V. What is the Environmental Impact of This Proposed Rule?

The agency has determined under 21 CFR 25.30(h) and (i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. What is the Economic Impact of This Proposed Rule?

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule, if finalized, would not be a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The rule would amend the existing medical device reporting regulation to remove § 803.55, which requires that manufacturers submit baseline reports, and make conforming amendments to §§ 803.1(a), 803.3, 803.10(c), and 803.58(b) to remove references to baseline reports and to § 803.55 and to remove the terms ''device family'' and ''shelf life.'' The rule would not impose any new requirements but instead would remove a reporting requirement for manufacturers that FDA deems no longer necessary. The agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $127 million, using the most current (2006) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. How Does the Paperwork Reduction Act of 1995 Apply to This Proposed Rule?

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VIII. What are the Federalism Impacts of This Proposed Rule?

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, the agency has concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. How Do You Submit Comments on This Proposed Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

List of Subjects in 21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR part 803 as follows:

PART 803—MEDICAL DEVICE REPORTING

1. The authority citation for 21 CFR Part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

§ 803.1 [Amended]

2. Section 803.1 is amended in paragraph (a), in the fourth sentence, by removing the phrase ''and baseline reports''.

§ 803.3 [Amended]

3. Section 803.3 is amended by removing the definitions for ''Device family'' and ''Shelf life''.

§ 803.10 [Amended]

4. Section 803.10 is amended by removing paragraph (c)(3) and redesignating paragraph (c)(4) as paragraph (c)(3).

§ 803.55 [Removed]

5. Section 803.55 is removed.

§ 803.58 [Amended]

6. Section 803.58 is amended in paragraph (b)(1) by removing ''803.55,''.

Dated: June 5, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–13349 Filed 6–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0215]

RIN 1625–AA00

Safety Zones: Festival of Sail San Francisco, San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish temporary safety zones in support of the scheduled Festival of Sail Events from July 23, 2008, through July 27, 2008. The event will include a parade and mock cannon battles. The temporary safety zones are necessary to provide for the safety of spectators, participating vessels and crews.

DATES: Comments and related material must reach the Coast Guard on or before July 14, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket

number USCG–2008–0215 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online: http://www.regulations.gov*.

(2) *Mail:* 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.

(3) *Hand delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Lieutenant Junior Grade Sheral Richardson, U.S. Coast Guard Sector San Francisco, at (415) 399–7436. 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:

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. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2008–0215), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them 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. We may change this proposed rule in view of them.

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* at any time. Enter the docket number for this rulemaking (USCG–2008–0215) in the Search box, and click ''Go >>.'' You may also visit either the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; or the Coast Guard Sector San Francisco, 1 Yerba Buena Island, San Francisco, California, 94130 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can search the electronic form of all 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 the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://DocketsInfo.dot.gov*.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one 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**.

Background and Purpose

The American Sail Training Association, in coordination with the local sponsor, Festival of Sail San Francisco, is sponsoring the 2008 Festival of Sail Event. This event is a part of the Tall Ships® Challenge race series transiting the Pacific Ocean along the west coast of North America. Between the races, the participating vessels will visit several ports, including San Francisco. Vessels will be docked along the waterfront offering the public the opportunity to tour vessels, sail, and learn. There are many activities on the water scheduled to take place; such as mock cannon battles and the parade. Safety zones will be established along with the issuance of marine event permits for this event. The temporary safety zones are necessary to provide for the safety of the crews, spectators, and participants of the Festival of Sail and are also necessary to protect other vessels and users of waterway.

Discussion of Proposed Rule

The Coast Guard proposes to establish a moving safety zone extending 100 yards around each vessel participating in the Festival of Sail—Parade of Ships as each vessel transits through San Francisco Bay. The safety zones surrounding the participant vessels will be enforced on July 23, 2008. The parade route is as follows, it will commence at the Golden Gate Bridge, extend east to Alcatraz Island and then south to Pier 40, and will be bounded by a line connecting the following points: 37°48′40″ N and 122°28′38″ W, 37°49′10″ N and 122°28′41″ W, 37°49′31″ N and 122°25′18″ W, 37°49′06″ N and 122°24′08″ W, 37°47′53″ N and 122°22′42″ W, and 37° 46′54″ N and 122°23′09″ W.

The Coast Guard proposes to establish a temporary safety zone for the mock cannon battles taking place west of Alcatraz Island. This location will be called location ''alpha''. The safety zone will be bounded by a line connecting the following points: 37°49′18″ N and 122°25′40″ W, 37°49′24″ N and 122°25′18″ W, 37°49′45″ N and 122°25′42″ W, and lastly 37°49′37″ N and 122°26′05″ W; and will include all navigable waters from the surface to the seafloor. This safety zone will be in effect on July 25, 2008 and July 26, 2008.

The Coast Guard proposes to establish a temporary safety zone for the mock cannon battles taking place west of Treasure Island in Anchorage 7. This location will be called location ''bravo''. The safety zone will be bounded by a line connecting the following points: 37°48′55″ N and 122°23′03″ W, 37°49′07″ N and 122°22′32″ W, 37°49′28″ N and 122°22′53″ W, and lastly 37°49′18″ N and 122°23′28″ W; and will include all navigable waters from the surface to the seafloor. This safety zone will be in effect on July 24, 2008 and July 27, 2008.

