

revised food safety labeling for trimethoprim and sulfadiazine injectable suspension, administered to horses as a systemic antibacterial.

DATES: This rule is effective May 31, 2006.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed a supplement to NADA 106-965 for use of TRIBRISSEN (trimethoprim and sulfadiazine) 48% Injection administered to horses as a systemic antibacterial. The supplement provides for revised food safety labeling. The supplemental NADA is approved as of April 26, 2006, and the regulations are amended in § 522.2610 (21 CFR 522.2610) to reflect the approval and a current format. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has found that a 1997 change of sponsorship for NADA 106-965 (62 FR 61625, November 19, 1997) is not reflected in the Code of Federal Regulations. Accordingly, § 522.2610 is being revised to reflect the correct sponsor drug labeler code. This action is 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(a)(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 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. Revise § 522.2610 to read as follows:

§ 522.2610 Trimethoprim and sulfadiazine.

(a) *Specifications.* Each milliliter (mL) contains:

(1) 40 milligrams (mg) trimethoprim suspended in a solution containing 200 mg sulfadiazine; or

(2) 80 mg trimethoprim suspended in a solution containing 400 mg sulfadiazine (as the sodium salt).

(b) *Sponsors.* See Nos. 000061 and 000856 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*—(1) Dogs—(i) *Amount.* 1 mL of the product described in paragraph (a)(1) of this section (40 mg trimethoprim and 200 mg sulfadiazine) per 20 pounds (9 kilograms) of body weight per day by subcutaneous injection.

(ii) *Indications for use.* For the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to *Streptococcus zooepidemicus*.

(2) Horses—(i) *Amount.* 2 mL of the product described in paragraph (a)(2) of this section (160 mg trimethoprim and 800 mg sulfadiazine) per 100 pounds (45 kilograms) of body weight per day by intravenous injection as single, daily dose for 5 to 7 days. The daily dose may also be halved and given morning and evening.

(ii) *Indications for use.* For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory tract infections, acute urogenital infections, and wound infections and abscesses.

(iii) *Limitations.* Not for use in horses intended for human consumption.

Dated: May 18, 2006.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. E6-8309 Filed 5-30-06; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD13-06-009]

RIN 1625-AA00

Safety Zones: Fireworks Displays in the Captain of the Port Portland Zone

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending its current regulations establishing additional safety zones on the waters of the Suislaw, Willamette, Columbia, Coos, and Chehalis Rivers, located in the Area of Responsibility (AOR) of the Captain of the Port, Portland, Oregon, during annual fireworks displays. The Captain of the Port, Portland, Oregon, is taking this action to safeguard watercraft and their occupants from safety hazards associated with these displays. Entry into these safety zones is prohibited unless authorized by the Captain of the Port.

DATES: This rule is effective June 30, 2006.

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 [CGD13-06-009] and are available for inspection or copying at U.S. Coast Guard Sector Portland 6767 N. Basin Ave, Portland, OR 97217 between 7 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Petty Officer Charity Keuter, c/o Captain of the Port, Portland 6767 N. Basin Avenue, Portland, Oregon 97217, (503) 240-9301.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On March 28, 2006, we published a notice of proposed rule making (NPRM) entitled Safety Zone: Fireworks Displays in the Captain of the Port Portland Zone in the **Federal Register** (71 FR 15365). We received no letters commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

The Coast Guard is establishing additional permanent safety zones to allow for safe annual fireworks displays. The Coast Guard is also revising 33 CFR 165.1315 paragraph (a)(8) because the current event is no longer an event which occurs with any regularity. All

events occur within the Captain of the Port, Portland, OR, Area of Responsibility (AOR). These events may result in a number of vessels congregating near fireworks launching barges and sites. The safety zones are needed to protect watercraft and their occupants from safety hazards associated with fireworks displays. These safety zones will be enforced by representatives of the Captain of the Port, Portland, Oregon. The Captain of the Port may be assisted by other Federal and local agencies.

This rule, for safety concerns, will control vessels, personnel and individual movements in a regulated area surrounding the fireworks event indicated in section 2 of this Final Rule. Entry into these zones is prohibited unless authorized by the Captain of the Port, Portland or his designated representative.

Discussion of Comments and Changes

The Coast Guard received no comments and thus has made no changes from the proposed rule.

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 this rule under that Order. This rule 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 expectation is based on the fact that the regulated areas established by the regulation will encompass small portions of the Columbia, Willamette, Coos, Chehalis and Siuslaw Rivers in the Portland AOR on different dates, all in the evening when vessel traffic is low.

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. These safety zones will not have significant economic impact on a substantial number of small entities for the following reasons. This rule will be in effect for only sixty minutes during the evenings when vessel traffic is low. Traffic will be allowed to pass through the zone with the permission of the Captain of the Port or his designated representatives on scene, if safe to do so.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance; please contact Petty Officer Keuter by phone at (503) 240–9301 or by e-mail at Charity.S.Keuter@uscg.mil. 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.

