Budget under the Paperwork Reduction Act of 1995 is not required.

For the effective date of this final rule, see the DATES section of this document.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:


§ 872.3700 [Removed]

2. Remove § 872.3700.

Dated: June 8, 2010.

Leslie Kux, Acting Assistant Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call Ensign Elizabeth Ellerson, U.S. Coast Guard Sector San Francisco, at 415–399–7436 or e-mail at D11-PF-MarineEvents@uscg.mil. 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), as it would be impracticable to publish an NPRM with respect to this rule because the event would occur before the rulemaking process could be completed. Because of the dangers posed by the pyrotechnics used in this fireworks display, the safety zone is necessary to provide for the safety of event participants, spectators, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

Background and Purpose

The City of Martinez is sponsoring a brief fireworks display on July 4, 2010. The fireworks show is meant for entertainment purposes and will be used to celebrate Independence Day. The fireworks display is scheduled to launch at 9:30 p.m., on July 4, 2010, and last twenty minutes. A safety zone around the launch site is necessary to protect spectators, vessels, and other property from the hazards associated with the pyrotechnics on the fireworks.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone on specified waters of the Carquinez Straits, for the City of Martinez Fourth of July Fireworks Display. The safety zone will apply to the navigable waters around the fireworks site within a radius of 500 feet. The fireworks launch site is on the shoreline of Martinez and will be located in position 38°01′31.77″ N., 122°08′23.75″ W. (NAD83).

The effect of the temporary safety zone will be to restrict general navigation in the vicinity of the fireworks launch site. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the safety zone. This safety zone is needed to keep spectators and vessels a safe distance away from the fireworks launch site to ensure the safety of participants, spectators, and transiting vessels.

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 rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified via public Broadcast Notice to Mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are pleasure craft engaged in recreational activities.

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.

This rule may affect owners and operators of pleasure craft engaged in recreational activities and sightseeing. This rule will not have a significant economic impact on a substantial number of small entities for several reasons: (i) Vessel traffic can pass safely around the area, (ii) vessels engaged in recreational activities and sightseeing have ample space outside of the effected portion of the area of Martinez, CA to engage in these activities, (iii) this rule will encompass only a small portion of the waterway for a limited period of time, and (iv) the maritime public will be advised in advance of this safety zone via Broadcast Notice to Mariners.

**Assistant for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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.

**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).

**Federalism**

A rule has implications for federalism under Executive Order 13132. Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

**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.

**Taking of Private Property**

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

**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.

**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.

**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.

**Energy Effects**

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

**Technical Standards**

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed and adopted by voluntary consensus standards bodies. This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

**Environment**

We have analyzed this rule under Department of Homeland Security Management Directive 0023.1 and Commandant Instruction M1647.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which 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 Instruction. This rule involves establishing, disestablishing, or changing Regulated Navigation Areas and security or safety zones. An environmental analysis checklist 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 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:

1. Add § 165.T11–320 to read as follows:

§ 165.T11–320  Safety Zone; City of Martinez 4th of July Fireworks, Martinez, CA.

(a) Location. This temporary safety zone is established for the waters of Martinez, CA. The fireworks launch site will be located in position 38°01′31.77″ N., 122°08′23.75″ W. (NAD 83). The temporary safety zone applies to the navigable waters around the fireworks site within a radius of 500 feet.

(b) Definitions. As used in this section, “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard Coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) Regulations. (1) Under the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or the COTP’s designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or the designated representative. Persons and vessels may request permission to enter the safety zone on VHF–16 or through the 24-hour Command Center at telephone (415) 399–3547.

(d) Effective period. This section is effective from 9 p.m. through 10:15 p.m. on July 4, 2010.


P.M. Gugg.
Captain, U.S. Coast Guard, Captain of the Port San Francisco.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

§ 52.2000 State implementation plan requirement.

(a) Location. This temporary safety zone is established for the waters of Martinez, CA. The fireworks launch site will be located in position 38°01′31.77″ N., 122°08′23.75″ W. (NAD 83). The temporary safety zone applies to the navigable waters around the fireworks site within a radius of 500 feet.

(b) Definitions. As used in this section, “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard Coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) Regulations. (1) Under the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the COTP or the COTP’s designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or a designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or the designated representative. Persons and vessels may request permission to enter the safety zone on VHF–16 or through the 24-hour Command Center at telephone (415) 399–3547.

(d) Effective period. This section is effective from 9 p.m. through 10:15 p.m. on July 4, 2010.


P.M. Gugg.
Captain, U.S. Coast Guard, Captain of the Port San Francisco.

SUPPLEMENTARY INFORMATION:

I. Background

On January 7, 2010 (75 FR 953), EPA published a notice of proposed rulemaking (NPR) for a SIP revision submitted by the State of Maryland. The NPR proposed approval of Maryland’s 2002 base year emissions inventory, RFP plan, RFP contingency measures, RACM, and MVEBs for the Maryland portion of the Philadelphia moderate 1997 8-hour ozone nonattainment area. EPA is approving the SIP revision because it satisfies the emission inventory, RFP, RACM, RFP contingency measure, and transportation conformity requirements of the section 110 and part D of the CAA and EPA’s regulations. The formal SIP revision was submitted by the State of Maryland on June 4, 2007.

II. Summary of SIP Revision

The SIP revision addresses emissions inventory, RACM, RFP and contingency measures requirements for the 1997 8-hour ozone NAAQS for the Maryland portion of the Philadelphia 8-hour ozone moderate nonattainment area. The SIP revision also establishes MVEBs for 2008. Other specific requirements of Maryland’s June 4, 2007 SIP revision for the Philadelphia 8-hour ozone nonattainment area and the rationale for EPA’s proposed action are explained in the NPR and will not be restated here. The following public comment was received on the NPR.

Comment: An anonymous commenter submitted the comment: “We do not need tighter regulations on ozone. Ragweed is more of problem than smog.”

Response: The comment, while vaguely expressing a general uncertainty about the rule, does not identify any particular defects in the rule substance or adoption. Importantly, the comment does not oppose EPA’s proposed full approval of the rule. Moreover, while the commenter expresses a general dislike for regulations addressing ozone pollution, the commenter does not question the legal obligation for the states to adopt and submit SIP revisions.