

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 direct final 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 Direct Final Rule?**

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the direct final rule have been approved by OMB in accordance with the PRA under the regulations governing labeling of medical devices (21 CFR part 801, OMB control number 0910–0485).

**VIII. What are the Federalism Impacts of This Direct Final Rule?**

FDA has analyzed this direct 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.

**IX. How Do You Submit Comments on This Direct Final Rule?**

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this direct final rule. 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 Division of Dockets Management 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 through FDMS only.

**List of Subjects in 21 CFR Part 801**

Incorporation by reference, Labeling, 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, 21 CFR part 801 is amended as follows:

**PART 801—LABELING**

■ 1. The authority citation for 21 CFR part 801 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 360i, 360j, 371, 374.

■ 2. Section 801.420 is amended by revising the second and third sentences of and adding a new fourth sentence to paragraph (c)(4) introductory text and by removing paragraph (d) to read as follows:

**§ 801.420 Hearing aid devices; professional and patient labeling.**

\* \* \* \* \*

(c) \* \* \*

(4) \* \* \* The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard “Specification of Hearing Aid Characteristics,” ANSI S3.22–2003 (Revision of ANSI S3.22–1996) (Includes April 2007 Erratum). The Director of the Office of the **Federal Register** approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005–3993, or are available for inspection at the Regulations Staff, CDRH (HFZ–215), FDA, 1350 Piccard Dr., rm. 150, Rockville, MD 20850, or at the National Archives and Records Administration (NARA). \* \* \*

\* \* \* \* \*

Dated: May 19, 2008.

**Jeffrey Shuren,**  
Associate Commissioner for Policy and Planning.  
[FR Doc. E8–11910 Filed 5–30–08; 8:45 am]  
**BILLING CODE 4160–01–S**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[Docket No. USCG–2008–0414]

RIN 1625–AA08

**Special Local Regulations for Marine Events; Pasquotank River, Elizabeth City, NC**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing special local regulations for the “Carolina Cup Regatta”, a powerboat race to be held on the waters of the Pasquotank River, Elizabeth City, North Carolina. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of the Pasquotank River adjacent to Elizabeth City, North Carolina during the powerboat races.

**DATES:** This rule is effective from 7:30 a.m. on June 6, through 6:30 p.m., June 8, 2008.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0414 and are available online at <http://www.regulations.gov>. They are also available for inspection or copying at 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 Fifth Coast Guard District, Office of Prevention, Room 416, 431 Crawford Street, Portsmouth, VA 23704 between 10 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 Dennis Sens, Project Manager, Fifth Coast Guard District, Prevention Division, (757) 398–6204 or e-mail at [Dennis.M.Sens@uscg.mil](mailto:Dennis.M.Sens@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. Publishing an NPRM would be impracticable and contrary to public interest since immediate action is needed to minimize potential danger to the public during the event. The necessary information to determine whether the marine event poses a threat to persons and vessels was not provided with sufficient time to publish an NPRM. The danger posed by powerboat racing makes special local regulations necessary to provide for the safety of 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. The Coast Guard will issue broadcast notice to mariners to advise vessel operators of navigational restrictions. On scene Coast Guard and local law enforcement vessels will also provide actual notice to mariners.

Under 5 U.S.C. 553(d)(3) and for the same reasons, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date would be contrary to public interest, because immediate action is needed to ensure the safety of the event participants, spectator craft and other vessels transiting the event area. However advance notification will be made to users of the Pasquotank River, via marine information broadcasts, Local Notice to Mariners, commercial radio stations and local area newspapers.

#### **Background and Purpose**

On June 6, 7, and 8, 2008, the Virginia Boat Racing Association will sponsor the “Carolina Cup Regatta”, on the waters of the Pasquotank River. The event will consist of approximately 75 inboard hydroplanes racing in counter clockwise heats around an oval race course. A fleet of spectator vessels is anticipated to gather nearby to view the competition. Due to the need for vessel control during the event, vessel traffic will be temporarily restricted to provide for the safety of event participants, spectators and transiting vessels.