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).

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 State, local, or tribal government, in the aggregate, or the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect 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 proposed 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. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs 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 Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

Under figure 2–1, paragraph (34)(g), of the Instruction, an “Environmental Analysis Check List” and “Categorical Exclusion Determination” are required for this rule and are available for review in the public docket for this rulemaking.

List of Subjects in 33 CFR Part 165

Harbors, 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. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6 and 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 165.1315 revise the heading and paragraph (a)(8) and add paragraphs (a)(9)–(14) to read as follows:

§ 165.1315 Safety Zones: Fireworks displays in the Captain of the Port Portland Zone.

(a) * * *

(8) Florence Chamber 4th of July Fireworks Display, Florence, OR

(i) *Location.* All water of the Siuslaw River enclosed by the following points: 43°58′05″ N, 124°05′54″ W following the shoreline to 43°58′20″ N 124°04′46″ W then south to 43°58′07″ N 124°04′40″ W following the shoreline to 43°57′48″ N 124°05′54″ W then back to the point of origin.

(ii) *Enforcement Period.* This section is enforced annually on July fourth from 9 p.m. to 11 p.m. (PDT).

(9) Oaks Park July 4th Celebration, Portland, OR

(i) *Location.* All water of the Willamette River enclosed by the following points: 45°28′26″ N 122°39′43″ W following the shoreline to 45°28′10″ N 122°39′54″ W then west to 45°28′41″ N 122°40′06″ W following the shoreline to 45°28′31″ N 122°40′01″ W then back to the point of origin.

(ii) *Enforcement Period.* This section is enforced annually on July fourth from 9 p.m. to 11 p.m. (PDT).

(10) Rainier Days Fireworks Celebration, Rainier, OR

(i) *Location.* All water of the Columbia River enclosed by the following points: 46°06′04″ N, 122°56′35″ W following the shoreline to 46°05′53″ N 122°55′58″ W then south to 46°05′24″ N 122°55′58″ W following the shoreline to 46°05′38″ N 122°56′35″ W then back to the point of origin.

(ii) *Enforcement Period.* This section is enforced annually on the second Saturday of July each year from 9 p.m. to 11 p.m. (PDT). Except that when the first Saturday falls on July 1, this section will be enforced on the third Saturday of July.

(11) Ilwaco July 4th Committee Fireworks, Ilwaco, WA

(i) *Location.* All water of the Columbia River extending out to a 700′ radius from the launch site at 46°18′17″ N 124°01′55″ W.

(ii) *Enforcement Period.* This section is enforced annually on the first Saturday of July from 9 p.m. to 11 p.m. (PDT).

(12) Milwaukie Centennial Fireworks Display, Milwaukie, OR

(i) *Location.* All water of the Willamette River enclosed by the

following points: 45°26′41″ N, 122°38′46″ W following the shoreline to 45°26′17″ N 122°38′36″ W then west to 45°26′17″ N 122°38′55″ W following the shoreline to 45°26′36″ N 122°38′50″ W then back to the point of origin.

(ii) *Enforcement Period.* This section is enforced annually on the third Saturday of July each year from 9 p.m. to 11 p.m. (PDT). Except that when the first Saturday falls on July 1, this section will be enforced on the fourth Saturday of July.

(13) Splash Aberdeen Waterfront Festival, Aberdeen, WA

(i) *Location.* All water of the Chehalis River extending out to 500 feet of the following points: 46°58′40″ N, 123°47′45″ W.

(ii) *Enforcement Period.* This section is enforced annually on July fourth from 9 p.m. to 11 p.m. (PDT).

(14) City of Coos Bay July 4th Celebration, Coos Bay, OR

(i) *Location.* All water of the Coos River extending out to 1200 feet of the following points: 43°22′12″ N, 124°12′39″ W.

(ii) *Enforcement Period.* This section is enforced annually on July fourth from 9 p.m. to 11 p.m. (PDT).

* * * * *

Dated: May 9, 2006.

Patrick G. Gerrity,

Captain, U.S. Coast Guard, Captain of the Port, Portland, OR.

[FR Doc. E6–8218 Filed 5–30–06; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R06–OAR–2005–NM–0003; FRL–8175–6]

Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Albuquerque/Bernalillo County

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA is approving two separate State Implementation Plan (SIP) revisions submitted by the Governor of New Mexico. The first submittal, dated September 7, 2004, adopts local Ambient Air Quality Standards (AAQS) and incorporates by reference the Federal National Air Quality Standards (NAAQS) for the Albuquerque/Bernalillo County, New Mexico area. The second submittal,