

(d) *Followup communications.* The person named in the cease distribution and notification order or mandatory recall order shall ensure that followup communications are sent to all who fail to respond to the initial communication.

(e) *Responsibility of the recipient.* Health professionals, device user facilities, and consignees who receive a communication concerning a cease distribution and notification order or a mandatory recall order should immediately follow the instructions set forth in the communication. Where appropriate, these recipients should immediately notify their consignees of the order in accordance with paragraphs (b) and (c) of this section.

§ 810.16 Cease distribution and notification or mandatory recall order status reports.

(a) The person named in a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 shall submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order. The frequency of such reports and the agency official to whom such reports shall be submitted will be specified in the order.

(b) Unless otherwise specified in the order, each status report shall contain the following information:

(1) The number and type of health professionals, device user facilities, consignees, or individuals notified about the order and the date and method of notification;

(2) The number and type of health professionals, device user facilities, consignees, or individuals who have responded to the communication and the quantity of the device on hand at these locations at the time they received the communication;

(3) The number and type of health professionals, device user facilities, consignees, or individuals who have not responded to the communication;

(4) The number of devices returned or corrected by each health professional, device user facility, consignee, or individual contacted, and the quantity of products accounted for;

(5) The number and results of effectiveness checks that have been made; and

(6) Estimated timeframes for completion of the requirements of the cease distribution and notification order or mandatory recall order.

(c) The person named in the cease distribution and notification order or recall order may discontinue the submission of status reports when the

agency terminates the order in accordance with § 810.17.

§ 810.17 Termination of a cease distribution and notification or mandatory recall order.

(a) The person named in a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 may request termination of the order by submitting a written request to FDA. The person submitting a request shall certify that he or she has complied in full with all of the requirements of the order and shall include a copy of the most current status report submitted to the agency under § 810.16. A request for termination of a recall order shall include a description of the disposition of the recalled device.

(b) FDA may terminate a cease distribution and notification order issued under § 810.10 or a mandatory recall order issued under § 810.13 when the agency determines that the person named in the order:

(1) Has taken all reasonable efforts to ensure and to verify that all health professionals, device user facilities, consignees, and, where appropriate, individuals have been notified of the cease distribution and notification order, and to verify that they have been instructed to cease use of the device and to take other appropriate action; or

(2) Has removed the device from the market or has corrected the device so that use of the device would not cause serious, adverse health consequences or death.

(c) FDA will provide written notification to the person named in the order when a request for termination of a cease distribution and notification order or a mandatory recall order has been granted or denied. FDA will respond to a written request for termination of a cease distribution and notification or recall order within 30 working days of its receipt.

§ 810.18 Public notice.

The agency will make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new mandatory recall issued under § 810.13. The agency will delay public notification of orders when the agency determines that such notification may cause unnecessary and harmful anxiety in individuals and that initial consultation between individuals and their health professionals is essential.

Dated: November 8, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07-96-048]

RIN 2115-AE46

Special Local Regulations; Christmas Parade of Boats, Charleston, SC

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing permanent special local regulations for the Charleston Christmas Parade of Boats. This one-day event will be held on December 7, 1996, December 13, 1997, December 12, 1998, December 4, 1999, and December 9, 2000, on the Ashley, Wando and Cooper Rivers in Charleston, South Carolina, between 4:30 and 8:30 p.m. Eastern Standard Time (EST). The customary presence of commercial and recreational traffic, and the nature of the event create an extra or unusual hazard on the navigable waters during the event. These regulations are necessary for the safety of life on the navigable waters during the event.

EFFECTIVE DATE: November 20, 1996.

FOR FURTHER INFORMATION CONTACT: Ensign Mike Daponte, Project Officer, Coast Guard Group Charleston, at (803) 724-7621.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. § 553, the final rule will be made effective in less than 30 days from the date of publication in the Federal Register. Following normal rulemaking procedures will be impracticable, unnecessary, and contrary to the public interest. A notice of proposed rulemaking for this rule was published in the Federal Register (61 FR 188) with a thirty day comment period. The final rule will be made effective in less than thirty days from the date of publication in order to hold the event. During this comment period, no comments were received about this rulemaking.

Regulatory History

On September 26, 1996, the Coast Guard published a notice of proposed rulemaking entitled Charleston Christmas Parade of Boats, Charleston, SC [CGD07-96-048] in the Federal Register (61 FR 188). The comment period ended on October 28, 1996. The Coast Guard received no comments during the notice of proposed rulemaking comment period. A public hearing was not requested and no hearing was held.