These proposed safety zones are necessary to provide for the safety of the crews, spectators, and participants of the Festival of Sail. Persons and vessels would be prohibited from entering into,

transiting through, or anchoring within these safety zones unless authorized by the Captain of the Port, or his designated representative.

Regulatory Evaluation

This proposed 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.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed 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 proposed rule would 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 San Francisco Bay 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.

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.

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 so that they can better evaluate its effects on them and participate in the rulemaking. 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 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 proposed rule would call 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 proposed 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 or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would 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 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.

Protection of Children

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.

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.

Energy Effects

We have analyzed this proposed 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 or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.lD which guides 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 not likely to have a significant effect on the human environment. A preliminary ''Environmental Analysis Check List'' supporting this preliminary 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

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 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. 1226, 1231; 46 U.S.C. Chapter 701; 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 temporary § 165–T11–025 to read as follows:

§ 165–T11–025 Safety Zones; Festival of Sail, San Francisco, CA.

(a) *Location*. These temporary safety zones are established for the Festival of Sail Events taking place in the following locations:

(1) For the Festival of Sail-Parade of Ships the moving safety zone extends 100 yards around each vessel participating in the Parade of Ships as each vessel transits through San Francisco Bay to its respective mooring site.

(2) For the mock cannon battles, the safety zone for location ''alpha'' will take place west of Alcatraz Island. The safety zone will be bounded by a line connecting the following points: 37[deg]49′18″ N and 122[deg]25′40″ W, 37[deg]49′24″ N and 122[deg]25′18″ W, 37[deg]49′45″ N and 122[deg]25′42″ W, and lastly 37[deg]49′37″ N and 122[deg]26′05″ W; and will include all navigable waters from the surface to the seafloor.

(3) For the mock cannon battles, the safety zone for location ''bravo'' will take place west of Treasure Island in Anchorage 7. The safety zone will be bounded by a line connecting the following points: 37[deg]48′55″ N and 122[deg]23′03″ W, 37[deg]49′07″ N and 122[deg]22′32″ W, 37[deg]49′28″ N and 122[deg]22′53″ W and lastly 37[deg]49′18″ N and 122[deg]23′28″ W; and will include all navigable waters from the surface to the seafloor. This safety zone will be in effect on July 24, 2008, and July 27, 2008.

(b) *Enforcement Period*. This section will be effective from July 23, 2008, to July 27, 2008. If the events conclude prior to their scheduled termination times, the Coast Guard will cease enforcement of these safety zones and will announce that fact via Broadcast Notice to Mariners.

(c) *Regulations*.

(1) In accordance with the general regulations in § 165.23 of this part, entry into, transit through, or anchoring within these safety zones by all vessels and persons is prohibited, unless specifically authorized by the Captain of the Port San Francisco, or his designated representative.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port, San Francisco, or the designated representative.

(3) Designated representative means any commissioned, warrant, and petty officer of the Coast Guard onboard a Coast Guard, Coast Guard Auxiliary, local, state, or federal law enforcement vessel who is authorized to act on behalf of the Captain of the Port, San Francisco.

(4) Upon being hailed by U.S. Coast Guard patrol personnel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. Person and vessels may request permission to enter the safety zones on VHF–16 or the 24-hour Command Center via telephone at (415) 399–3547.

(5) The U.S. Coast Guard may be assisted in the patrol and enforcement of these safety zones by local law enforcement as necessary.

Dated: June 5, 2008.

P.M. Gugg.

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

[FR Doc. E8–13268 Filed 6–12–08; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2008–0257; FRL–8579–8]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Determination of Attainment of the Fine Particle Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to determine that the Harrisburg-Lebanon-Carlisle, Pennsylvania nonattainment area for the 1997 fine particle ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS) has attained the 1997 $PM_{2.5}$ NAAQS. This proposed determination is based upon quality assured, quality controlled, and certified ambient air monitoring data that show that the area has monitored attainment of the 1997 $PM_{2.5}$ NAAQS since the 2004–2006 monitoring period, and continues to monitor attainment of the standard based on 2005–2007 data. In addition, quality controlled and quality assured monitoring data for 2008 that are available in the EPA Air Quality System (AQS) database, but not yet certified, show this area continues to attain the 1997 $PM_{2.5}$ NAAQS. If this proposed determination is made final, the requirements for this area to submit an attainment demonstration and associated reasonably available measures, a reasonable further progress plan, contingency measures, and other planning State Implementation Plans (SIPs) related to attainment of the standard shall be suspended for so long as the area continues to attain the 1997 $PM_{2.5}$ NAAQS.

DATES: Written comments must be received on or before July 14, 2008.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2008–0257 by one of the following methods:

A. *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. E-mail: fernandez.cristina@epa.gov.

C. *Mail:* EPA–R03–OAR–2008–0257, Cristina Fernandez, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and