

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165****[Docket No. USCG–2013–0192]****RIN 1625–AA00****Safety Zones; Tall Ship Safety Zones; War of 1812 Bicentennial Commemoration, Great Lakes****AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone around each tall ship participating in the Tall Ships Challenge Great Lakes 2013 and the War of 1812 Bicentennial Commemoration. These safety zones will ensure the safety of participating tall ships, spectator vessels, and commercial traffic throughout the Great Lakes.

DATES: This rule will be enforced with actual notice from 12:01 a.m. on July 3, 2013, until July 23, 2013. This rule is effective in the Code of Federal Regulations from July 23, 2013, until September 10, 2013, at 11:59 p.m.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2013–0192. 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–2013–0192) 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email Mr. Mark Bobal, Prevention Department, Ninth Coast Guard District, Cleveland, OH telephone (216) 902–6052, email mark.d.bobal@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

TFR Temporary Final Rule

A. Regulatory History and Information

On May 1, 2013, the Coast Guard published an NPRM in the **Federal Register** (78 FR 25410), proposing to establish temporary safety zones around each of the twenty-one tall ships participating in the Tall Ships Challenge Great Lakes 2013 and the War of 1812 Bicentennial Commemoration. The comment period for this NPRM concluded on May 31, 2013, and no comments were received. No public meeting was requested and none was held.

In another regulation, the Coast Guard will establish a special local regulation for the tall ships celebration parade in Bay City, Michigan, on July 11, 2013 (USCG–2013–0368).

Under 5 U.S.C. 553(d)(3), The Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. The final details of this event were not known to the Coast Guard until there was insufficient time for allow for a 30 day delayed effective date. Although the Coast Guard provided for a 30 day comment period, waiting an additional 30 days for the delayed effective period to run would be impractical and contrary to the public interest because it would inhibit the Coast Guard’s ability to protect spectators and vessels from the hazards associated with a large gathering of sailboats in preparation for a race, which are discussed further below.

B. Basis and Purpose

As announced the Notice of Proposed Rulemaking, the U.S. Navy has planned to hold a series of events along the Great Lakes during the summer of 2013. Detailed information about remaining commemorations can be found at <http://www.visit1812.com>.

Also to commemorate the War of 1812 over the summer of 2013, twenty-five tall ships will traverse all five Great Lakes as part of the Tall Ships Challenge Great Lakes 2013. Between June 13 and September 17, 2013, the tall ships will appear in twenty-two Great Lakes ports and participate in five separate races. Millions of spectators are expected to attend the tall ships events throughout the Great Lakes. Information about the Tall Ships Challenge can be found at: <http://www.sailtraining.org/tallships/2013greatlakes/>.

The Coast Guard expects the following tall sailing ships to participate in the Tall Ships Challenge Great Lakes 2013: the APPLEDORE IV, CHALLENGE, COASTER, DENIS SULLIVAN, EMPIRE SANDY, FAIR

JEANNE, FRIENDS GOOD WILL, HALIE & MATTHEW, HINDU, KAJAMA, LA REVENANTE, LIANAS RANSON, LYNX, MADELINE, MIST OF AVALON, NIAGARA, PATHFINDER, PEACEMAKER, PLAYFAIR, PRIDE OF BALTIMORE II, RED WITCH, SORLANDET, ST. LAWRENCE II, UNICORN, and the WINDY.

The Ninth District Commander has determined that the War of 1812 Bicentennial Commemoration and the Tall Ships Challenge Great Lakes 2013 may pose serious dangers to the boating public. This determination is based on the high concentration of recreational boaters expected to be drawn to these events. The number of spectators is expected to be particularly high in the port areas of Erie, PA; Cleveland, OH; Put-in-Bay, OH; Bay City, MI; Chicago, IL; Green Bay, WI; and Duluth, MN because of events planned for those ports. The Ninth District Commander’s determination is also based on the decreased maneuverability of tall sailing ships and the commercial vessel traffic known to frequent the aforementioned port areas.

With these dangers in mind, the Ninth District Commander will establish temporary safety zones pursuant to the authority granted in the Ports and Waterways Safety Act (33 U.S.C. 1221 et seq.).

C. Discussion of Comments, Changes and the Final Rule

To alleviate the dangers posed by the expected high concentration of recreational boaters, commercial traffic operations, and the limited maneuverability of tall sailing ships, the Ninth District Commander has determined that it is necessary to establish a safety zone around each tall ship participating in the War of 1812 Bicentennial Commemoration and the Tall Ships Challenge Great Lakes 2013. Accordingly, the Ninth District Commander will establish a safety zone around each of the tall ships listed in the *Basis and Purpose* section above.

These safety zones will be in effect and enforced from 12:01 a.m. on July 3, 2013, until 11:59 p.m. on September 10, 2013. On September 2, 2013, each tall ship participating in the re-enactment of the Battle of Lake Erie will be surrounded by a safety zone 500 yards in radius. At all other times, between July 3, 2013, and September 10, each tall ship will be surrounded by a safety zone 100 yards in radius. These safety zones will be in effect and enforced around each tall ship regardless of whether the tall ship is underway, at anchor, or moored.