Background and Purpose

These regulations are needed to provide for the safety of life during the Christmas Parade of Boats. This one-day event will be held on December 7, 1996, December 13, 1997, December 12, 1998, December 4, 1999, and December 9, 2000, on the Ashley, Wando and Cooper Rivers in Charleston, South Carolina, between 4:30 and 8:30 p.m. (EST). These regulations are intended to promote safe navigation on the waters of the Ashley, Wando and Cooper Rivers in Charleston Harbor during the boat parade by controlling the traffic entering, exiting, and traveling within the parade formation. The anticipated concentration of non-participating vessels within the area poses a safety concern, which is addressed in these regulations.

These regulations will not permit the entry or movement of spectator vessels and other non-participating vessel traffic within an area 500 yards ahead of the lead vessel, 100 yards astern of the last vessel, and 50 yards to either side of all vessels participating in the parade of boats between Wando River Terminal buoy 4 (LLNR 2720) at approximate position 32°49.20'N, 079°54.3'W, and City Marina on the Ashley River, from 4:30 to 8:30 p.m. EST, on December 7, 1996, December 13, 1997, December 12, 1998, December 4, 1999, and December 9, 2000. All coordinates referenced use datum: NAD 1983. However, the regulations will permit the movement of non-participating vessels after the termination of parade.

Regulatory Evaluation

This rule is not a significant regulatory action under Section 3(f) of the Executive Order 12866 and does not require an assessment of the potential costs and benefits under Section 5 (a)(3) of that Order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. The regulated area encompasses less than six miles of Ashley, Wando and Cooper Rivers, and will be in effect for only 4 hours on the day of the event.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rulemaking

will have a significant impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under Section 3 of the Small Business Act (15 U.S.C. 632).

The Coast Guard certifies under 5 U.S.C. 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities. The regulated area encompasses a limited area of the Ashley, Wando and Cooper Rivers, and will be in effect for only 4 hours on the day of the event.

Collection of Information

This rule contains no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this rulemaking does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this action consistent with Section 2.B.2. of Commandant Instruction M16475.1B, (as revised by 59 FR 38654, July 29, 1994). In accordance with that instruction section 2.B.4.g., this action has been environmentally assessed (EA completed), and the Coast Guard has concluded that it will not significantly affect the quality of the human environment. An environmental assessment and a finding of no significant impact have been prepared and are available in the docket for inspection or copying.

List of Subjects in 33 CFR Part 100

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

For reasons set out in the preamble, the Coast Guard amends Part 100 of Title 33, Code of Federal Regulations, as follows:

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

PART 100—[AMENDED]

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.

2. A new section 100.721 is added to read as follows:

§ 100.721 Charleston Christmas Parade of Boats, Charleston Harbor, SC.

(a) *Definitions.* (1) *Regulated Area.* A regulated area includes the area 500 yards ahead of the lead parade vessel, 100 yards astern of the last parade vessel, and 50 yards to either side of all parade vessels along the parade route described in paragraph (a)(2) of this section.

(2) *Parade Route.* The parade route begins from that portion of Charleston Harbor commencing at Wando River Terminal buoy 4 (Light List Number 2720) at approximate position 32°49.2'N, 079°54.3'W, thence to the upper end of Hog Island Reach at approximate position 32°48.7'N, 079°54.85'W, thence to approximate position 32°48.15'N, 079°54.95'W, below the Cooper River Bridges, thence southeast to approximately two-tenths of a nautical mile north of USS Yorktown at position 32°47.7'N, 079°54.7'W, thence south past the USS Yorktown to approximate position 32°47.2'N, 079°54.7'W, thence west to Custom House Reach at approximate position 32°47.2'N, 079°55.3'W, thence south to 32°45.7'N, 079°55.3'W (approximately one half nautical mile southeast of Battery Point), thence up the Ashley River, and continuing to the finishing point at City Marina (32°46.6'N, 079°57.2'W). All coordinates referenced use datum: NAD 1983.

(3) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant or petty officer of the Coast Guard who has been designated in writing by the Commander, Coast Guard Group Charleston, South Carolina.

(b) *Special local regulations.* (1) Entry into the regulated area by other than authorized parade participants or official patrol vessels is prohibited, unless otherwise authorized by the Patrol Commander.

(2) After termination of the Christmas Parade of Boats and departure of parade participants from the regulated area, all vessels may resume normal operations.

(c) *Effective Date:* These regulations are effective from 4:30 p.m. to 8:30 p.m., EST, on December 7, 1996, December 13, 1997, December 12, 1998, December 4, 1999, and December 9, 2000.

Dated: November 4, 1996.

J.W. Lockwood,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

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