

(iv) *Conforming labeling requirements.* Upon FDA approval of changes to the labeling of the reference listed drug or, if the application for the reference listed drug has been withdrawn, upon FDA approval of changes to the labeling of an abbreviated application that relied on the reference listed drug, any other abbreviated application holder that relied upon the reference listed drug must submit a supplement under paragraph (c)(6)(iii)(E) of this section with conforming labeling revisions within 30 days of FDA's posting of the approval letter on its Web site, unless FDA requires the abbreviated application holder's labeling revisions at a different time in accordance with sections 505(o)(4) or 505-1 of the Federal Food, Drug, and Cosmetic Act.

§ 314.97 [Amended]

■ 3. Revise § 314.97 to read as follows:

§ 314.97 Supplements and other changes to an approved abbreviated application.

(a) The applicant must comply with the requirements of §§ 314.70 and 314.71 regarding the submission of supplemental applications and other changes to an approved abbreviated application.

(b) A supplement to an approved abbreviated application for a safety-related change in the labeling that is submitted under § 314.70(b) or (c)(6) will be approved upon approval of the same labeling change for the reference listed drug, except that if approval of the application for the reference listed drug has been withdrawn under § 314.150, FDA may approve such a supplement to an approved abbreviated application.

§ 314.150 [Amended]

■ 4. Amend § 314.150 as follows:

■ a. In paragraph (b)(10)(i), remove the word "or";

■ b. In paragraph (b)(10)(ii), remove the period and replace with a semicolon followed by the word "or"; and

■ c. Add paragraph (b)(10)(iii).

§ 314.150 Withdrawal of approval of an application or abbreviated application.

* * * * *

(b) * * *

(10) * * *

(iii) Changes to the labeling for the drug product that is the subject of the abbreviated application under § 314.70(c)(6)(iii) of this chapter.

* * * * *

PART 601—LICENSING

■ 5. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451-1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c-360f, 360h-360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec 122, Pub. L. 105-115, 111 Stat. 2322 (21 U.S.C. 355 note).

■ 6. Amend § 601.12 by revising paragraphs (f)(1), (f)(2)(i) introductory paragraph, and (f)(2)(ii); and by adding new paragraph (f)(2)(iii) to read as follows:

§ 601.12 Changes to an approved application.

* * * * *

(f) * * * (1) *Labeling changes requiring supplement submission—FDA approval must be obtained before distribution of the product with the labeling change.* Except as described in paragraphs (f)(2) and (f)(3) of this section, an applicant shall submit a supplement describing a proposed change in the package insert, package label, container label, or, if applicable, a Medication Guide required under part 208 of this chapter, and include the information necessary to support the proposed change. The supplement shall clearly highlight the proposed change in the labeling. An applicant may report the minor changes to the information specified in paragraph (f)(3)(i)(D) of this section in an annual report. The applicant shall obtain approval from FDA prior to distribution of the product with the labeling change.

(2) *Labeling changes requiring supplement submission—product with a labeling change that may be distributed before FDA approval.* (i) An applicant shall submit, at the time such change is made, a supplement for any change in the package insert, package label, or container label to reflect newly acquired information to accomplish any of the following:

* * * * *

(ii) Pending approval of the supplement by FDA, the applicant may distribute a product with a package insert, package label, or container label bearing such change at the time the supplement is submitted, except that if FDA determines during its review period that the supplement does not meet the criteria described in paragraph (f)(2)(i) of this section, the supplement will be converted to a prior approval supplement, and the manufacturer must cease distribution of the drug product(s) accompanied by the revised labeling. The supplement shall clearly identify the change being made and include necessary supporting data. The

supplement and its mailing cover shall be plainly marked: "Special Labeling Supplement—Changes Being Effected."

(iii) FDA will promptly post on its Web site information regarding the labeling changes proposed in the changes being effected supplement. The applicant must verify that the correct information regarding the labeling changes proposed in the changes being effected supplement appears on FDA's Web site and must contact FDA within 5 business days of posting if the information is incorrect.

* * * * *

Dated: November 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-26799 Filed 11-8-13; 11:15 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2013-0319]

RIN 1625-AA09

Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Treasure Island, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the operating schedule that governs the Treasure Island Causeway Bridge, mile 119.0, Treasure Island, Florida. The Treasure Island Bridge is a double-leaf bascule bridge that provides a vertical clearance of 21 feet in the closed position. The Treasure Island Bridge crosses the Gulf Intracoastal Waterway at mile 119.0, Treasure Island, Pinellas County, Florida. Changing the schedule from on signal to three times an hour during the week and twice an hour on the weekends and Federal holidays between the hours of 7 a.m. and 7 p.m. will reduce vehicle traffic issues caused by the bridge openings. Between 7 p.m. and 7 a.m. the bridge will continue to open only on signal.

DATES: Comments and related material must reach the Coast Guard on or before February 11, 2014.

ADDRESSES: You may submit comments identified by docket number USCG-2013-0319 using any one of the following methods:

(1) *Federal Rulemaking Portal:*
<http://www.regulations.gov>.

(2) Fax: 202-493-2251.

(3) Mail or Delivery: Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202-366-9329.

