

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

2. Section 310.545 is amended by adding paragraph (a)(6)(ii)(C) to read as follows:

**§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.**

- (a) \* \* \*
- (6) \* \* \*
- (ii) \* \* \*

(C) Approved as of [Date 18 months after date of publication of the final rule in the Federal Register]; [date 24 months after date of publication of the final rule in the Federal Register], for products with annual sales less than \$25,000. Any ingredient(s) labeled with claims or directions for use for sinusitis or for relief of nasal congestion associated with sinusitis.

\* \* \* \* \*

**PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTI-ASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE**

3. The authority citation for 21 CFR part 341 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

4. Section 341.80 is amended by removing paragraph (b)(1)(iii).

Dated: July 23, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-17445 Filed 7-30-04; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

[CGD05-04-135]

RIN 1625-AA00

**Safety Zone; Upper Chesapeake Bay, Patapsco and Severn Rivers, MD**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Coast Guard proposes to establish a temporary safety zone on portions of the upper Chesapeake Bay and its tributaries during the movement of the U.S.S. *Constellation*. This action is necessary to provide for the safety of life on navigable waters during the dead ship tow of the vessel from its berth in

Baltimore, Maryland to the United States Naval Academy seawall in Annapolis, Maryland, and return. This action will restrict vessel traffic in portions of the Patapsco River (including the Inner Harbor and the Northwest Harbor), Chesapeake Bay and Severn River.

**DATES:** Comments and related material must reach the Coast Guard on or before September 16, 2004.

**ADDRESSES:** You may mail comments and related material to Commander, U.S. Coast Guard Activities, 2401 Hawkins Point Road, Building 70, Waterways Management Branch, Baltimore, Maryland, 21226-1791. Coast Guard Activities Baltimore, Waterways Management Branch, maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at Commander, U.S. Coast Guard Activities, 2401 Hawkins Point Road, Building 70, Port Safety, Security and Waterways Management Branch, Baltimore, Maryland 21226-1791 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ron Houck, at Coast Guard Activities Baltimore, Port Safety, Security and Waterways Management Branch, at telephone number (410) 576-2674 or (410) 576-2693.

**SUPPLEMENTARY INFORMATION:**

**Request for Comments**

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD05-04-135), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, 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.

**Public Meeting**

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Coast Guard Activities Baltimore, Waterways Management Branch, 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 U.S.S. *Constellation* Museum is celebrating the 150th anniversary of the launch of the U.S.S. *Constellation* in 2004, and to commemorate this occasion, is sponsoring a dead ship tow of the historic sloop-of-war U.S.S. *Constellation* on October 26, 2004, from Baltimore, Maryland to Annapolis, Maryland. The event will mark the 23 years that the ship was stationed at the Naval Academy as a training vessel, from 1871 to 1893. Planned events include an eight-hour dead ship tow of the U.S.S. *Constellation* with an onboard salute with navy pattern cannon while off Fort McHenry National Monument and Historic Site. A return dead ship tow of the U.S.S. *Constellation* to Baltimore, Maryland is expected to occur on November 1, 2004.

The Coast Guard anticipates a large recreational boating fleet during this event. Operators should expect significant vessel congestion along the planned route.

The purpose of this rule is to promote maritime safety and protect participants and the boating public in the Port of Baltimore, in the approaches to Baltimore Harbor, and the Severn River immediately prior to, during, and after the scheduled event. The rule will provide for a clear transit route for the participating vessels, and provide a safety buffer around the participating vessels while they are in transit. The rule will impact the movement of all vessels operating in the specified areas of the upper Chesapeake Bay and its tributaries.

Interference with normal port operations will be kept to the minimum considered necessary to ensure the safety of life on the navigable waters immediately before, during, and after the scheduled event.

**Discussion of Proposed Rule**

The historic sloop-of-war U.S.S. *Constellation* is scheduled to be towed "dead ship" on October 26, 2004. The U.S.S. *Constellation* is scheduled to be towed from its berth at Pier 1, Baltimore, Maryland to the Naval Academy seawall, Annapolis, Maryland, to take place along a route of approximately 30 nautical miles one-way, that includes specified waters of the Patapsco River (including the Inner Harbor and the Northwest Harbor), Chesapeake Bay and Severn River. On

November 1, 2004, a dead ship tow of the U.S.S. *Constellation* to return to Pier 1, Baltimore, Maryland from the Naval Academy seawall, Annapolis, Maryland is expected to occur.

