

§ 520.622b [Amended]

■ 6. In § 520.622b, remove and reserve paragraph (b).

§ 520.1720c [Amended]

■ 7. In § 520.1720c, in paragraph (b)(1), remove “Nos. 000061 and 010797” and in its place add “No. 000061”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 8. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 9. In § 522.1696a, revise paragraphs (b)(1), (b)(3), (d)(1)(iii), and (d)(2)(iii) to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

* * * * *

(b) * * *

(1) Nos. 000856, 055529, and 061623 for use as in paragraph (d)(1) of this section.

* * * * *

(3) No. 000856 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Not for use in beef cattle within 30 days of slaughter. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(iii) *Limitations.* Not for use within 30 days of slaughter. For Nos. 055529, 059130, and 061623: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

■ 11. Revise § 524.390 to read as follows:

§ 524.390 Chloramphenicol ophthalmic ointment.

(a) *Specifications.* Each gram contains 10 milligrams chloramphenicol.

(b) *Sponsors.* See Nos. 000856 and 025463 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—(1) Amount.* Apply every 3 hours around the clock for 48 hours, after

which night instillations may be omitted.

(2) *Indications for use.* For treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§§ 524.390a, 524.390b, and 524.390d [Removed]

■ 12. Remove §§ 524.390a, 524.390b, and 524.390d.

§§ 524.1484a, 524.1484j, and 524.1484k [Removed]

■ 13. Remove 524.1484a, 524.1484j, and 524.1484k.

§§ 524.1880 [Removed]

■ 14. Remove 524.1880.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 15. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.1455 [Removed]

■ 16. Remove 529.1455.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 17. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.274 [Amended]

■ 18. In § 558.274, remove and reserve paragraph (a)(7); and in the table in paragraphs (c)(1)(i) and (c)(1)(ii), in the “Sponsor” column, remove “012286”.

§ 558.485 [Amended]

■ 19. In paragraph (b)(3) of § 558.485, remove “012286”.

§ 558.625 [Amended]

■ 20. In § 558.625, remove and reserve paragraphs (b)(10), (b)(12), and (b)(67).

§ 558.630 [Amended]

■ 21. In § 558.630, remove and reserve paragraph (b)(2) and in paragraph (b)(5), remove “012286”.

Dated: January 26, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012-2103 Filed 1-31-12; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket No. USCG-2012-0010]

RIN 1625-AA00

Safety Zone; M/V Del Monte Live-Fire Gun Exercise, James River, Isle of Wight, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the James River in Isle of Wight, VA. This action is necessary to provide for the safety of life on navigable waters during the live-fire gun exercises on the M/V Del Monte. This action is intended to restrict vessel traffic movement to protect mariners from the hazards associated with the live-fire gun exercise.

DATES: This rule is effective in the CFR on February 1, 2012 through February 3, 2012. This rule is effective with actual notice for purposes of enforcement at 11 a.m. on January 30, 2012. This rule will remain in effect through 9 a.m. on February 3, 2012.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2012-0010 and are available online by going to <http://www.regulations.gov>, inserting USCG-2012-0010 in the “Keyword” box, and then clicking “Search.” They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email LCDR Christopher A. O’Neal, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757-668-5581, email Christopher.A.ONeal@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:**Regulatory Information**

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act

(APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because this exercise is necessary to train and qualify Navy personnel in the use of weapons. This training is necessary to ensure that Coast Guard personnel located within the Fifth Coast Guard District are properly trained and qualified before conducting military and national security operations for use in securing ports and waterways. Navy policy requires that Navy personnel meet and maintain certain qualification standards before being allowed to carry weapons on board vessels. Failure to conduct this required training at this time will result in a lapse in personnel qualification standards and, consequently, the inability of Navy personnel to carry out important national security functions at any time. It is impracticable, unnecessary, and contrary to public interest to delay the issuance of this rule.

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**. Delaying the effective date would be contrary to the public interest since immediate action is needed to ensure the safety of vessels transiting the area.

Background and Purpose

Coast Guard Sector Hampton Roads was notified that the U.S. Navy will conduct a live fire and explosive training event onboard the M/V Del Monte in the vicinity of the James River Reserve Fleet. The event is scheduled to take place from January 30, 2012 until February 3, 2012. Due to the need to protect mariners transiting on the James River in the vicinity of the exercise from the hazards associated with live fire and explosive events, the Coast Guard is establishing a safety zone bound by a 1500-foot radius around approximate position 37°06'11" N/076°38'40" W (NAD 1983). Access to this area will be temporarily restricted for public safety purposes.

Discussion of Rule

The Coast Guard is establishing a 1500-foot radius safety zone on specified waters of James River around approximate position 37°06'11" N/076°38'40" W (NAD 1983) in the

vicinity of the James River Reserve Fleet. This safety zone is being established in the interest of public safety during the live fire and explosive training exercise and will be enforced from 11 a.m. on January 30, 2012 until 9 a.m. on February 3, 2012. Access to the safety zone will be restricted during the specified dates and times. Except for vessels authorized by the Captain of the Port or his Representative, no person or vessel may enter or remain in the safety zone.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under that those Orders. Although this regulation restricts access to the safety zone, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration; (ii) the safety zone is of limited size; (iii) mariners may transit the waters in and around this safety zone at the discretion of the Captain of the Port or designated representative; and (iv), the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this 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 rule will not have a significant economic impact on a substantial number of small entities.

The rule would affect the following entities, some of which might be small entities: the owners or operators of

vessels intending to transit or anchor in a portion of the James River from 11 a.m. January 30, 2012 until 9 a.m. on February 3, 2012.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: (i) The safety zone will only be in place for a limited duration and is of a limited size; and (ii) Before the enforcement period, maritime advisories will be issued allowing mariners to adjust their plans accordingly.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this 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 offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). 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 rule calls 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 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 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect 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 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 rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does 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 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 rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, Under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves a temporary safety zone that will be in effect for only five days and is intended to keep mariners safe from the hazards associated with live fire and explosive exercises. An environmental analysis checklist and a categorical exclusion determination will be available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 subpart C 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. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195;

33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0427 to read as follows:

§ 165.T05–0427 Safety Zone; M/V Del Monte Live-Fire Gun Exercise, James River, Isle of Wight, Virginia.

(a) *Regulated Area.* The following area is a safety zone: All waters in the vicinity of the James River Reserve Fleet on the James River within a 1500-foot radius of position 37°06′11″ N/ 076°38′40″ W (NAD 1983).

(b) *Definition:* For the purposes of this part, Captain of the Port Representative means any U.S. Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port, Hampton Roads, Virginia to act on his behalf.

(c) *Regulations:*

(1) In accordance with the general regulations in 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port, Hampton Roads or his designated representatives.

(2) The operator of any vessel in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(ii) Proceed as directed by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(3) The Captain of the Port, Hampton Roads can be reached through the Sector Duty Officer at Sector Hampton Roads in Portsmouth, Virginia at telephone Number (757) 668–5555.

(4) The Coast Guard Representatives enforcing the safety zone can be contacted on VHF–FM marine band radio channel 13 (165.65 Mhz) and channel 16 (156.8 Mhz).

(d) *Enforcement Period:* This rule will be enforced from 11 a.m. January 30, 2012 until 9 a.m. on February 3, 2012.

Dated: January 17, 2012.

Mark S. Ogle,

Captain, U.S. Coast Guard, Captain of the Port Hampton Roads.

[FR Doc. 2012–2221 Filed 1–31–12; 8:45 am]

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