

basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday to Friday.

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 520**

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 520 is amended as follows:

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.447 is amended by revising paragraph (b) to read as follows:

**§ 520.447 Clindamycin hydrochloride liquid.**

\* \* \* \* \*

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter for use as in paragraphs (c) and (d) of this section. See No. 059130 for use as in paragraph (c) of this section.

\* \* \* \* \*

Dated: August 22, 1997.

**Michael J. Blackwell,**

*Deputy Director, Center for Veterinary Medicine.*

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**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Part 100**

[CGD 05-97-007]

RIN 2115-AE46

**Special Local Regulations for Marine Events; Norfolk Harbor, Elizabeth River, Norfolk, Virginia and Portsmouth, Virginia**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is amending permanent special local regulations established for marine events held in the Norfolk Harbor, Elizabeth River, between Norfolk and Portsmouth, Virginia, by identifying specific annual events for which the regulated area will be in effect. This rule updates the regulation in order to enhance the safety of life and property during the events.

**EFFECTIVE DATE:** This final rule is effective on June 6, 1997.

**FOR FURTHER INFORMATION CONTACT:** S.L. Phillips, Project Manager, Search and Rescue Branch, at (757) 398-6204.

**SUPPLEMENTARY INFORMATION:**

**Regulatory History**

On February 21, 1997, the Coast Guard published a notice of proposed rulemaking entitled Special Local Regulations for Marine Events; Norfolk Harbor, Elizabeth River, Norfolk, Virginia and Portsmouth, Virginia, in the **Federal Register** (62 FR 7969). The Coast Guard received no comments on the proposed rulemaking. No public hearing was requested, and none was held. The final rule was inadvertently published as a quarterly on 8 August 1997 (62 FR 42671).

**Background and Purpose**

33 CFR 100.501 established special local regulations for marine events held in the Norfolk Harbor, Elizabeth River, between Norfolk and Portsmouth, Virginia. The effect of these regulations is the control of vessel traffic during marine events to enhance the safety of participants, spectators, and transiting vessels. The regulations are implemented at various times, for various events throughout the year by publishing notice in the **Federal Register** and the Fifth Coast Guard District Local Notice to Mariners. This rule updates the regulations to reflect specific events for which the regulated area will be in effect.

**Discussion of Comments and Changes**

The Coast Guard received no comments on the proposed rulemaking; however, the Coast Guard has learned that the sponsoring organization for the Harborfest event will be Festevents, Ltd. Therefore, Table 1 of the proposed rule has been amended to reflect this 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 because timely action is required to protect vessel traffic and event participants during these events.

**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 final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This rule merely changes the effective period of an existing regulation and does not impose any new restrictions on vessel traffic.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule will have a significant economic 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). This rule does not impose any new restrictions on vessel traffic, but merely changes the effective period of the regulation. Therefore, the Coast Guard certifies under Section 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.

**Collection of Information**

This final rule contains no collection of information requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

**Federalism**

The Coast Guard has analyzed this 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 rule and concluded that, under section 2.b.2.e(34)(h) of Commandant Instruction M16475.1b (as amended, 61 FR 13564; 27 March 1996), this rule is categorically excluded from further environmental documentation.

**List of Subjects in 33 CFR Part 100**

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

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

**PART 100—[AMENDED]**

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

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

2. Section 100.501 is amended by revising paragraph (c) and adding Table 1 to read as follows:

**§ 100.501 Norfolk Harbor, Elizabeth River, Norfolk, Virginia and Portsmouth, Virginia.**

\* \* \* \* \*

(c) *Effective periods.* This section is effective annually for the duration of each marine event listed in Table 1, or as otherwise specified in the Coast Guard Local Notice to Mariners and a **Federal Register** notice. The Coast Guard Patrol Commander will announce by Broadcast Notice to Mariners the specific time periods during which the regulations will be enforced.

TABLE 1 OF § 100.501

Harborfest:	Sponsor: Festevents, Ltd. Date: First Friday, Saturday, and Sunday in June
Great American Picnic:	Sponsor: Festevents, Ltd. Date: July 4
Cock Island Race:	Sponsor: Ports Events, Inc. Date: Third Saturday in July
Rendezvous at Zero Mile Marker:	Sponsor: Ports Events, Inc. Date: Third Saturday in August
US Navy Fleet Week Celebration:	Sponsor: U.S. Navy Date: Second Friday in October
Holidays in the City:	

TABLE 1 OF § 100.501—Continued

Sponsor: Festevents, Ltd. Date: Fourth Saturday in November
New Years Eve Fireworks Display: Sponsor: Festevents, Ltd. Date: December 31

Dated: May 30, 1997.

**Roger T. Rufe, Jr.,**  
*Vice Admiral, U.S. Coast Guard Commander,  
Fifth Coast Guard District.*

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**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Part 165**

[CGD01-97-089]

RIN 2115-AA97

**Safety Zone: Harbor Festival Fireworks Display, Greenport, NY**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone, September 27, 1997, for the Harbor Festival Fireworks Display to be held in Greenport Harbor, Greenport, NY. This temporary safety zone is needed to protect persons, facilities, vessels and others in the maritime community from the safety hazards associated with this fireworks display. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or the Coast Guard Patrol Commander.

**EFFECTIVE DATE:** This regulation is effective September 27, 1997, from 8:45 p.m. until 10:15 p.m.

**ADDRESSES:** Documents relating to this temporary final rule are available for inspection and copying at U.S. Coast Guard Group Long Island Sound, 120 Woodward Ave., New Haven, CT 06512. Normal office hours are between 8:00 a.m. and 4:00 p.m., Monday through Friday, except holidays. Comments may also be faxed to this address. Our fax number is (203) 468-4445.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander T.J. Walker, Chief of Port Operations, Captain of the Port, Long Island Sound at (203) 468-4444.

**SUPPLEMENTARY INFORMATION:**

**Regulatory History**

Pursuant to 5 U.S.C. 553, good cause exists for not publishing a notice of proposed rulemaking (NPRM) and for making this rule effective in less than 30

days after **Federal Register** publication. The sponsor of the event did not provide the Coast Guard with the final details for the event in sufficient time to publish a NPRM or a final rule 30 days in advance. The delay encountered if normal rulemaking procedures were followed would effectively cancel the event. Cancellation of this event is contrary to the public interest since the fireworks display is for the benefit of the public.

**Background and Purpose**

The sponsor, East End Maritime Museum, of Greenport, NY, requested that a fireworks display be permitted in Greenport Harbor, Greenport, NY. This regulation establishes a temporary safety zone in all waters of Greenport Harbor within a 600 foot radius of the fireworks barges. The safety zone is in effect on September 27, 1997, from 8:45 p.m. until 10:15 p.m. and is necessary to protect the maritime community from the safety hazards associated with this fireworks display. Entry into or movement within this zone will be prohibited unless authorized by the Captain of the Port or the Coast Guard Patrol Commander.

**Regulatory Evaluation**

This temporary final 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 not been reviewed 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. Entry into this zone will be restricted for a brief period of time on September 27, 1997, the effect of this regulation will not be significant for several reasons: the duration of the event is limited; the event is at a late hour; and extensive, advance maritime advisories will be made.

**Small Entities**

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