

Federal Register of March 18, 2004 (69 FR 12810).

DATES: Written requests for presentations and summaries of the presentations must be submitted by April 6, 2004.

ADDRESSES: Submit a request for presentations and a summary of your presentation to Karen Strambler, Office of Policy, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, e-mail: Karen.Strambler@fda.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 18, 2004 (69 FR 12810), FDA published a notice of public meeting and establishment of docket announcing that it established a docket to receive information and comments on certain issues related to the importation of prescription drugs. FDA also announced a public meeting to enable interested individuals, organizations, and other stakeholders to present information to the Task Force for consideration in the study on importation mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. Speakers were asked to submit requests for presentations along with a short summary of their presentation by close of business on March 30, 2004. FDA is extending that deadline to April 6, 2004.

All other information and requirements of the March 18, 2004, **Federal Register** notice remain the same.

Dated: March 31, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-7714 Filed 4-1-04; 11:04 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01-04-021]

RIN 1625-AA09

Drawbridge Operation Regulations; Harlem River, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to temporarily change the drawbridge operating regulations governing the operation of the Triborough (125th Street) Bridge, mile 1.3, across the Harlem River at New York City, New

York. This proposed rule would allow the bridge owner to require a forty-eight hour notice for bridge openings from June 1, 2004 through January 31, 2005. This action is necessary to facilitate structural rehabilitation at the bridge.

DATES: Comments and related material must reach the Coast Guard on or before May 5, 2004.

ADDRESSES: You may mail comments and related material to Commander (obr), First Coast Guard District Bridge Branch, One South Street, Battery Park Building, New York, New York, 10004, or deliver them to the same address 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. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the First Coast Guard District, Bridge Branch, 7 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Joe Arca, Project Officer, First Coast Guard District, (212) 668-7165.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments or related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD01-04-021), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know if they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the First Coast Guard District, Bridge Branch, at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background

The Triborough (125th Street) Bridge has a vertical clearance of 54 feet at mean high water and 59 feet at mean low water in the closed position.

The existing drawbridge operation regulations listed at 33 CFR § 117.789(d) require the bridge to open on signal from 10 a.m. to 5 p.m. after at least a four-hour notice is given.

The owner of the bridge, the Triborough Bridge and Tunnel Authority (TBTA), requested a temporary change to the drawbridge operation regulations to allow the bridge owner to require a forty-eight hour notice for bridge openings from June 1, 2004 through January 31, 2005, to facilitate structural rehabilitation at the bridge.

The owner of the Triborough (125th Street) Bridge has not received any requests to open the bridge for the past three years.

The bridge owner plans to replace the structural steel deck system at the bridge between June 1, 2004 and January 31, 2005. Temporary concrete roadway barriers will be used to redirect vehicular traffic over the bridge to facilitate lane closures required to structurally rehabilitate sections of the bridge roadway steel decking.

Under the existing drawbridge operation regulations, which require a four-hour advance notice, unscheduled bridge opening requests would be impossible to grant because the time necessary to safely remove construction equipment, concrete barriers, and construction workers from the lift span would be considerably longer than four hours.

The Coast Guard believes the requested forty-eight hour advance notice requirement is reasonable based upon the lack of bridge opening requests over the past three years and the fact that the bridge will continue to open on signal provided a forty-eight hour notice is given.

It is expected that this rule, by requiring a forty-eight hour notice for bridge openings, will provide adequate notification to the contractor to facilitate the safe removal of equipment and personnel from the bridge in order to provide any requested bridge openings.

A shortened comment period of 30 days is necessary to allow this rule to become effective in time for the start of the necessary construction at the bridge on June 1, 2004.

The Coast Guard believes this shortened comment period is reasonable because the bridge repairs are necessary repairs that must be performed without delay in order to assure the continued

safe reliable operation of the bridge and prevent an unscheduled closure due to component failure.

Discussion of Proposal

This proposed change would amend 33 CFR 117.789 by suspending paragraph (d) and adding a new temporary paragraph (h) from June 1, 2004 through January 31, 2005.

Under this proposed rule the Triborough (125th Street) Bridge would open on signal from 10 a.m. to 5 p.m. if at least a forty-eight hour notice is given.