The safety of dead ship tow participants requires that persons and vessels be kept at a safe distance from the intended route during this evolution. The Coast Guard proposes to establish a temporary moving safety zone around the U.S.S. *Constellation* dead ship tow participants on October 26, 2004 and on November 1, 2004, to ensure the safety of participants immediately prior to, during, and following the dead ship tow.

#### 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. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS 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 proposed rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to operate or anchor in portions of the Patapsco River (including the Inner Harbor and the Northwest Harbor), Chesapeake Bay and Severn River, Maryland. Because the zone is of limited size and duration, it is expected that there would be minimal disruption to the maritime community. Before the effective period, the Coast Guard would issue maritime advisories widely available to users of

the river to allow mariners to make alternative plans for transiting the affected areas. In addition, smaller vessels not constrained by their draft, which are more likely to be small entities, may transit around the zone and request permission from the COTP Baltimore on a case-by-case basis to enter the zone.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed 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 the person listed under **FOR FURTHER INFORMATION CONTACT**. 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.ID, which guides 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)(g), of the Instruction, from further environmental documentation because this rule establishes a safety zone.

A draft “Environmental Analysis Check List” and a draft “Categorical Exclusion Determination” are available in the docket where indicated under **ADDRESSES**. Comments on this section will be considered before we make the final decision on whether the rule should be categorically excluded from further environmental review.

### 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 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(g), 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.T05–135 to read as follows:

#### § 165.T05–135 Safety Zone; Upper Chesapeake Bay, Patapsco and Severn Rivers, MD.

(a) *Definitions.*

*Captain of the Port.* The Captain of the Port means the Commander, Coast Guard Activities Baltimore or any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port to act on his behalf.

U.S.S Constellation dead ship tow participants. Includes the U.S.S Constellation, and its accompanying towing and pre-designated emergency egress vessels.

(b) *Location.* The following area is a moving safety zone: all waters of the Patapsco River (including the Inner Harbor and the Northwest Harbor), Chesapeake Bay and Severn River, surface to bottom, within 200 yards ahead of and 100 yards outboard and aft of the historic sloop-of-war U.S.S Constellation, while operating from Baltimore, Maryland to Annapolis, Maryland, and return.

(c) *Regulations.* (1) All persons are required to comply with the general regulations governing safety zones found in § 165.23 of this part.

(2) Persons or vessels requiring entry into or passage through a safety zone must first request authorization from the Captain of the Port or his designated representative. The Coast Guard vessels enforcing this section can be contacted on VHF Marine Band Radio, channels 13 and 16. The Captain of the Port can be contacted at (410) 576–2693.

(3) No vessel movement is allowed within the safety zone unless expressly authorized by the Captain of the Port or his designated representative.

(d) *Enforcement period.* This section will be enforced from 7 a.m. to 5 p.m. on October 26, 2004, and from 7 a.m. to 5 p.m. on November 1, 2004.

Dated: July 22, 2004.

**Jonathan C. Burton,**

*Commander, U.S. Coast Guard, Acting Captain of the Port, Baltimore, Maryland.*

[FR Doc. 04–17529 Filed 7–30–04; 8:45 am]

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### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Parts 52 and 81

[MD160–3107; FRL–7795–5]

#### Approval and Promulgation of Air Quality Implementation Plans; Maryland; Redesignation of Kent and Queen Anne’s Counties Ozone Nonattainment Area to Attainment and Approval of the Area’s Maintenance Plan

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve a redesignation request and a State Implementation Plan (SIP) submitted by the State of Maryland. The SIP revision establishes a maintenance plan for Kent and Queen Anne’s Counties that provides requirements for continued attainment of the one-hour ozone National Ambient Air Quality Standard (NAAQS) for the next 10 years.

**DATES:** Written comments must be received on or before September 1, 2004.

**ADDRESSES:** Submit your comments, identified by MD160–3107 by one of the following methods:

A. Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

B. E-mail: [morris.makeba@epa.gov](mailto:morris.makeba@epa.gov).

C. Mail: Makeba Morris, 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 special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. MD160–3107. EPA’s policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of