

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 CFR section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response (in hours) | Total hours |
|----------------|-----------------------|------------------------------------|------------------------|--|-------------|
| 1.281 | 129,757 | 22 | 2.8 million | 0.016 | 44,960 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of annual responses is equivalent to the annual number of entries that are submitted. In 2010, FDA received 10,116,018 prior notices. By dividing the number of prior notices by the average number of lines per entry, we estimate 2.8 million entries. By further dividing the number of entries by the number of respondents, we estimate the average annual frequency per response to be 22. We estimate that it would take on average about 58 seconds (0.016 hours) for each respondent to submit the additional information as part of prior notice. By multiplying the number of entries by the additional 58 seconds, we estimate the total number of hours to provide the additional information to be an average of approximately 45,000 hours per year which also translates to about 20 minutes (0.35 hours) per year per respondent.

The information collection provisions for this interim final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995. The requirements were approved and assigned OMB control number 0910–0683. This approval expires April 30, 2014. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Interested persons are requested to fax comments regarding information collection by June 6, 2011, to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the title, Information Required in Prior Notice of Imported Food.

V. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) 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. Federalism

FDA has analyzed this final 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 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.

VII. Comments

The requirements in this interim final rule will be in effect on July 3, 2011. FDA invites public comment on this interim final rule, and will consider modifications to it based on comments made during the comment period. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Section 1.281 is amended by adding paragraphs (a)(18), (b)(12), and (c)(19) to read as follows:

§ 1.281 What information must be in a prior notice?

- (a) * * *
- (18) Any country to which the article has been refused entry.
- (b) * * *
- (12) Any country to which the article has been refused entry.
- (c) * * *
- (19) Any country to which the article has been refused entry.

Dated: April 29, 2011.

Janet Napolitano,

Secretary of Homeland Security.

Dated: April 29, 2011.

Kathleen Sebelius,

Secretary of Health and Human Services.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0097]

RIN 1625–AA00

Safety Zone; Blue Crab Festival Fireworks Display, Little River, Little River, SC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of Little River in Little River, South Carolina during the Blue Crab Festival Fireworks Display on Friday,

May 13, 2011. The safety zone is necessary to protect the public from the hazards associated with launching fireworks over the navigable waters of the United States. Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative.

DATES: This rule is effective from 9 p.m. until 10:30 p.m. on May 13, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0097 and are available online by going to <http://www.regulations.gov>, inserting USCG–2010–0097 in the “Keyword” box, and then clicking “Search.” They are also available for inspection or copying at 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary final rule, call or e-mail Lieutenant Julie Blanchfield, Sector Charleston Waterways Management Division, Coast Guard; telephone 843–740–3184, e-mail Julie.E.Blanchfield@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) with respect to this rule because the Coast Guard did not receive notice of the Blue Crab Festival Fireworks Display with sufficient time to publish an NPRM and to receive public comments prior to the event. Any delay in the effective date of this rule would be contrary to the public interest because immediate action is needed to minimize the potential danger to the public during the fireworks display.

For the same reason discussed 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**. The Coast Guard will issue a Local Notice to Mariners and Broadcast Notice to Mariners to advise mariners of the restriction.

Background and Purpose

On May 13, 2011, The Little River Blue Crab Festival Inc., in partnership with Zambelli Fireworks Manufacturing Co., will be conducting a fireworks display in Little River, South Carolina as part of the 30th Annual Blue Crab Festival. The fireworks will explode over the waters of Little River. The fireworks display is scheduled to commence at 9:30 p.m. and conclude at 9:45 p.m. This temporary safety zone is necessary to protect the public from the hazards associated with the launching of fireworks over navigable waters of the United States.

Discussion of Rule

The safety zone encompasses certain waters of Little River in Little River, South Carolina. The safety zone will be enforced from 9 p.m. until 10:30 p.m. on May 13, 2011. The safety zone will be enforced from 9 p.m., 30 minutes prior to the scheduled commencement of the fireworks display at approximately 9:30 p.m., to ensure the safety zone is clear of persons and vessels. Enforcement of the safety zone will cease at 10:30 p.m., 45 minutes after the scheduled conclusion of the fireworks display, to account for possible delays.

Persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the safety zone unless authorized by the Captain of the Port Charleston or a designated representative. Persons and vessels desiring to enter, transit through, anchor in, or remain within the safety zone may contact the Captain of the Port Charleston via telephone at 843–740–7050, or a designated representative via VHF radio on channel 16, to seek authorization. The Coast Guard will provide notice of the safety zone by Local Notice to Mariners, Broadcast Notice to Mariners, and on-scene designated representatives.

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.

Executive Order 12866 and Executive Order 13563

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, 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.

The economic impact of this rule is not significant for the following reasons: (1) The rule will be enforced for only one and a half hours; (2) vessel traffic in the area is expected to be minimal during the enforcement period; (3) although persons and vessels will not be able to enter, transit through, anchor in, or remain within the safety zone without authorization from the Captain of the Port Charleston or a designated representative, they may operate in the surrounding area during the enforcement period; (4) persons and vessels may still enter, transit through, anchor in, or remain within the safety zone if authorized by the Captain of the Port Charleston or a designated representative; and (5) the Coast Guard will provide advance notification of the safety zone to the local maritime community by Local Notice to Mariners and Broadcast Notice to Mariners.

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 the following entities, some of which may be small entities: The owners or operators of vessels intending to enter, transit through, anchor in, or remain within that portion of Little River encompassed within the safety zone from 9 p.m. until 10:30 p.m. on May 13, 2011. For the reasons discussed in the Executive Order 12866 and Executive Order 13563 section above, this rule will not have a significant economic impact on a substantial number of small entities.