In accordance with 33 CFR 165.33, no vessel or person may enter one of these safety zones without the permission of the Ninth District Commander, the cognizant Captain of the Port, or the on-scene designated representative. Permission may be obtained to enter a safety zone by contacting the on-scene designated representative on VHF channel 16. Each vessel permitted to enter a safety zone must remain at least 25 yards from any tall ships within the zone. Additionally, each vessel permitted to enter one of the safety zones established by this rule must operate at the minimum speed necessary to maintain a safe course and must proceed as directed by the Ninth District Commander, the cognizant Captain of the Port, or the on-scene designated representative.

D. Regulatory Analyses

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

1. Regulatory Planning and Review

This 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. It is not “significant” under the regulatory policies and procedures of the Department of Homeland Security.

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues.

Although these safety zones will be enforced throughout the Great Lakes, each zone will be relatively small and only enforced in any one particular geographic area for a minimal time. This is because the safety zones will follow the tall ships through the Great Lakes and not remain in any given area for more than a few days. Even when these safety zones are being enforced in a given port area, vessels will have the opportunity to transit through a zone by obtaining permission from the Ninth District Commander, the cognizant Captain of the Port, or the on-scene

designated representative. For these reasons, restrictions on vessel movement within any particular geographic area of the Great Lakes are expected to be minimal, and therefore, the Coast Guard considers this rulemaking not to be a significant regulatory action.

2. Impact on Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered the impact of this rule on small entities. 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 rule would affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in one of the safety zones established by this rule. This safety zone will not have a significant economic impact on a substantial number of small entities for the reasons discussed in the *Regulatory Planning and Review* section above.

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 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** above. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. 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).

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

8. Taking of Private Property

This temporary rule will 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 temporary 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 temporary rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This temporary rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

This temporary 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.

12. *Energy Effects*

This 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 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 guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321-4370f), and have determined 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 under figure 2-1, paragraph (34)(g), of the Commandant Instruction because it involves the establishment of safety zones. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for Part 165 continues to read as follows:

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

- 2. Add § 165.T09-0192 to read as follows:

§ 165.T09-0192 Tall Ship Safety Zones; War of 1812 Bicentennial Commemoration, Great Lakes.

(a) *Locations.* The following are safety zones:

(1) All navigable waters of the United States located in the Ninth Coast Guard

District within a 100 yard radius of the following tall ships: APPLIEDORE IV, CHALLENGE, DENIS SULLIVAN, EMPIRE SANDY, FAIR JEANNE, FRIENDS GOOD WILL, HINDU, KAJAMA, LA REVENANTE, LYNX, MADELINE, NIAGARA, PATHFINDER, PEACEMAKER, PLAYFAIR, PRIDE OF BALTIMORE II, RED WITCH, SORLANDET, ST. LAWRENCE II, UNICORN, and the WINDY. These safety zones will be enforced around each tall ship regardless of whether the tall ship is underway, at anchor, or moored.

(2) All navigable waters of the United States located in the Ninth Coast Guard District within a 500 yard radius of each tall ship participating in the re-enactment of the Battle of Lake Erie on September 2, 2013.

(b) *Effective and enforcement period.* This rule is effective and will be enforced between 12:01 a.m. on July 3, 2013 until 11:59 p.m. on September 10, 2013.

(c) *Regulations.* (1) In accordance with the general regulations in section 165.23 of this part, entry into a safety zone established by this section is prohibited without the authority of the Ninth District Commander, the cognizant Captain of the Port, or the on-scene designated representative.

(2) The “designated representative” of the Ninth District Commander is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Ninth District Commander or the cognizant Captain of the Port to act on his or her behalf.

(3) Permission may be obtained to enter a safety zone established herein by contacting the on-scene designated representative on VHF channel 16.

(4) Each vessel permitted to enter a safety zone established herein must remain at least 25 yards from any tall ships within that zone.

(5) Each vessel permitted to enter a safety zone established by this section must operate at the minimum speed necessary to maintain a safe course and must proceed as directed by the Ninth District Commander, the cognizant Captain of the Port, or the on-scene designated representative.

Dated: June 26, 2013.

M.N. Parks

Rear Admiral, U. S. Coast Guard, Ninth District Commander.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906-AA94

Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: HHS is issuing this final rule to clarify how section 340B(e) of the Public Health Service Act (PHSA) will be implemented. The final rule applies section 340B(e) of the PHSA only to drugs transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FFDCA). The final rule also sets forth that it is the responsibility of the 340B covered entity to maintain auditable records that demonstrate compliance with the terms of the orphan drug exclusion requirements. This rule will provide clarity in the marketplace, maintain the 340B savings for newly-eligible covered entities, and protect the financial incentives for manufacturing orphan drugs designated for a rare disease or condition as indicated in the Affordable Care Act and intended by Congress.

DATES: This final rule is effective on October 1, 2013.

FOR FURTHER INFORMATION CONTACT: CDR Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C-03, Rockville, Maryland 20857, or by telephone at (301) 594-4353.

SUPPLEMENTARY INFORMATION:

I. Background

The 340B Program was established by section 602 of the Veterans Health Care Act of 1992 (Pub. L. 102-585) and is codified as section 340B of the PHSA. Section 340B instructs HHS to enter into agreements with drug manufacturers of covered outpatient drugs. 42 U.S.C. 256b(a). Pursuant to section 340B(a)(1) of the PHSA, when a manufacturer signs a Pharmaceutical Pricing Agreement (PPA), it agrees that the prices charged for covered outpatient drugs to covered entities (organizations eligible under section 340B to receive 340B discounted pricing) will not exceed defined ceiling prices, which are based on pricing data