

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “Novopharm Ltd.” and alphabetically add a new entry for “Teva Canada Ltd.”; and in the table in paragraph (c)(2), revise the entry for “043806” to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

* * * * *				
(c) * * *				
(1) * * *				
Firm name and address				Drug labeler code
* * * * *				*
Teva Canada Ltd., 30 Novopharm Ct., Toronto, Ontario, Canada M1B 2K9 .....				043806
* * * * *				*
(2) * * *				
Drug labeler code		Firm name and address		
* * * * *		* * * * *		
043806 .....		Teva Canada Ltd., 30 Novopharm Ct., Toronto, Ontario, Canada M1B 2K9.		
* * * * *		* * * * *		

Dated: May 29, 2012.

**Bernadette Dunham,**  
Director, Center for Veterinary Medicine.

[FR Doc. 2012-13409 Filed 6-1-12; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

[Docket Number USCG-2011-1029]

RIN 1625-AA00; AA87

### Safety & Security Zones; OPSAIL 2012 Connecticut, Thames River, New London, CT

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is establishing temporary safety and security zones on the Thames River near New London, CT for OPSAIL 2012

Connecticut (CT) activities. This action is necessary to provide for the safety of life and protection of naval vessels on navigable waters during OPSAIL 2012 CT. This action will restrict vessel from entering into, transiting through, mooring or anchoring within the zones unless authorized by the Captain of the Port (COTP) Sector Long Island Sound (SLIS).

**DATES:** This rule is effective from 7:30 a.m. on July 3, 2012 until 5 p.m. on July 9, 2012.

This rule will be enforced during the following dates and times:

1. Naval Vessel Security Zones will be enforced from 7:30 a.m. on July 3, 2012 until 5 p.m. on July 9, 2012.

2. Admiral Shear State Pier Security Zone will be enforced from 7:30 a.m. on July 3, 2012 until 5 p.m. on July 9, 2012.

3. Fireworks Safety Zone will be enforced from 8:30 p.m. until 10 p.m. on July 7, 2012. If the fireworks display is postponed, it will be enforced from 8:30 p.m. until 10 p.m. on July 8, 2012.

**ADDRESSES:** Documents mentioned in this preamble are part of docket [USCG-2011-1029]. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number 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 rule, call or email Petty Officer Joseph Graun, Prevention Department, U.S. Coast Guard Sector Long Island Sound, (203) 468-4544, [Joseph.L.Graun@uscg.mil](mailto:Joseph.L.Graun@uscg.mil). If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366-9826.

### SUPPLEMENTARY INFORMATION:

#### Table of Acronyms

COTP Captain of the Port  
CT Connecticut  
DHS Department of Homeland Security  
FR Federal Register  
SLIS Sector Long Island Sound

### A. Regulatory History and Information

On March 20, 2012 the Coast Guard published a notice of proposed rulemaking entitled Safety & Security Zones; OPSAIL 2012 Connecticut,

Thames River, New London, CT in the **Federal Register** (77 FR 16198). We received no comments on the proposed rule. No public meeting was requested and none were held.

*Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the Federal Register. Due to the need for immediate action, the restriction of vessel traffic is necessary to protect life, property and the environment; therefore, a 30-day notice is impracticable. Delaying the effective date would be contrary to the regulation's intended objectives of protecting persons and vessels, and enhancing public and maritime safety.*

### B. Basis and Purpose

The legal basis for the temporary rule is 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; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define safety and security zones.

OPSAIL 2012 CT is a multi-day marine event involving a gathering of naval vessels, and a fireworks display. This rule is necessary to: (1) protect participating naval vessels from security threats. (2) Protect waterway users from the dangers inherent to fireworks displays.

### C. Discussion of Comments, Changes and the Final Rule

No comments were received and no changes were made to the final rule.

### 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 or 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.

The Coast Guard has determined this rule is not a significant regulatory action for the following reasons: (1) The regulated areas will be of limited

duration and cover only a small portion of the navigable waterways; (2) vessels may transit the navigable waterways outside of the safety and security zones and (3) Vessels requiring entry into the safety and security zones may be authorized to do so by the COTP SLIS or designated representative.

Advanced public notifications will also be made to the local maritime community through the Local Notice to Mariners as well as Broadcast Notice to Mariners. In addition, the sponsoring organization, OPSAIL, Inc., is planning to publish information of the event in local newspapers, pamphlets, internet sites, television and radio broadcasts.

## 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 Coast Guard received no comments from the Small Business Administration on this rule. 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 temporary rule might affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit the Thames River from July 3–9, 2012. The regulated areas will be of limited duration and cover only a small portion of the navigable waterways. Vessels would be able transit the navigable waterways outside of the safety and security zones. Vessels requiring entry into the safety and security zones may be authorized to do so by the COTP or designated representative. Before the effective period, the Coast Guard will make notifications to the public through the Local Notice to Mariners and Broadcast Notice to Mariners. In addition, the sponsoring organization, OPSAIL, Inc., is planning to publish information of the event in local newspapers, pamphlets, internet sites, television and radio broadcasts.

## 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.

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

## 8. Taking of Private Property

This 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 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

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 create an environmental risk to health or risk to safety that may disproportionately affect children.

