

general and ophthalmic surgery made from a blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene).

FDA gave interested persons until June 1, 1999, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the **Federal Register** of April 30, 1999, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the April 30, 1999, final rule. Accordingly, the amendments issued thereby became effective June 2, 1999.

Dated: July 15, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05-99-064]

RIN 2115-AE46

Special Local Regulations for Marine Events; Chesapeake Challenge, Patapsco River, Baltimore, MD

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary special local regulations are being adopted for the Chesapeake Challenge powerboat race to be held on the waters of the Patapsco River near Baltimore, Maryland. These regulations are needed to protect boaters, spectators and participants from the dangers associated with the event. This action is intended to enhance the safety of life and property during the event.

DATES: This temporary final rule is effective from 1 p.m. EDT (Eastern Daylight Time) to 4 p.m. EDT on July 24 and 25, 1999.

ADDRESSES: Documents as indicated in this preamble are available for

inspection or copying at Commander (Aoaax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004, between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays. The telephone number is (757) 398-6204.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer R. Houck, Marine Events Coordinator Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore Maryland, 21226-1791, telephone number (410) 576-2674.

SUPPLEMENTARY INFORMATION:

Regulatory History

A notice of proposed rulemaking (NPRM) was not published for this regulation. In keeping with 5 U.S.C. 553(B), the Coast Guard finds that good cause exists for not publishing a NPRM. In keeping with the requirements of 5 U.S.C. 553(d)(3), the Coast Guard also finds that good cause exists for making this regulation effective less than 30 days after publication in the **Federal Register**. The Coast Guard received confirmation of this request for special local regulations on June 8, 1999. There was not sufficient time to publish a proposed rule in advance of the event. Publishing a NPRM and delaying the effective date of the regulation would be contrary to the public interest, because immediate action is necessary to protect vessel traffic from the potential hazards associated with this event.

Background and Purpose

On July 24 and 25, 1999, the Chesapeake Bay Power Boat Association will sponsor the Chesapeake Challenge, a marine event to be held on the waters of the Patapsco River near Baltimore, Maryland. The event will consist of 65 to 80 offshore power boats racing in heats around an oval race course. A large fleet of spectator vessels is anticipated. Due to the need for vessel control during the races, vessel traffic will be temporarily restricted to provide for the safety of spectators, participants and transiting vessels.

Discussion of Regulations

The Coast Guard is establishing temporary special local regulations on specified waters of the Patapsco River. The temporary special local regulations will be in effect from 1 p.m. EDT (Eastern Daylight Time) to 4 p.m. EDT on July 24 and 25, 1999 and will restrict general navigation in the regulated areas during the event. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area. Special anchorage areas will also

be established for spectator vessels to view the event. These regulations are needed to control vessel traffic during the marine event to enhance the safety of participants, spectators, and transiting vessels.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(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. This conclusion is based on the fact that the regulated areas will only be in effect for a limited amount of time, extensive advisories have been and will be made to the affected maritime community so that they may adjust their schedules accordingly, and the event schedule will allow commercial interests to coordinate their activities to allow for minimal disruption to their enterprise.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this temporary final rule will have a significant economic impact on a substantial number of small entities. "Small Entities" include 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.

Because this temporary final rule will only be in effect for a short period of time and extensive advisories will be made to the affected maritime community so that they may adjust their schedules accordingly, the Coast Guard expects the impact of this temporary final rule to be minimal.

Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this temporary final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This temporary final rule does not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this temporary final rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this temporary final rule and concluded that, under figure 2-1, paragraph (34)(h) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation. Special local regulations issued in conjunction with a marine event are excluded under that authority.

List of Subjects in 33 CFR Part 100

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

Regulation

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations is amended as follows:

PART 100—[AMENDED]

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

Authority: 33 U.S.C. 1233 through 1236; 49 CFR 1.46 and 33 CFR 100.35.

2. A temporary section, § 100.35-T05-064 is added to read as follows:

§ 100.35-T05-064 Chesapeake Challenge, Patapsco River, Baltimore, Maryland.

