(6) For purposes of paragraph (f)(2) of this section, information will be considered newly acquired if it consists of data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

* * * * *

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 6. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 7. Section 814.3 is amended by adding paragraph (o) to read as follows:

§ 814.3 Definitions.

* * * * *

(o) *Newly acquired information* means data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

■ 8. Section 814.39 is amended by revising paragraphs (d)(1) introductory text and (d)(2)(i) to read as follows:

§ 814.39 PMA supplements.

* * * * *

(d)(1) After FDA approves a PMA, any change described in paragraph (d)(2) of this section to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt under § 814.17 of a written FDA order approving the PMA supplement provided that:

* * * * *

(2) * * *

(i) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association.

* * * * *

Dated: August 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19572 Filed 8–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2008–0424]

Special Local Regulation; U.S. Nationals Waterski Racing Championship; Mission Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the U.S. Nationals Waterski Racing Championship special local regulation on Mission Bay from 8 a.m. on October 10, 2008 through 5 p.m. on October 12, 2008. This action is necessary to provide for the safety of the participants, crew, spectators, participating vessels, and other vessels and users of the waterway. During the enforcement period, no person or vessel may enter the special local regulation without permission of the Captain of the Port.

DATES: The regulations in 33 CFR 100.1101 will be enforced from 8 a.m. on October 10, 2008 through 5 p.m. on October 12, 2008.

FOR FURTHER INFORMATION CONTACT: Petty Officer Kristen Beer, USCG, Waterways Management, U.S. Coast Guard Sector San Diego at (619) 278–7233.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation for the U.S. Nationals Waterski Racing Championship in 33 CFR 100.1101 on October 10, 2008, from 8 a.m. to 7 p.m., October 11, 2008, from 8 a.m. to 7 p.m., and October 12, 2008, from 8 a.m. to 7 p.m.

Under the provisions of 33 CFR 100.1101, a vessel may not enter the regulated area, unless it receives permission from the COTP. Spectator vessels may safely transit outside the regulated area but may not anchor, block, loiter in, or impede the transit of participants or official patrol vessels. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 33 CFR 100.1101(a) and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with extensive advance notification of this enforcement period via the Local Notice to Mariners, marine information broadcasts, local radio stations and area newspapers. If the COTP or his designated representative determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: August 8, 2008.

T.H. Farris,

Captain, U.S. Coast Guard, Captain of the Port Sector San Diego.

[FR Doc. E8–19532 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2008–0769]

Oregon Symphony Celebration Fireworks Display, Portland, OR

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the ''Oregon Symphony Celebration Fireworks Display safety zone on the Willamette River''; from 8:30 p.m. through 11:30 p.m. on August 28, 2008. This action is necessary to provide a safe display for the public and to keep them clear of the fall out area of the fireworks. During the enforcement period, no person or vessel may enter the safety zone without permission of the Captain of the Port Portland or his designated representative.

DATES: The regulations in 33 CFR 165.1315(a)(7) will be enforced from 8:30 p.m. through 11:30 p.m. on August 28, 2008.

FOR FURTHER INFORMATION CONTACT: BM2 Joshua Lehner, Sector Portland Waterways Management at (503) 247–4015.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone for the Oregon Symphony Celebration Fireworks Display in 33 CFR 165.1315(a)(7) on August 28, 2008 from 8:30 p.m. to 11:30 p.m.

Under the provisions of 33 CFR 165.1315, a vessel may not enter the regulated area, unless it receives permission from the Captain of the Port (COTP) or his designated representative. The Coast Guard may be assisted by other Federal, state, or local law enforcement agencies in enforcing this regulation.

This notice is issued under authority of 33 CFR 165.1315 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and a marine information broadcast. If the COTP determines that the regulated area need not be enforced for the full duration stated in this notice, he may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: August 13, 2008.

F.G. Myer,

Captain, U.S. Coast Guard, Captain of the Port Portland.

[FR Doc. E8–19531 Filed 8–21–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–2008–0759]

RIN 1625–AA00

Safety Zone; American Music Festival; Chesapeake Bay, Virginia Beach, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a 420-foot radius safety zone on the Chesapeake Bay in the vicinity of the Virginia Beach Oceanfront, Virginia Beach, VA in support of the American Music Festival Fireworks event. This action is intended to protect mariners from the hazards associated with fireworks displays by restricting vessel traffic movement in the vicinity of the event.

DATES: This rule is effective from August 29, 2008 at 10 p.m. until August 31, 2008 at 11 p.m.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0759 and are available online at *http://www.regulations.gov.* They are also available for inspection or copying in two locations: The 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; and the Sector Hampton Roads, Norfolk Federal Building, 200 Granby St., 7th Floor, Norfolk, VA 23510 between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call LT Tiffany Duffy, Chief Waterways Management Division, Sector Hampton Roads at (757) 668–5580. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because any delay encountered in this regulation's effective date by publishing a NPRM would be contrary to public interest since immediate action is needed to provide for the safety of life and property on navigable waters. Additionally, this temporary safety zone will only be enforced for 1 hour on August 29, 2008 and for 1 hour on August 31, 2008 and should have minimal impact on vessel transits due to the fact that vessels can safely transit through the zone when authorized by the Captain of the Port or his Representative and that they are not precluded from using any portion of the waterway except the safety zone area itself. For the same reasons above, 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**.

Background and Purpose

On August 29 and August 31, 2008, Dominion Fireworks will sponsor a fireworks display on the Chesapeake Bay shoreline centered on position 36°49′58″ N/75°57′57″ W (NAD 1983). Due to the need to protect mariners and spectators from the hazards associated with the fireworks display, access will be temporarily restricted within 420 feet of the fireworks launch site.

Discussion of Rule

The Coast Guard is establishing a safety zone on the navigable waters of the Chesapeake Bay within 420 feet of position 36°49′58″ N/075°57′57″ W (NAD 1983). This safety zone will be established in the vicinity of Virginia Beach, VA on August 29, 2008 at 10 p.m. to August 31, 2008 at 11 p.m. In the interest of public safety, access to the safety zone will be restricted from 10 p.m. to 11 p.m. on August 29, 2008 and from 10 p.m. to 11 p.m. on August 31, 2008. Except for participants and vessels authorized by the Coast Guard Captain of the Port or his representative, no person or vessel may enter or remain in the regulated area.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This 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 section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. Although this regulation restricts access to the safety zone, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration; (ii) the zone is of limited size; and (iii) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

Small Entities

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