A forty-eight hour advance notice for bridge openings would allow sufficient time for the contractor to safely remove construction equipment, personnel, and concrete barriers from the bridge in order to provide any requested bridge openings.

Regulatory Evaluation

This proposed 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 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.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation, under the regulatory policies and procedures of DHS, is unnecessary.

This conclusion is based on the fact that the bridge will continue to open for vessel traffic at all times after a forty-eight hour notice is given.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this proposed 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 section 5 U.S.C. 605(b), that this proposed rule would not have a significant economic impact on a substantial number of small entities.

This conclusion is based on the fact that the bridge will continue to open for vessel traffic at all times after a forty-eight hour notice is given.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see ADDRESSES) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Collection of Information

This proposed rule would call 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 proposed 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed 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 proposed 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 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 would 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 proposed 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 environment documentation because it has been determined that the promulgation of operating regulations or procedures for drawbridges are categorically excluded.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons set out in the preamble, the Coast Guard proposes to amend 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; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. In § 117.789, from June 1, 2004 through January 31, 2005, paragraph (d) is temporarily suspended and a new temporary paragraph (g) is added to read as follows:

§ 117.789 Harlem River.

* * * * *

(g) The draw of the Triborough (125th Street) Bridge, mile 1.3, shall open on signal from 10 a.m. to 5 p.m. if at least a forty-eight hour notice is given.

Dated: March 25, 2004.

John L. Grenier,

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

[FR Doc. 04-7625 Filed 4-2-04; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01-04-025]

RIN 1625-AA09

Drawbridge Operation Regulations; Long Island, New York Inland Waterway From East Rockaway Inlet to Shinnecock Canal, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the drawbridge operating regulations governing the operation of Meadowbrook State Parkway Bridge, at mile 12.8, across Sloop Channel, New York. This proposed rule would allow the bridge to remain closed to the passage of vessel traffic from 9 p.m. to midnight, on the Fourth of July each year. This action is necessary to facilitate the annual Fourth of July Jones Beach State Park fireworks display.

DATES: Comments must reach the Coast Guard on or before June 4, 2004.

ADDRESSES: You may mail comments and related material to Commander (obr), First Coast Guard District Bridge Branch, One South Street, Battery Park Building, New York, New York, 10004, or deliver them to the same address 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. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for

inspection or copying at the First Coast Guard District, Bridge Branch, 7 a.m. to 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Judy Yee, Project Officer, First Coast Guard District, (212) 668-7165.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments or related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD01-04-025), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know if they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the First Coast Guard District, Bridge Branch, at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Meadowbrook State Parkway Bridge has a vertical clearance of 22 feet at mean high water and 25 feet at mean low water in the closed position, unlimited vertical clearance in the full open position. The existing regulations are listed at 33 CFR 117.799(h).

The New York State Office of Parks, Recreation and Historic Preservation, requested that the bridge be allowed to remain closed from 9 p.m. to midnight, during the annual Fourth of July fireworks event at the Jones Beach State Park. The bridge has been closed for the past several years to facilitate this annual event.

Traditionally, this bridge closure was accomplished each year by publishing a temporary final rule in the **Federal Register**. This proposed rule would make the traditional Fourth of July bridge closure part of the permanent drawbridge operation regulations.

The Coast Guard believes this rule is reasonable because it would simplify

the traditional bridge closure process that has become a traditional closure each year on the Fourth of July.

Discussion of Proposal

This proposed change would amend 33 CFR § 117.799 by revising paragraph (h), which identifies the operating schedule of the Meadowbrook State Parkway Bridge.

This proposed rule would allow the bridge to need not open for the passage of vessel traffic from 9 p.m. to midnight of the Fourth of July each year.

This proposed rule, by allowing the bridge to need not open during the annual Fourth of July fireworks display at Jones Beach, would facilitate the safe and orderly flow of vehicular traffic to the beach before and after this annual public event.

Regulatory Evaluation

This proposed 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 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.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation, under the regulatory policies and procedures of DHS, is unnecessary.

This conclusion is based on the fact that the bridge closure is of short duration for the purpose of public safety during the annual Fourth of July Fireworks display at Jones Beach.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we considered whether this proposed 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 section 5 U.S.C. 605(b), that this proposed rule would 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 of short duration for the purpose of public safety during the annual Fourth of July fireworks display at Jones Beach.