

as of May 13, 2004, and the regulations are amended in 21 CFR part 524 by adding § 524.590 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning May 13, 2004.

The agency has determined under 21 CFR 25.33(d)(1) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 524

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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: 21 U.S.C. 360b.

■ 2. Section 524.590 is added to read as follows:

§ 524.590 Diclofenac.

(a) *Specifications.* Each gram of cream contains 10 milligrams diclofenac sodium.

(b) *Sponsor.* See No. 065274 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Apply a 5-inch (5") ribbon of cream twice daily over the affected joint for up to 10 days and rub thoroughly into the hair covering the joint until it disappears.

(2) *Indications for use in horses.* For the control of pain and inflammation associated with osteoarthritis in tarsal, carpal, metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal (hock, knee, fetlock and pastern) joints.

(3) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: June 17, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04-15426 Filed 7-6-04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 151

[USCG-2002-13147]

RIN 1625-AA51

Penalties for Non-Submission of Ballast Water Management Reports

AGENCY: Coast Guard, DHS.

ACTION: Final rule; correction.

SUMMARY: The Coast Guard is correcting a final rule that appeared in the **Federal Register** of June 14, 2004 (69 FR 32864). The final rule changes regulations for vessels equipped with ballast water tanks bound for ports or places within the United States. These corrections clarify the final rule.

DATES: This correction is effective on June 14, 2004.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Mr. Bivan Patnaik, Project Manager, Environmental Standards Division, Coast Guard, telephone 202-267-1744, e-mail: bpatnaik@comdt.uscg.mil. If you have questions on viewing the docket, call Ms. Andrea M. Jenkins, Program Manager, Docket Operations, telephone 202-366-0271.

SUPPLEMENTARY INFORMATION: In FR Doc. 04-13173 appearing on page 32864 of the **Federal Register** of Monday, June 14, 2004, the following corrections are made:

■ 1. On page 32865, the paragraph beginning at the end of the second column and continuing in the third column is corrected to read as follows:

“Although, the penalty amount of \$25,000 was discussed in the notice of proposed rulemaking, the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt

Collection Improvement Act of 1996, requires the Coast Guard to adjust penalties for violating Federal laws set by Congress long ago where the deterrent value of the penalties have weakened with time due to inflation. As such, we have changed the monetary amount authorized by NISA, from \$25,000 to \$27,500. With respect to the commenters' concern about the penalty amount, we believe there is some confusion. The penalty is not \$27,500; rather, the penalty is not to exceed \$27,500. We have the discretion to issue a penalty of up to \$27,500, depending on the facts of each individual case.”

■ 2. On page 32866, the first paragraph of the third column, remove the three asterisks in the first sentence.

■ 3. On page 32867, in the second full paragraph of the second column, remove the word “COPT” and in its place, add the word “COTP”.

■ 4. To clarify the Coast Guard's response to comments submitted in the Comments on Definitions section on page 32867, the second paragraph of the third column is corrected as follows:

The Coast Guard disagrees with this comment. “Ports and places” are defined in § 151.2025 and are defined in the exact way as in 33 CFR 160.204 of, “Notification of Arrivals, Departures, Hazardous Conditions, and Certain Dangerous Cargoes.” The Coast Guard must evaluate the BWM operations of all vessels operating within U.S. waters. Therefore, MODUs or OSVs servicing OCS facilities within the EEZ while moving from one COTP zone to another, must submit ballast water reporting forms. MODUs or OSVs servicing OCS facilities outside the EEZ will not be required to submit ballast water reporting forms, however, upon returning to ports or places of the U.S. they will have to submit ballast water reporting forms. Regulatory language in § 151.2041 will be amended to reflect this clarification. If, after a period of time we determine that we are receiving data that does not benefit our evaluation, we will then revisit the program and adjust it accordingly.

■ 5. On page 32869, in the middle column, in amendatory instruction numbers 1 and 4, remove the word “continues”.

§ 151.2041 [Amended]

■ 6. On page 32870, in the second column, correct the section heading for § 151.2041 and paragraph (a) by removing the phrase “bound for ports or places in the United States” and add in its place the phrase “bound for ports or places of the United States”.

Dated: June 23, 2004.

Howard L. Hime,

Acting Director of Standards, Marine Safety, Security and Environmental Protection.