#### **Discussion of Rule**

The Coast Guard is establishing a special local regulation on specified

waters of the Pasquotank River, Elizabeth City, North Carolina. The special local regulations include all waters from shoreline to shoreline, bound to the west by the Elizabeth City Draw Bridge and on the east by a line originating at a point along the shoreline at latitude 36[deg]17'54" N, longitude 076[deg]12'00" W, thence southwesterly to latitude 36[deg]17'35" N, longitude 076[deg]12'18" W at Cottage Point. All coordinates reference Datum NAD 1983. The special local regulation will be in effect from 7:30 a.m. to 6:30 p.m., June 6 through June 8, 2008. The effect will be to restrict general navigation in the regulated area during the power boat races. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area during the enforcement period. The Patrol Commander will notify the public of specific enforcement times by marine band radio safety broadcast. These regulations are needed to control vessel traffic during the event to enhance the safety of event 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. It is not “significant” under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

Although this regulation restricts vessel traffic from transiting a segment of the Pasquotank River during the event, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via marine information broadcasts, commercial radio stations and local area newspapers 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. This rule affects the following entities, some of which may be small entities: The owners or operators of vessels intending to transit this section of the Pasquotank River during the event.

This rule would not have a significant economic impact on a substantial number of small entities for the following reasons. This rule will be enforced for only a short period, from 7:30 a.m. to 6:30 p.m. on June 6, 7 and 8, 2008. The regulated area will apply to a segment of the Pasquotank River adjacent to Elizabeth City. Marine Traffic may be allowed to pass through the regulated area with the permission of the Coast Guard Patrol Commander. In the case where the Patrol Commander authorizes passage through the regulated area during the event, vessels will be required to proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the race course. Before the enforcement period, we would issue maritime advisories so mariners can adjust their plans accordingly.

#### **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 Commandant Instruction M16475.ID and Department of Homeland Security Management Directive 5100.1, 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 that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction, from further environmental documentation. Special local regulations issued in conjunction with a regatta or marine event permit are specifically excluded from further

analysis and documentation under those sections.

Under figure 2–1, paragraph (34)(h), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

### List of Subjects in 33 CFR Part 100

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

### Words of Issuance and Regulatory Text

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

#### PART 100—REGATTAS AND MARINE PARADES

■ 1. The authority citation for part 100 continues to read as follows:

**Authority:** 33 U.S.C. 1233.

■ 2. Add a temporary § 100.35–T05–0414 to read as follows:

#### § 100.35–T05–0414 Pasquotank River, Elizabeth City, NC.

(a) *Regulated area.* The regulated area is established for the waters of the Pasquotank River, adjacent to Elizabeth City, NC, from shoreline to shoreline, bound on the west by the Elizabeth City Draw Bridge and bound on the east by a line originating at a point along the shoreline at latitude 36[deg]17'54" N, longitude 076[deg]12'00" W, thence southwesterly to latitude 36[deg]17'35" N, longitude 076[deg]12'18" W., at Cottage Point. All coordinates reference Datum NAD 1983.

(b) *Definitions:* (1) *Coast Guard Patrol Commander* means a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Sector North Carolina.

(2) *Official Patrol* means any vessel assigned or approved by Commander, Coast Guard Sector North Carolina with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

(3) *Participant* includes all vessels participating in the 2008 Carolina Cup Regatta power boat race under the auspices of the Marine Event Permit issued to the event sponsor and approved by Commander, Coast Guard Sector North Carolina.

(c) *Special local regulations:* (1) Except for event participants and persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(2) The operator of any vessel in the regulated area must: (i) Stop the vessel

immediately when directed to do so by any Official Patrol.

(ii) Proceed as directed by any Official Patrol.

(iii) When authorized to transit the regulated area, all vessels shall proceed at the minimum speed necessary to maintain a safe course that minimizes wake near the event area.

(d) *Enforcement period.* (1) This section will be enforced from 7:30 a.m. to 6:30 p.m. on June 6, 7, and 8, 2008 and if the event's daily activities should conclude prior to 6:30 p.m., enforcement of this regulation may be terminated for that day at the discretion of the Patrol Commander.

(2) The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue marine information broadcast on VHF-FM marine band radio announcing specific event dates and times.

Dated: May 21, 2008.

