

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 522

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 522 is amended as follows:

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.

§ 522.1720 [Amended]

■ 2. Section 522.1720 is amended in paragraph (b)(2) by removing "No. 000010" and by adding in its place "Nos. 000010 and 058005".

Dated: July 26, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–16240 Filed 8–16–05; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–05–040]

RIN 1625–AA09

Drawbridge Operation Regulation; Massalina Bayou, Panama City, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary rule.

SUMMARY: The Commander, Eighth Coast Guard District, has temporarily changed the regulation governing the operation of the Tarpon Dock bascule span drawbridge across Massalina Bayou, mile 0.0, at Panama City, Bay County, Florida. The regulation will allow the draw of the bridge to remain closed to navigation for one hour to facilitate the American Heart Walk.

DATES: This temporary rule is effective from 9 a.m. to 10 a.m. on October 15, 2005.

ADDRESSES: Documents referred to in this rule are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, 500 Poydras Street, New Orleans, Louisiana 70130–3310, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. The Eighth District Bridge Administration Branch maintains the public docket for this rulemaking.

FOR FURTHER INFORMATION CONTACT: David Frank, Bridge Administration Branch, (504) 589–2965.

SUPPLEMENTARY INFORMATION:

Good Cause for Not Publishing an NPRM

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Thousands of pedestrians will cross the bridge during the event and this temporary rule is necessary to ensure their safety as they cross the bridge. Additionally, the event will only impact the waterway users for one hour and will open for vessels in distress.

Background and Purpose

The American Heart Association, on behalf of the City of Panama City, has requested a temporary rule changing the operation of the Tarpon Dock bascule span drawbridge across Massalina Bayou, mile 0.0, in Panama City, Bay County, Florida. This temporary rule is needed to accommodate approximately 2,000 pedestrians that are expected to participate in a 3.5-mile walk. The bridge is near the beginning of the walk and allowing the bridge to open for navigation during this short time period would disrupt the event and could result in injury. The bridge has a vertical clearance of 7 feet above mean high water in the closed-to-navigation position and unlimited in the open-to-navigation position. Navigation on the waterway consists primarily of commercial fishing vessels, sailing vessels and other recreational craft. Presently, Title 33, Code of Federal Regulations (CFR), Part 117.301 states: The draw of the Tarpon Dock bascule span bridge, Massalina Bayou, mile 0.0, shall open on signal; except that from 9 p.m. until 11 p.m. on July 4, each year, the draw need not open for the passage of vessels. The draw will open at any time for a vessel in distress. This temporary rule will allow the bridge to be maintained in the closed-to-navigation position from 9 a.m. to 10

a.m. on October 15, 2005 to facilitate the American Heart Walk.

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 temporary rule will be effective for only one hour and is therefore expected to have only a minor affect on the local economy.

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 temporary rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit through the Tarpon dock bridge across Massalina Bayou during the closure. There is not expected to be a significant impact due to the short duration of the closure and the publicity given to the event.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule so that they can 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 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 the 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 does not cause an environmental risk to health or risk to safety that may 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. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

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.

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 temporary 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 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. Effective 9 a.m. until 10 a.m. on October 15, 2005, § 117.301 is temporarily suspended and a new § 117.T302 is added to read as follows:

§ 117.T302 Massalina Bayou.

The draw of the Tarpon Dock bascule span bridge, Massalina Bayou, mile 0.0, shall open on signal; except that from 9 a.m. until 10 a.m. on October 15, 2005, the draw need not open for the passage of vessels. The draw will open at any time for a vessel in distress.

Dated: August 5, 2005.

Kevin L. Marshall,

Captain, U.S. Coast Guard, Commander 8th Coast Guard Dist. Acting.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD13-05-034]

RIN 1625-AA87

Security Zone; Port Townsend Waterway, Puget Sound, WA, Naval Exercise

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone for Naval and Army vessels while conducting ammunitions transfers in a designated area near Indian Island, Washington. The Coast Guard is taking this action to provide safety and security for Naval and Army vessels from terrorism, sabotage, other subversive acts, to allow sufficient maneuvering area for the vessel, and to maintain a sufficient blast radius from land in an event of an accident. Entry into this zone is prohibited unless authorized by the Captain of the Port,