[FR Doc. 04-15033 Filed 7-6-04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD05-04-067]

RIN 1625-AA87 (Formerly 1625-AA00)

Security Zone; Captain of the Port Hampton Roads Zone, Hampton Roads, VA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing security zones around passenger vessels and vessels carrying Certain Dangerous Cargo (CDC) while they are in the navigable waters of the Captain of the Port (COTP) Hampton Roads zone. These security zones mitigate potential terrorist acts and enhance the public and maritime safety and security. These security zones prohibit entry into or movement within 500-yards of passenger vessels and vessels carrying CDC unless traveling at the minimum speed to navigate safely. No vessel or person may approach within 100 yards of a passenger vessel or vessel carrying CDC unless authorized by the COPT Hampton Roads or his or her designated representative.

DATES: This rule is effective July 7, 2004.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD05-04-067 and are available for inspection or copying at Coast Guard Marine Safety Office Hampton Roads, 200 Granby Street, Suite 700, Norfolk, Virginia 23510, between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LT Mike Dolan, Chief of Waterways Management, USCG Marine Safety Office Hampton Roads, at (757) 668-5590.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On May 4, 2004, we published a notice of proposed rulemaking (NPRM) entitled, "Security Zone; Captain of the

Port Hampton Roads Zone," in the **Federal Register** (69 FR 24549). We received no letters commenting on the proposed rule. No public meeting was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Upon implementation of this rule, the Captain of the Port will have increased ability to provide for the safety and security of passenger vessels and vessels carrying Certain Dangerous Cargo (CDC). Given the urgent need to improve maritime and homeland security measures, this rule should be made effective as soon as possible.

Background and Purpose

Terrorist attacks on September 11, 2001, inflicted catastrophic human casualties and property damage. These attacks highlighted terrorists' desire and ability to utilize multiple means in different geographic areas to successfully carry out their mission.

Since the September 11, 2001 terrorist attacks on the World Trade Center in New York, the Pentagon in Arlington, Virginia and Flight 93, the Federal Bureau of Investigation has issued several warnings concerning the potential for additional terrorist attacks within the United States. The October 2002 attack on a tank vessel, MV LIMBURG, off the coast of Yemen, and the prior attack on the USS COLE demonstrate the maritime terrorism threat. These attacks manifest a continuing threat to U.S. maritime assets as described in the President's finding in Executive Order 13273 of August 21, 2002 (67 FR 56215, September 3, 2002) that the security of the U.S. is endangered by the September, 11, 2001 attacks and that such disturbances continue to endanger the international relations of the United States. See also Continuation of the National Emergency with Respect to Certain Terrorist Attacks, (67 FR 58317, September 13, 2002); Continuation of the National Emergency With Respect To Persons Who Commit, Threaten To Commit, Or Support Terrorism, (67 FR 59447, September 20, 2002).

The U.S. Maritime Administration (MARAD) in Advisory 02-07 advised U.S. shipping interests to maintain a heightened state of alert against possible terrorist attacks. MARAD more recently issued Advisory 03-06 informing operators of maritime interests of increased threat possibilities to vessels and facilities and a higher risk of terrorist attack to the transportation community in the United States.

The ongoing hostilities in Afghanistan and Iraq have made it prudent for U.S. ports and waterways to be on a higher state of alert because the Al Qaeda organization and other similar organizations have declared an ongoing intention to conduct armed attacks on U.S. interests worldwide.

Due to increased awareness that future terrorist attacks are possible, the Coast Guard, as lead federal agency for maritime homeland security, has determined that the Captain of the Port must have the means to be aware of, detect, deter, intercept, and respond to asymmetric threats, acts of aggression, and attacks by terrorists on the American homeland while maintaining our freedoms and sustaining the flow of commerce. The security zones are established around all passenger vessels or vessels carrying CDC that are anchored, moored, or underway within the Captain of the Port Hampton Roads zone. A security zone is a tool available to the Coast Guard that may be used to control vessel traffic operating in the vicinity of passenger vessels and vessels carrying CDC.

Discussion of Comments and Changes

No comments were received on the notice of proposed rulemaking. No changes have been made to the regulatory text.

Regulatory Evaluation

This 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 rule to be so minimal that a full regulatory evaluation under the regulatory policies and procedures of DHS is unnecessary. This finding is based on the relatively small percentage of ships that would fall within the applicability of the regulation, the relatively small size of the limited access area around each ship, the minimal amount of time that vessels will be restricted in course or speed when the zone is being enforced, and the ease with which vessels may transit around the affected area. In addition, vessels that may need to enter the zones may request permission on a case-by-case basis from the COTP Hampton Roads or his designated representatives.