(a) Definitions:

(1) *Regulated Area.* The waters of the Patapsco River enclosed by:

Latitude	Longitude
39° 15' 27.5" N	076° 33' 10.0" W, to
39° 13' 23.0" N	076° 31' 14.0" W, to
39° 12' 06.0" N	076° 29' 43.5" W, to
39° 12' 00.0" N	076° 29' 08.0" W, to
39° 11' 24.0" N	076° 29' 27.5" W, to
39° 11' 48.0" N	076° 30' 58.0" W, to
39° 14' 53.5" N	076° 34' 15.0" W, to
39° 15' 24.0" N	076° 33' 53.0" W, to
39° 15' 27.5" N	076° 33' 10.0" W

(2) *Curtis Bay South Spectator Anchorage Area.* The waters south of Curtis Bay Channel bounded by a line connecting the following points:

Latitude	Longitude
39° 13' 16.0" N	076° 32' 31.5" W, to
39° 13' 00.0" N	076° 32' 16.0" W, to
39° 12' 49.5" N	076° 32' 31.5" W, to
39° 13' 06.0" N	076° 32' 48.5" W, to
39° 13' 16.0" N	076° 32' 31.5" W

(3) *Curtis Bay North Spectator Anchorage Area.* The waters north of

Curtis Bay Channel bounded by a line connecting the following points:

Latitude	Longitude
39° 14' 00.0" N	076° 33' 18.5" W, to
39° 13' 33.0" N	076° 32' 50.0" W, to
39° 13' 20.5" N	076° 33' 13.5" W, to
39° 13' 37.0" N	076° 33' 40.0" W, to
39° 14' 00.0" N	076° 33' 18.5" W

(4) *Fort McHenry Spectator Anchorage Area.* The waters south of Hawkins Point bounded by a line connecting the following points:

Latitude	Longitude
39° 12' 26.5" N	076° 31' 39.0" W, to
39° 11' 48.0" N	076° 30' 58.0" W, to
39° 11' 40.0" N	076° 30' 33.0" W, to
39° 11' 16.5" N	076° 30' 46.5" W, to
39° 12' 19.5" N	076° 31' 50.5" W, to
39° 12' 26.5" N	076° 31' 39.0" W

All coordinates reference Datum NAD 1983.

(5) *Coast Guard Patrol Commander.* The Coast Guard Patrol Commander is a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Activities Baltimore.

(b) *Special Local Regulations:*

(1) All persons and/or vessels not authorized as participants or official patrol vessels are considered spectators. The "official patrol" consists of any Coast Guard, public, state, county or local law enforcement vessels assigned and/or approved by Commander, Coast Guard Activities Baltimore.

(2) Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated areas.

(3) The operator of any vessel in these areas shall:

(i) Stop the vessel immediately when directed to do so by any official patrol, including any commissioned, warrant, or petty officer on board a vessel displaying a Coast Guard ensign.

(ii) Proceed as directed by any official patrol, including any commissioned, warrant, or petty officer on board a vessel displaying a Coast Guard ensign.

(4) Spectator vessels may enter and anchor in the special spectator anchorage areas described in paragraph (a) of this section without the permission of the Patrol Commander. They shall use caution not to enter the regulated area. No vessel shall anchor within a tunnel, cable or pipeline area shown on a Government chart.

(c) *Effective Dates.* The regulated area described in paragraph (a)(1) of this section and the spectator anchorage areas described in paragraphs (a)(2) through (a)(4) of this section are effective from 1 p.m. EDT (Eastern

Daylight Time) to 4 p.m., EDT on July 24 and 25, 1999.

Roger T. Rufe, Jr.,

Vice Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[CA-010-0002, FRL-6401-6]

Classification of the San Francisco Bay Area Ozone Nonattainment Area for Congestion Mitigation and Air Quality (CMAQ) Improvement Program Purposes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On July 10, 1998 (63 FR 37258), EPA redesignated the San Francisco Bay Area from maintenance to nonattainment, without a classification, for the federal one-hour ozone standard. By not assigning a classification, EPA inadvertently affected the Bay Area's funding appropriation under the Transportation Equity Act for the 21st Century (TEA 21), Congestion Mitigation and Air Quality Improvement Program (CMAQ). On March 18, 1999, EPA proposed to assign the Bay Area a nonattainment classification for the federal one-hour ozone standard for CMAQ purposes only so that the Bay Area would be able to receive CMAQ funding commensurate with the severity of its air pollution problem (65 FR 13383). After providing a 30-day extension to the public comment period (64 FR 24123, May 5, 1999), EPA is today finalizing the classification.

EFFECTIVE DATE: This action is effective on August 23, 1999.

ADDRESSES: A copy of this document is available in the air programs section of EPA Region 9's website, <http://www.epa.gov/region09/air>. The docket for this rulemaking is available for inspection during normal business hours at EPA Region 9, Planning Office, Air Division, 17th Floor, 75 Hawthorne Street, San Francisco, California 94105. A reasonable fee may be charged for copying parts of the docket. Please call (415) 744-1249 for assistance.

FOR FURTHER INFORMATION CONTACT: Celia Bloomfield, (415) 744-1249, Planning Office (AIR-2), Air Division, EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105.