See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or email, Mr. Michael Lieberum, Chief Operations Section, Seventh Coast Guard District Bridge Branch at 305-415-6744, email michael.b.lieberum@uscg.mil. If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change to <http://www.regulations.gov> and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this proposed rulemaking (USCG-2013-0319), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at <http://www.regulations.gov>, or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a

phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, type the docket number [USCG-2013-0319] in the "SEARCH" box and click "SEARCH." Click on "Submit a Comment" on the line associated with this rulemaking. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number (USCG-2013-0319) in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC, 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting 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**.

A. Basis and Purpose

The City of Treasure Island has requested a change to the Treasure

Island Causeway Bridge regulation due to an increase in vehicle traffic in this area. Based on the bridge logs this bridge opens on average less than twice an hour on signal. Scheduled openings at regular intervals between 7 a.m. and 7 p.m. would reduce the vehicle traffic back-ups caused by the opening of the bridge. Motorists will be able to better judge when the bridge will be open, and this will lead to less vehicle congestion on the surface streets surrounding the bridge.

B. Discussion of Proposed Rule

The current operating regulation governing the Treasure Island Causeway Bridge 33 CFR 117.5 requires the bridge to open on signal. The proposed schedule would have the bridge open at regular intervals between the hours of 7 a.m. and 7 p.m. The intervals will occur three times an hour during the week and twice an hour on the weekends. The Coast Guard does not anticipate longer bridge opening periods due to an accumulation of vessels, since the bridge currently opens less than twice an hour on average.

C. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes or executive orders.

1. Regulatory Planning and Review

This proposed rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

This action will have a minor impact on vessels transiting the Gulf Intracoastal Waterway in the vicinity of Treasure Island, Florida and will still meet the reasonable needs of navigation. This action is designed to improve vehicle traffic flow in downtown Treasure Island.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601-612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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 proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which might be small entities: the owners or operators of vessels needing to transit the bridge daily from 7 a.m. to 7 p.m. This proposed rule would change the regulations from one signal to three times an hour during the week and twice an hour on weekends and Federal holidays which should not have a substantial impact on any vessel traffic.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rulemaking 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 proposed rule would economically affect it.

3. 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 proposed rule. If the rulemaking would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

4. 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.).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. 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 (adjusted for inflation) or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this rulemaking elsewhere in this preamble.

8. Taking of Private Property

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

9. 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.

10. Protection of Children From Environmental Health Risks

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 might disproportionately affect children.

11. Indian Tribal Governments

This proposed 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.

12. Energy Effects

This proposed rule is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and 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 made a preliminary determination that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This proposed rule simply promulgates the operating regulations or procedures for drawbridges. This rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Commandant Instruction. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed 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; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 117.287, revise paragraph (g) to read as follows:

§ 117.287 Gulf Intracoastal Waterway.

* * * * *

(g) The draw of the Treasure Island Causeway bridge, mile 119.0 shall open on signal except that from 7 a.m. to 7 p.m. the draw need open on the hour, 20 minutes after the hour and 40 minutes after the hour Monday through Friday and on the quarter hour and three quarter hour on Saturday, Sunday and Federal holidays.

* * * * *

Dated: October 3, 2013.

J.H. Korn,

*Rear Admiral, U.S. Coast Guard, Commander,
Seventh Coast Guard District.*

[FR Doc. 2013-27066 Filed 11-12-13; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2013-0933]

RIN 1625-AA00

Safety Zone for Fireworks Display, Baltimore Harbor, Baltimore, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone encompassing certain waters of Baltimore Harbor. This action is necessary to provide for the safety of life on navigable waters during a fireworks display launched from a barge located in Baltimore's Inner Harbor at Baltimore, MD on December 31, 2013. This safety zone is intended to protect the maritime public in a portion of Baltimore Harbor.

DATES: Comments and related material must be received by the Coast Guard on or before December 13, 2013.

ADDRESSES: You may submit comments identified by docket number using any one of the following methods:

(1) Federal eRulemaking Portal:

<http://www.regulations.gov>.

(2) Fax: 202-493-2251.

(3) Mail or Delivery: Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202-366-9329.

See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Ronald Houck, Sector Baltimore Waterways Management Division, Coast Guard; telephone 410-576-2674, email Ronald.L.Houck@uscg.mil.

uscg.mil. If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

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To submit your comment online, go to <http://www.regulations.gov>, type the docket number [USCG-2013-0933] in the "SEARCH" box and click "SEARCH." Click on "Submit a Comment" on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

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4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting 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**.

B. Regulatory History and Information

This proposed rule involves a fireworks display associated with a New Year's Eve event that will take place in Baltimore, Maryland on December 31, 2013 and will attract thousands of spectators. The launch sites for the fireworks display are from discharge barges located in Baltimore Harbor. The permanent safety zones listed in the Table to 33 CFR 165.506 also apply to this event. This rulemaking adds the location of an additional barge from which fireworks will be launched.

C. Basis and Purpose

Fireworks displays are frequently held from locations on or near the navigable waters of the United States. The potential hazards associated with fireworks displays are a safety concern during such events. The purpose of this proposed rule is to promote public and maritime safety during a fireworks display, and to protect mariners transiting the area from the potential hazards associated with a fireworks