

contains substantial evidence of effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. Exclusivity applies only to the additional indications.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 524.1193 [Amended]

2. Section 524.1193 *Ivermectin pour-on* is amended by adding to the end of paragraph (d)(2) the sentence "It is also used to control infections of gastrointestinal roundworms *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment."

Dated: July 8, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-19124 Filed 7-18-97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD05-97-013]

RIN 2115-AE47

Drawbridge Operation Regulations; Isle of Wight Bay, Ocean City, Maryland

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: At the request of the Maryland Department of Transportation (MDOT), the Coast Guard is changing the regulations that govern the operation of the Route 50 drawbridge across Isle of Wight Bay, mile 0.5, located in Ocean City, Maryland, by requiring restricted drawbridge openings for all vessels each Saturday between May 25 through September 15, between the hours of 1 p.m. to 5 p.m. During these times, the bridge need open only on the hour, and must remain in the open position until all waiting vessels pass. All other provisions of the existing regulation for the Route 50 bridge remain the same. This final rule will help reduce motor vehicle traffic delays and congestion related to summer traffic entering and exiting the town of Ocean City, while still providing for the reasonable needs of navigation.

EFFECTIVE DATE: This rule is effective on July 18, 1997.

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for inspection and copying at the Office of the Commander (Aowb), USCG Atlantic Area, Federal Building, 4th Floor, 431 Crawford Street, Portsmouth, Virginia 23704-5004, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The telephone number is (757) 398-6222.

FOR FURTHER INFORMATION CONTACT: Ann B. Deaton, Bridge Administrator, USCG Atlantic Area, at (757) 398-6222.

SUPPLEMENTARY INFORMATION:

Regulatory History

On April 21, 1997, the Coast Guard published a notice of proposed rulemaking entitled Drawbridge Operation Regulations; Isle of Wright Bay, Ocean City, Maryland in the **Federal Register** (62 FR 19245). The comment period ended June 20, 1997. The Coast Guard received no comments on the proposed rulemaking. No public hearing was requested, and none was held.

Background and Purpose

The drawbridge across Isle of Wight Bay, mile 0.5 Ocean City, Maryland, is currently required to open on signal, except that, from October 1 through April 30 from 6 p.m. to 6 a.m., the draw shall open if at least three hours notice is given and, from May 25 through September 15 from 9:25 a.m. to 9:55 p.m. the draw shall open at 25 minutes and 55 minutes after the hour for a maximum of 5 minutes to permit accumulated vessels to pass.

The Maryland Department of Transportation's (MDOT) original

request to change the existing regulation was based on a large number of vacationers traveling to and from Ocean City on Saturday afternoons during the tourist season (summer months). Vacationers check in and out of hotels on Ocean City Island every Saturday afternoon of the season. This creates a traffic surge of vehicles entering and exiting the island with only two highway bridges (Route 50 and Route 90) available for access. The Route 90 bridge is a fixed-span structure, and the Route 50 bridge is a drawbridge. Over 350 charter boats regularly pass through the Route 50 drawbridge. This produces a dilemma to both waterway users and vehicular traffic trying to access the same drawbridge. MDOT requested hourly openings on Saturday afternoons as opposed to the current half-hourly openings, in order to help reduce vehicular traffic congestion on U.S. 50 and thereby improve highway safety. MDOT requested a change in the operating schedule to reduce the number of times the bridge must open on signal. The new schedule would restrict drawbridge openings for all vessels every Saturday between May 25 through September 15, between the hours of 1 p.m. to 5 p.m. During these times, the bridge need open only on the hour, and must remain in the open position until all waiting vessels pass. The Coast Guard tested this change through a temporary deviation, which modified the opening schedule from July 13 through August 31, 1996. The test was intended to determine whether the Coast Guard should change the regulation to better balance the needs of both waterway users and vehicular traffic. Following the test, no comments were received. The Coast Guard contacted MDOT, the local Police Department and the US 50 bridge tenders. Based on their information the test did not create any undue hardships for waterway users, yet the hourly closures substantially improved highway conditions.

Discussion of Comments and Changes

The Coast Guard received no comments on the proposed rulemaking. Therefore, the proposed rule is being implemented without change.

Good Cause Statement

This final rule is effective in less than 30 days because it is contrary to the public interest to delay the effective date. Immediate action is required to alleviate the overwhelming traffic congestion caused by tourists who are prevented from entering and exiting Ocean City, Maryland while the Route 50 drawbridge is in the open position.

Because Ocean City is in the height of the tourist season and because no comments were received about the bridge schedule change, good cause exists to make the final rule effective upon publication.

Regulatory Evaluation

This regulation 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 final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the U.S. Coast Guard considered whether this rule would have a significant economic impact on a substantial number of small entities. "Small entities" included 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). Because it expects the impact of this final rule to be minimal on the maritime industry, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that the rule will not have a significant economic impact on a substantial number of small entities.

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 regulation does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this final rule and concluded that under section 2.B.2.e.(32)(e) of Commandant Instruction M16475.1B (as amended by 59 FR 38654, 29 July 1994), this final

rule is categorically excluded from further environmental documentation. A Categorical Exclusion Determination statement has been prepared and placed in the rulemaking docket.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

In consideration of the foregoing, the Coast Guard is amending part 117 of title 33, Code of Federal Regulations, as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues as follows

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Section 117.559 is revised to read as follows:

§ 117.559 Isle of Wight Bay

The draw of the US50 bridge, mile 0.5, at Ocean City, shall open on signal; except that, from October 1 through April 30 from 6 p.m. to 6 a.m., the draw shall open if at least three hours notice is given and from May 25 through September 15 from 9:25 a.m. to 9:55 p.m. the draw shall open at 25 minutes after and 55 minutes after the hour for a maximum of five minutes to let accumulated vessels pass, except that, on Saturdays from 1 p.m. to 5 p.m., the draw shall open on the hour for all waiting vessels and shall remain in the open position until all waiting vessels pass.

Dated: July 14, 1997.

Roger T. Rufe, Jr.,

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

[FR Doc. 97–19224 Filed 7–18–97; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TN159–1–9704(b); TN174–1–9726(b); TN175–1–9725(b); FRL–5859–5]

Approval of Source Specific Revisions to the Tennessee SIP Regarding Volatile Organic Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: In this document, EPA is taking action on three source specific

revisions to the Tennessee State Implementation Plan (SIP) which establish reasonably available control technology requirements (RACT) for the control of volatile organic compound (VOC) emissions from certain operations at Brunswick Marine Corporation, Outboard Marine Corporation, and Essex Group Incorporated. EPA is approving the operating permits for these sources into the SIP with the exception of the portion of one permit which allows the Tennessee Technical Secretary to determine RACT which is being disapproved. These permits were issued consistent with the alternate control plans which established RACT requirements in accordance with the provisions of the Tennessee SIP for developing VOC emission control requirements for major sources for which there is no regulation or guidance for determining RACT.

DATES: This action is effective September 19, 1997, unless adverse or critical comments are received by August 20, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Written comments on this action should be addressed to William Denman at the Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303. Copies of documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Reference files TN159–01–9704, TN174–01–9726, and TN175–01–9726. The Region 4 office may have additional background documents not available at the other locations.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303. William Denman, 404/562–9030.

Tennessee Department of Environment and Conservation, Division of Air Pollution Control, L & C Annex, 9th Floor, 401 Church Street, Nashville, Tennessee 37243–1531.

FOR FURTHER INFORMATION CONTACT: William Denman at 404/562–9030.

SUPPLEMENTARY INFORMATION: On December 20, 1995, Tennessee submitted a permit for Brunswick