

adds claims for persistent effectiveness against various species of external and internal parasites that were approved for the pioneer product with 3 years of marketing exclusivity (69 FR 501, January 6, 2004). The supplemental ANADA is approved as of March 26, 2010, and 21 CFR 524.1193 is amended to reflect the approval.

In addition, FDA has noticed the regulations do not accurately reflect approved indications for generic products. At this time, the regulations are being revised to reflect which generic products have approved labeling for the durations of persistent effectiveness approved for the pioneer product. FDA is also adding a parasite species that was inadvertently omitted in the previously cited January 6, 2004, final rule. These actions are being taken to improve the accuracy of the regulations.

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.

The agency has determined under 21 CFR 25.33 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 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. In § 524.1193, revise paragraphs (b) and (e)(2) to read as follows:

§ 524.1193 Ivermectin topical solution.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) Nos. 050604, 055529, 058829 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(iii), and (e)(3) of this section.

(2) Nos. 054925, 059130, 061623, and 066916 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii), and (e)(3) of this section.

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(e) * * *

(2) *Indications for use*—(i) It is used for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Oesophagostomum radiatum*; (adults) *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis*, *H. lineatum*; mites *Sarcoptes scabiei* var. *bovis*; lice *Linognathus vituli*, *Haematopinus eurysternus*, *Damalinea bovis*, *Solenoptes capillatus*; and horn flies *Haematobia irritans*.

(ii) It controls infections and prevents reinfection with *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *C. punctata*, and *C. oncophora* for 14 days after treatment.

(iii) It controls infections and prevents reinfection with *O. radiatum* and *D. viviparus* for 28 days after treatment, *C. punctata* and *T. axei* for 21 days after treatment, *O. ostertagi*, *H. placei*, *C. oncophora*, and *C. surnabada* for 14 days after treatment, and *D. bovis* for 56 days after treatment.

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Dated: May 6, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2010-11244 Filed 5-11-10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2010-0285]

RIN 1625-AA00

Safety Zones; May Fireworks Displays Within the Captain of the Port Puget Sound Area of Responsibility (AOR)

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The U.S Coast Guard is establishing two safety zones on the waters of Puget Sound, WA for two fireworks displays. This action is necessary to provide for the safety of life on navigable waters during the fireworks displays. Entry into, transit through, mooring, or anchoring within these zones is prohibited unless authorized by the Captain of the Port, Puget Sound or Designated Representative.

DATES: This rule is effective from 12:01 a.m. May 14, 2010 through 11:59 p.m. May 23, 2010 unless canceled sooner by the Captain of the Port.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2010-0285 and are available online by going to <http://www.regulations.gov>, inserting USCG-2010-0285 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 e-mail Ensign Rebecca E. McCann, Waterways Management, Sector Seattle, Coast Guard; telephone 206-217-6088, email SectorSeattleWWM@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 it is contrary to public interest to delay the effective date of this rule. Delaying the effective date by first publishing an NPRM would be contrary to the safety zone's intended objectives since

immediate action is needed to protect persons and vessels against the hazards associated with fireworks displays on navigable waters. Such hazards include premature detonations, dangerous projectiles and falling or burning debris.

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**. Due to the need for immediate action, the restriction of vessel traffic is necessary to protect life, property and the environment; therefore, a 30-day notice is impracticable. Delaying the effective date would be contrary to the safety zone's intended objectives of protecting persons and vessels involved in the event, and enhancing public and maritime safety.

Basis and Purpose

Fireworks displays are frequently held from locations on or near the navigable waters of the United States. The potential hazards associated with fireworks displays are a safety concern during such events. The purpose of this rule is to promote public and maritime safety during fireworks displays, and to protect mariners transiting the area from the potential hazards associated with the fireworks displays, such as the accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. This rule is needed to ensure safety on the waterway during the scheduled events.

This rule will restrict access to the specified waters surrounding the fireworks events indicated in the temporary final rule. The restriction of vessel traffic is necessary to protect life, property and the environment.

