September 11, 2001 attacks and that such aggression continues to endanger the international relations of the United States. See also Continuation of the National Emergency with Respect to Certain Terrorist Attacks (67 FR 58317, September 13, 2002), and Continuation of the National Emergency with Respect to Persons Who Commit, Threaten To Commit, Or Support Terrorism (67 FR 59447, September 20, 2002). The U.S. Maritime Administration (MARAD) in Advisory 02–07 advised U.S. shipping interests to maintain a heightened status of alert against possible terrorist attacks. MARAD more recently issued Advisory 03–05 informing operators of maritime interests of increased threat possibilities to vessels and facilities and a higher risk of terrorist attack to the transportation community in the United States. The ongoing foreign hostilities have made it prudent for U.S. ports and waterways to be on a higher state of alert because the Al-Qaeda organization and other similar organizations have declared an ongoing intention to conduct armed attacks on U.S. interests worldwide.

In its effort to thwart terrorist activity, the Coast Guard has increased safety and security measures on U.S. ports and waterways. As part of the Diplomatic Security and Antiterrorism Act of 1986 (Pub. L. 99–399), Congress amended section 7 of the Ports and Waterways Safety Act (PWSA), 33 U.S.C. 1226, to allow the Coast Guard to take actions, including the establishment of security and safety zones, to prevent or respond to acts of terrorism against individuals, vessels, or public or commercial structures. The Coast Guard also has authority to establish security zones pursuant to the Act of June 15, 1917, as amended by the Magnuson Act of August 9, 1950 (50 U.S.C. 191 *et seq.*), and implementing regulations promulgated by the President in subparts 6.01 and 6.04 of part 6 of title 33 of the Code of Federal Regulations.

In this particular rulemaking, to address the aforementioned security concerns and to take steps to prevent a terrorist attack against a Coast Guard Cutter, the Coast Guard is establishing a permanent, fixed security zone around and under the United States Coast Guard Island Pier that encompasses all