

**ADDRESSES:** You may submit comments to the proposed rule by any of the following methods:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written submissions in the following ways:

- **Mail/Hand delivery/Courier (for paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**Instructions:** All submissions received must include the Docket No. FDA-2007-N-0363 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Emily Gebbia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993, 240-402-0980.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of December 18, 2014, FDA published a proposed rule to amend its labeling regulations for human prescription drugs and biological products to require that the prescribing information intended for health care professionals that is on or within the package from which the product is dispensed be distributed electronically and not in paper form, except as provided by the proposed rule. The proposed rule is intended to facilitate the distribution of updated prescribing information as new information becomes available and as changes in prescribing information are made. FDA is proposing the change to help ensure that the most current

prescribing information will be available and readily accessible to health care professionals at the time of clinical decision making and dispensing. FDA provided a 90-day comment period (*i.e.*, until March 18, 2015) for the proposed rule.

The Agency has received a request for a 60-day extension of the comment period for the proposed rule. The request conveyed concern that the current 90-day comment period does not allow sufficient time for entities and individuals who will be most affected by a final rule to examine and to comment upon the proposed rule. The request suggested that FDA would benefit by granting stakeholders sufficient time to develop their comments and to address as many relevant issues as possible.

FDA has considered the request and is extending the comment period for the proposed rule for 60 days, until May 18, 2015. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on this important issue.

##### II. Request for Comments

Interested persons may submit either electronic comments regarding the proposed rule to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: March 3, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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BILLING CODE 4164-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2015-0071]

RIN 1625-AA08

#### Safety Zone; 24 Mile Tampa Bay Marathon Swim, Tampa Bay, Tampa, FL

AGENCY: Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a temporary moving safety zone on the waters of the Tampa Bay in Tampa, Florida during the 24 Mile Tampa Bay Marathon Swim. The swim is scheduled to take place from 4 a.m. to 9 p.m. on April 25, 2015.

Approximately 30 swimmers are anticipated to participate in the marathon swim event. No spectators are expected to be present during the event. The safety zone is necessary to provide for the safety of the participants, participant vessels, and the general public on the navigable waters of the United States during the event. The safety zone will establish a moving protective area around all swimmers involved in the race. Persons and vessels, except those participating in the event, will be prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port St. Petersburg or a designated representative.

**DATES:** Requests for public meetings, comments or related material must be received by the Coast Guard on or before March 16, 2015.

**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 Tyrone J. Stafford, Sector St. Petersburg Prevention Department, Coast Guard; telephone (813) 228-2191, email [D07-SMB-Tampa-WWM@uscg.mil](mailto:D07-SMB-Tampa-WWM@uscg.mil). If you have questions on viewing or submitting material to the docket, call Cheryl Collins, 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 rulemaking, 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 telephone 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–2015–0071 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

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–2015–0071 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 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

The Coast Guard is proposing to establish this temporary moving safety zone on the waters of the Tampa Bay in Tampa, Florida during the 24 Mile Tampa Bay Marathon Swim. The race is scheduled to take place from 4 a.m. to 9 p.m. on April 25, 2015. This proposed rule is necessary to protect the safety of the participants, participant vessels, and the general public on the navigable waters of the United States during the event.

### C. Basis and Purpose

The legal basis for the proposed rule is the Coast Guard’s authority to establish safety zones: 33 U.S.C. 1231; 33 CFR 1.05–1, 6.04–1, 160.5; Department of Homeland Security Delegation No. 0170.1.

The purpose of the proposed rule is to provide for the safety of life on navigable waters of the United States during the 24 Mile Tampa Bay Marathon Swim.

### D. Discussion of Proposed Rule

This proposed rule is to establish a temporary moving safety zone that will encompass certain waters of Tampa Bay in Tampa, Florida. The proposed safety zone will be enforced from 4 a.m. to 9 p.m. on April 25, 2015. The safety zone

will establish a moving protective area around all swimmers involved in the race. Persons and vessels, except those participating in the event, will be prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port St. Petersburg or a designated representative.

Persons and vessels may request authorization to enter, transit through, anchor in, or remain within the enforcement areas by contacting the Captain of the Port St. Petersburg by telephone at (727) 824–7506, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the enforcement areas is granted by the Captain of the Port St. Petersburg or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port St. Petersburg or a designated representative.

### E. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of 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 Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders.

The economic impact of this proposed rule is not significant for the following reasons: (1) The temporary moving safety zone would be enforced for 17 hours; (2) although persons and vessels are prohibited to enter, transit through, anchor in, or remain within the enforcement areas without authorization from the Captain of the Port St. Petersburg or a designated representative, they may operate in the surrounding area during the enforcement period; (3) persons and vessels may still enter, transit through, anchor in, or remain within the enforcement areas during the enforcement period if authorized by the Captain of the Port St. Petersburg or a designated representative; and (4) the

Coast Guard would provide advance notification of the safety zone to the local maritime community by Local Notice to Mariners, Broadcast Notice to Mariners and/or on-scene designated representatives.

## 2. Impact on Small Entities

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

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.

## 3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule 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** section 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 will not call for a 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 determined that this rule 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 would not result in such expenditure, we do discuss the effects of this rule 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 proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide 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 that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination is available in the docket where indicated under **ADDRESSES**. 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 165

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

## PART 165—SAFETY ZONES

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a temporary § 165.T07–0071 to read as follows:

**§ 165.T07–0071 Safety Zone; 24 Mile Tampa Bay Marathon Swim, Tampa Bay; Tampa, FL.**

(a) *Regulated Areas.* All waters within a 50-yard radius around the swimmers and safety vessels including kayaks.

(b) *Definition.* The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the

Captain of the Port St. Petersburg in the enforcement of the regulated areas.

(c) *Regulations.* (1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port St. Petersburg or a designated representative.

(2) Non-participant persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port St. Petersburg by telephone at (727) 824-7506, or a designated representative via VHF radio on channel 16. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port St. Petersburg or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port St. Petersburg or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast Notice to Mariners, and/or on-scene designated representatives.

(d) *Effective Date.* This rule is effective on April 25, 2015 and will be enforced from 4 a.m. to 9 p.m.

Dated: February 18, 2015.

**G.D. Case,**

*Captain, U.S. Coast Guard, Captain of the Port St. Petersburg.*

[FR Doc. 2015-05471 Filed 3-6-15; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket Number USCG-2015-0093]

RIN 1625-AA08

#### Safety Zone; Swim Around Lido Key; Tampa Bay; Sarasota, FL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard is proposing to establish a temporary moving safety zone on the waters of the Sarasota Bay in Sarasota, Florida during the Swim Around Lido Key. The swim is scheduled to take place from 8 a.m. to 2 p.m. on April 12, 2015. Approximately 100 swimmers are anticipated to participate in the swim event. No spectators are expected to be present during the event. The safety zone is necessary to provide for the

safety of the participants, participant vessels, and the general public on the navigable waters of the United States during the event. The safety zone will establish a moving protective area around all swimmers involved in the race. Persons and vessels, except those participating in the event, will be prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port St. Petersburg or a designated representative.

**DATES:** Comments and related material must be received by March 20, 2015.

Requests for public meetings must be received by the Coast Guard on or before March 16, 2015.

**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.

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