**Fred M. Rosa, Jr.,**

*Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.*

[FR Doc. E8-12154 Filed 5-30-08; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2008-0341]

RIN 1625-AA00

#### Safety Zone; Piscataqua River, Portsmouth, NH, and Kittery, ME; Frontier Sentinel 2008

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing temporary moving safety zones around Coast Guard and Navy vessels as well as five fixed safety zones off to the west and south of Gerrish Island, south of Kittery Point, east of Jaffrey Point, and east of Odiornes Point during the Frontier Sentinel Exercise on the Piscataqua River, a homeland security exercise that will involve underwater equipment and operations. This rule will establish multiple fixed and moving safety zones that will be enforced from 8 a.m. to 5 p.m. daily on June 9, 2008 through June 12, 2008 from the General Sullivan Bridge, U.S. Route 16 to one mile seaward of the Red "2KR" buoy at the mouth of the river. This action is necessary to protect federal, state, and local assets (including unmanned underwater vehicles (UUV))

and others in the maritime community from the safety hazards that may arise from this large scale exercise.

**DATES:** This rule is effective from 8 a.m. on June 9, 2008 through 5 p.m. on June 12, 2008.

**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-2008-0341 and are available online at [www.regulations.gov](http://www.regulations.gov). This material is also available for inspection or copying at 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 at U.S. Coast Guard Sector Northern New England, 259 High Street, South Portland, ME 04106 between the hours of 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LTJG Kevin Miller at (207) 741-5431.

#### SUPPLEMENTARY INFORMATION:

#### Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM. In conjunction with preparations for this exercise, the U.S. Navy and Coast Guard were not able to finalize the exercise scope, location, and timetables until April 23, 2008. Therefore, publishing of a proposed rule was not feasible. Nonetheless, the temporary establishment of the safety zones established by this rule is in the public interest.

For the same reasons, 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**. Immediately implementing this rule promotes the public interest by protecting the maritime public and agency participants on the Piscataqua River during Frontier Sentinel 2008.

#### Background and Purpose

This rule establishes five fixed safety zones as well as moving safety zones for the duration of the exercise. The rule is necessary to protect the federal, state, local, and public entities on the Piscataqua River during Frontier Sentinel 2008, a large scale mine countermeasures exercise. The exercise area will encompass all waters of the Piscataqua River from the General

Sullivan Bridge, U.S. Route 16, seaward to one mile past the Red "2KR" buoy at the mouth of the river. Within this exercise area, there will be numerous federal, state, and local vessels participating with divers and unmanned underwater vehicles (UUV). The UUV's will be monitored by Coast Guard, Navy, or state patrol vessels, designated with the blue and white Alpha (Diver Down) Flag.

#### Discussion of Rule

The five fixed safety zones will be established where continuous diving operations will take place during the hours of the exercise. These fixed safety zones will be located near Gerrish Island, Kittery Point, Jaffrey Point, and Odiornes Point. The five temporary fixed safety zones will be enforced between the hours of 8 a.m. to 5 p.m. on June 9, 2008 through June 12, 2008:

All waters on the Piscataqua River enclosed by a box starting from a point located south of Kittery Point at latitude 43[deg]04'41" N, longitude 70[deg]43'03" W; thence to latitude 43[deg]04'36" N, longitude 70[deg]43'02" W; thence to latitude 43[deg]04'40" N, longitude 70[deg]42'34" W; thence to latitude 43[deg]04'45" N, longitude 70[deg]42'36" W; thence to the point of beginning.

All waters on the Piscataqua River enclosed by a box starting from a point located east of Jaffrey Point at latitude 43[deg]03'48" N, longitude 70[deg]42'36" W; thence to latitude 43[deg]03'15" N, longitude 70[deg]42'39" W; thence to latitude 43[deg]03'15" N, longitude 70[deg]42'21" W; thence to latitude 43[deg]03'48" N, longitude 70[deg]42'28" W; thence to the point of beginning.

All waters on the Piscataqua River enclosed by a box starting from a point located west of Gerrish Island at latitude 43[deg]04'32" N, longitude 70[deg]42'09" W; thence to latitude 43[deg]04'13" N, longitude 70[deg]42'05" W; thence to latitude 43[deg]03'55" N, longitude 70[deg]42'04" W; thence to latitude 43[deg]03'59" N, longitude 70[deg]41'53" W; thence to latitude 43[deg]04'15" N, longitude 70[deg]41'56" W; thence to the point of beginning.

All waters on the Piscataqua River enclosed by a box starting from a point located east of Odiornes Point at latitude 43[deg]03'05" N, longitude 70[deg]42'45" W; thence to latitude 43[deg]02'32" N, longitude 70[deg]42'33" W; thence to latitude 43[deg]02'40" N, longitude