## 11. 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.

## 12. Energy Effects

This action 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 M16475.1D, 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 establishes temporary safety and security zones. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are 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 rule.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and 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, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T01–1029 to read as follows:

##### § 165.T01–1029 Safety & Security Zones; OPSAIL 2012 Connecticut, Thames River, New London, CT.

(a) The following areas are established as security zones:

(1) 100 yards around all U.S. naval vessels measuring 100 feet or less in length while in the navigable waters of the Thames River, CT between 41°21'46" N, 072°05'17" W (Thames River Railroad Bridge in the Port of New London) and 41°18'21.14" 72°04'38.78" (New London Ledge light), whether the U.S. naval vessel is underway, anchored, or moored.

(2) 100 yards around all foreign naval vessels in the navigable waters of the Thames River, CT between 41°21'46" N, 072°05'17" W (Thames River Railroad Bridge in the Port of New London) and 41°18'21.14" 72°04'38.78" (New London Ledge light), whether the foreign naval vessel is underway, anchored, or moored.

(3) All navigable waters surrounding Admiral Shear State Pier shoreward of a boundary line created by connecting the following coordinates. Beginning at position 41°21'37" N, 072°05'26" W then to position 41°21'25" N, 072°05'16" W then to position 41°21'21" N, 072°05'24" W then ending at position 41°21'23" N, 072°05'26" W (NAD 83).

(b) The following area is established as a safety zone: All navigable waters within a 1000-foot radius of each fireworks barge located in approximate positions 41°20'57.1" N, 072°05'22.1" W and 41°21'03.3" N, 072°05'24.5" W (NAD 83).

(c) *Regulations.*

(1) The general regulations contained in 33 CFR 165.23 and 165.33 apply.

(2) In accordance with the general regulations in § 165.23 and § 165.33 of

this part, entry into or movement within these zones is prohibited unless authorized by the Captain of the Port (COTP) Sector Long Island Sound (SLIS) or designated representative.

(3) All persons and vessels shall comply with the instructions of the COTP SLIS or designated representative. These designated representatives are comprised of commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing lights or other means the operator of a vessel shall proceed as directed.

(4) Persons and vessels desiring to enter, transit through, anchor in, or remain within the safety or security zones must contact the COTP SLIS by telephone at (203) 468–4401, or designated representative via VHF radio on channel 16, to request authorization. If authorization to enter, transit through, anchor in, or remain within the safety or security zones is granted by the COTP SLIS or designated representative, all persons and vessels receiving such authorization must comply with the instructions of the COTP SLIS or designated representative.

(5) The Coast Guard will provide notice of the safety and security zones, prior to the event through the Local Notice to Mariners and Broadcast Notice to Mariners. Notice will also be provided by on-scene designated representatives.

(d) *Enforcement period.* This section will be enforced during the following times.

(1) Naval Vessel Security Zones will be enforced from 7:30 a.m. on July 3, 2012 until 5 p.m. on July 9, 2012.

(2) Admiral Shear State Pier Security Zone will be enforced from 7:30 a.m. on July 3, 2012 until 5 p.m. on July 9, 2012.

(3) Fireworks Safety Zone will be enforced from 8:30 p.m. until 10 p.m. on July 7, 2012. If the fireworks display is postponed, it will be enforced from 8:30 p.m. until 10 p.m. on July 8, 2012.

Dated: May 25, 2012.

**J.M. Vojvodich,**

*Captain, U.S. Coast Guard, Captain of the Port Sector Long Island Sound.*

[FR Doc. 2012–13503 Filed 5–31–12; 4:15 pm]

**BILLING CODE 9110–04–P**

#### FEDERAL COMMUNICATIONS COMMISSION

#### 47 CFR Part 73

[MB Docket No. 11–168; RM–11642; DA 12–790]

#### Radio Broadcasting Services; Llano, TX

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** The Audio Division, at the request of Bryan King (“petitioner”), removes FM Channel 293C3 and allots FM Channel 242C3 at Llano, Texas, contingent upon the final outcome in MB Docket No. 05–112. Channel 242C3 can be allotted at Llano, consistent with the minimum distance separation requirements of the Commission’s rules, at coordinates 30–55–34 NL and 98–43–24 WL, with a site restriction of 19.1 km (11.9 miles) north of the community. The Government of Mexico has concurred with the allotment of Channel 242C3 at Llano, which is located within 320 kilometers (199 miles) of the U.S.-Mexican border. See **SUPPLEMENTARY INFORMATION** *infra*.

**DATES:** Effective July 5, 2012.

**FOR FURTHER INFORMATION CONTACT:** Deborah Dupont, Media Bureau, (202) 418–2180.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission’s *Report and Order*, MB Docket No. 11–168, adopted May 17, 2012, and released May 18, 2012. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Information Center, Portals II, 445 12th Street SW., Room CY–A257, Washington, DC 20554. The complete text of this decision also may be purchased from the Commission’s duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, (800) 378–3160, or via the company’s Web site, [www.bcpweb.com](http://www.bcpweb.com). This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed information collection burden “for small business concerns with fewer than 25 employees,” pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4). The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office