Assistance 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 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 or 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 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 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 a temporary safety zone to protect the public on the waters of Little River that will be enforced for a total of one and a half hours. 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, 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. 1226, 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; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add a temporary § 165.T07–0097 to read as follows:

§ 165.T07–0097 Safety Zone; Blue Crab Festival Fireworks Display, Little River, Little River, SC.

(a) *Regulated Area.* The following regulated area is a safety zone: All waters of Little River encompassed within a 100 yard radius of position 33°52'08" N, 78°36'42" W. All coordinates are North American Datum.

(b) *Definition.* The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the

Captain of the Port Charleston in the enforcement of the regulated area.

(c) *Regulations.*

(1) All persons and vessels are prohibited from entering, transiting through, anchoring in, or remaining within the regulated area unless authorized by the Captain of the Port Charleston or a designated representative.

(2) Persons and vessels desiring to enter, transit through, anchor in, or remain within the regulated area may contact the Captain of the Port Charleston by telephone at 843-740-7050, or a designated representative via VHF radio on channel 16, to seek authorization. If authorization to enter, transit through, anchor in, or remain within the regulated area is granted by the Captain of the Port Charleston or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Charleston or a designated representative.

(3) The Coast Guard will provide notice of the regulated area by Local Notice to Mariners, Broadcast notice to mariners, and on-scene designated representatives.

(d) *Effective Date.* This rule is effective from 9 p.m. until 10:30 p.m. on May 13, 2011.

Dated: April 26, 2011.

Michael F. White Jr.,
Captain, U.S. Coast Guard, Captain of the Port Charleston.

[FR Doc. 2011-10929 Filed 5-4-11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2009-0324]

RIN 1625-AA00

Safety Zone; Coast Guard Use of Force Training Exercises, San Pablo Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard will establish a safety zone in San Pablo Bay for Coast Guard Use of Force Training exercises. This safety zone will be established to ensure the safety of the public and participating crews from potential hazards associated with fast-moving Coast Guard small boats and/or helicopters taking part in the exercise. Unauthorized persons or vessels will be prohibited from entering into, transiting

through, or remaining in the safety zone without permission of the Captain of the Port or their designated representative.

DATES: This rule is effective June 6, 2011.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2009-0324 and are available online by going to <http://www.regulations.gov>, inserting USCG-2009-0324 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Lieutenant Simone Mausz, U.S. Coast Guard Sector San Francisco; telephone 415-399-7443, e-mail 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

On November 6, 2009, we published a Notice of Proposed Rulemaking (NPRM) entitled Safety Zone; Coast Guard Use of Force Training Exercises, San Pablo Bay, CA in the **Federal Register** (74 FR 214). We received four comments on the proposed rule from the San Francisco Bay Conservation and Development Commission (BCDC), Audubon California, Beth Huning, and San Francisco Joint Venture. No public meetings were requested or held as part of this rulemaking.

Basis and Purpose

The U.S. Coast Guard will establish a safety zone in the navigable waters of the San Pablo Bay, California that will apply to the navigable waters encompassing an area beginning at position 38°01'44" N, 122°27'06" W; 38°04'36" N, 122°22'06" W; 38°00'35" N, 122°26'07" W; 38°03'00" N, 122°20'20" W (NAD 83) and back to the starting point. U.S. Coast Guard Maritime Safety and Security Team (MSST) San Francisco, U.S. Coast Guard Air Station San Francisco, and various Coast Guard small boat stations will be conducting Use of Force training runs in the waters of San Pablo Bay. The exercises are designed to train and test Coast Guard personnel in the decision-making

processes necessary to safely and effectively employ Use of Force from a small boat or helicopter during Homeland Security operations. The training will generally involve the use of several Coast Guard small boats and/or a helicopter to intercept fast-moving, evasive target vessels on the water. The small boat and helicopter crews will fire weapons at the target vessels using blank ammunition and catch bags to ensure that cartridges and other debris do not fall to the water. This safety zone is issued to establish a restricted area in San Pablo Bay around the training site.

Background

The CG's primary missions include homeland security, search and rescue, and drug and environmental enforcement, and it is in the public interest for CG personnel to be trained and ready to serve the public at all times. Among the homeland security missions is port security training to develop the tactical qualifications and expertise necessary to fulfill this mission requirement. The small boats that conduct port security operations throughout San Francisco Bay are unable to conduct such training offshore due to conditions that often exceed the assets' operational parameters, frequent visibility restrictions, and unsuitability for the offshore environment. The San Pablo Bay safety zone provides an ideal location for the Coast Guard to conduct Use of Force training since it is at least 1.5 miles away from shore as well as a safe distance from shipping lanes, wildlife refuges, water trails and access points.

Discussion of Comments and Changes

The CG conducted Use of Force training at this very same location in San Pablo Bay on average twice a month in 2009. The training went on as planned, without incidents or interference with public access, except for one occasion where the CG rescheduled one of its training sessions to avoid potential interference with a San Francisco Flyway Festival bird-watching group.

On July 29, 2009, the CG sent an email to various potentially interested parties including BCDC informing those parties of our intention to prepare a Notice of Proposed Rulemaking and a Categorical Exclusion Determination under NEPA for the establishment of a safety zone for Use of Force training in San Pablo Bay. In January 2010, in a letter to the CG, the San Francisco Bay Conservation and Development Commission raised concerns about the possible "effect on both motorized and non-motorized recreational boat traffic,