Discussion of Rule

The U.S. Coast Guard is establishing temporary safety zones to allow for safe fireworks displays. A safety zone for the Viking Fest will be enforced from 6:30 p.m. to 11:30 p.m. on May 14, 2010 at 47°43'55" N, 122°39'08" W (NAD 83) extending to a 1000 foot radius from the launch site. A safety zone for a Private Party fireworks display North of Meadow Point in Central Puget Sound will be enforced from 8:30 p.m. until 11 p.m. on May 22, 2010 at 47°43'42" N, 122°24'26" W (NAD 83) extending to a 1500 foot radius from the launch site. These safety zones do not extend onto land.

These events may result in a number of vessels congregating near fireworks launching barges. These safety zones are needed to protect watercraft and their occupants from safety hazards associated with fireworks displays. The Captain of the Port, Puget Sound may be

assisted by other federal and local agencies in the enforcement of these safety zones. Vessels will be allowed to transit the waters of the Puget Sound outside the safety zones. Notification of the temporary safety zones will be provided to the public via marine information broadcasts.

Entry into these zones by all vessel operators or persons will be prohibited unless authorized by the Captain of the Port or Designated Representative. The Captain of the Port may be assisted by other federal, state, or local agencies as needed.

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, 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. Although this rule will restrict access to the areas, the effect of this rule will not be significant because: (1) The safety zones will be in effect for a limited duration of time, (ii) the safety zones are limited in size, and (iii) vessels may be granted permission to transit the area by the Captain of the Port or a designated representative.

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.

This temporary rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit the specified waters of Puget Sound while this rule is enforced. These safety zones will not have significant economic impact on a substantial number of small entities for the

following reasons. This temporary rule will be in effect for short periods of time, when vessel traffic volume is low and is comprised of mostly small pleasure craft. If safe to do so, traffic will be allowed to pass through these safety zones with the permission of the Captain of the Port or Designated Representative.

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 cause 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 that 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 establishes temporary safety zones to protect the public from dangers associated with fireworks displays.

An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under

ADDRESSES.

List of Subjects in 33 CFR Part 165

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

■ For the reasons discussed in the preamble, the Coast Guard amends 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. Chapters 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 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 § 165.T13-140 to read as follows:

§ 165.T13-140 Safety Zones; May Fireworks displays within the Captain of the Port Puget Sound Area of Responsibility (AOR)

(a) *Safety Zones.* The following areas are designated safety zones:

- (1) Viking Fest, Liberty Bay, WA
 - (i) *Location.* Liberty Bay, WA extending out to a 1000 foot radius from the launch site at 47°43'55" N 122°39'08" W.

(ii) *Enforcement.* 6:30 p.m. until 11:30 p.m. on May 14, 2010.

(2) Private Party, North of Meadowpoint in Central Puget Sound, WA

(i) *Location.* Two miles north of Meadowpoint in Central Puget Sound, WA extending out to 1500 foot radius from the launch site at 47°43'42" N 122°24'26" W.

(i) *Enforcement.* 8:30 p.m. until 11 p.m. on May 22, 2010.

(b) *Regulations.* In accordance with the general regulations in 33 CFR Part 165, Subpart C, no vessel operator may enter, transit, moor, or anchor within these safety zones, except for vessels authorized by the Captain of the Port or Designated Representative.

(c) *Authorization.* All vessel operators who desire to enter these safety zones must obtain permission from the Captain of the Port or Designated Representative by contacting either the on-scene patrol craft on VHF Ch 13 or Ch 16 or the Coast Guard Sector Seattle Joint Harbor Operations Center (JHOC) via telephone at 206-217-6002.

(d) *Effective Period.* This rule is effective from 12:01 a.m. May 14, 2010 through 11:59 p.m. May 23, 2010 unless canceled sooner by the Captain of the Port.

Dated: April 15, 2010.

S.W. Bornemann,

Captain, U.S. Coast Guard, Captain of the Port, Puget Sound.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2010-0129]

RIN 1625-AA00

Safety Zones; Annual Events Requiring Safety Zones in the Captain of the Port Lake Michigan Zone

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending the regulations establishing permanent safety zones in the Captain of the Port Lake Michigan zone during annual events. When these safety zones are activated, and thus subject to enforcement, this rule would restrict vessels from portions of water areas during annual events that pose a hazard to public safety. The safety zones established by this rule are necessary to