

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: 21 U.S.C. 360b.

§ 520.1196 [Amended]

2. Section 520.1196 *Ivermectin and pyrantel pamoate chewable tablet* is amended in paragraph (b) by removing “*Sponsor. See 050604*” and by adding in its place “*Sponsors. See Nos. 050604 and 065274*”.

Dated: June 20, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–17051 Filed 7–6–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Moxidectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Fort Dodge Animal Health. The NADA provides for veterinary prescription use of a sustained-release injectable moxidectin formulation for prevention of heartworm disease and treatment of existing hookworm infections in dogs.

DATES: This rule is effective July 9, 2001.

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.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Div. of American Home Products Corp., 800 Fifth St. NW., Fort Dodge, IA 50501, filed NADA 141–189 that provides for veterinary prescription use of ProHeart® 6 (moxidectin) Sustained Release Injectable for Dogs for prevention of heartworm disease caused by *Dirofilaria immitis* and treatment of existing larval and adult hookworm (*Ancylostoma caninum*) infections. The NADA is approved as of June 6, 2001, and the

regulations are amended in 21 CFR part 522 by adding new § 522.1451 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 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, 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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning June 6, 2001, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

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 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. Section 522.1451 is added to read as follows:

§ 522.1451 Moxidectin.

(a) *Specifications.* The drug product consists of two separate vials. One contains 10 percent moxidectin microspheres, and the other contains a vehicle for constitution of the

moxidectin microspheres. Each milliliter of constituted, sustained-release suspension contains 3.4 milligrams (mg) of moxidectin.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use; dogs—(1) Amount.* 0.17 mg per kilogram body weight (0.0773 mg per pound) as a single subcutaneous injection.

(2) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis*; for treatment of existing larval and adult hookworm (*Ancylostoma caninum*) infections.

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

Dated: June 25, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–17049 Filed 7–6–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD09–01–035]

RIN 2115–AA97

Safety Zone; Cleveland Harbor, Cleveland, OH

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone encompassing the navigable waters adjacent to the Cleveland Port Authority, on Cleveland Harbor, Lake Erie. The safety zone is necessary to ensure the safety of spectator vessels during a fireworks display launched from a barge in Cleveland Harbor on July 28, 2001. This regulation is intended to restrict vessel traffic from a portion of Lake Erie and Cleveland Harbor.

DATES: This temporary final rule is effective 9 p.m. until 10 p.m. (local time), July 28, 2001.

ADDRESSES: Comments and material received from the public are part of docket CGD09–01–035, and are available for inspection and copying at Coast Guard Marine Safety Office Cleveland, Ohio, 1055 East Ninth Street, Cleveland, Ohio, 44114, between 7:30 a.m. and 4 p.m. Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Lieutenant John Natale, U.S. Coast Guard Marine Safety Office Cleveland,

1055 East Ninth Street, Cleveland, Ohio 44114. The telephone number is (216) 937-0111.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM, and, under 5 U.S.C. 553(d)(3), good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The Coast Guard had insufficient advance notice to publish an NPRM followed by a temporary final rule. Publication of a notice of proposed rulemaking and delay of effective date would be contrary to the public interest because immediate action is necessary to prevent possible loss of life, injury, or damage to property.

Background and Purpose

On July 28, 2001 at approximately 9:30 p.m. a fireworks and pyrotechnic display will be launched from a barge in Cleveland Harbor, approximately 1500 feet north of Voinavich Park at coordinates 41°30'53" N, 081°42'00" W. Spectators are expected to view the display from various spots along the Lake Erie waterfront, and private and commercial spectator vessels are also expected in Cleveland Harbor. A safety zone will be in effect on July 28, 2001 from 9 p.m. until 10 pm. The safety zone will include the navigable waters of Cleveland Harbor and Lake Erie beginning at coordinates 41°30'50" N, 081°41'33" W (the northwest corner of Burke Lakefront Airport); continuing northwest to coordinates 41°31'11" N, 081°41'55" W; then southwest to 41°30'48" N, 081°42'34" W; then southeast to 41°30'27" N, 081°42'13" W (the northwest corner of dock 28 at the Cleveland Port Authority). All coordinates are based upon North American Datum 1983 (NAD 83).

Regulatory Evaluation

This temporary 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. The Office of Management and Budget has exempted it from review 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 proposal to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory

policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) the Coast Guard considered whether this rule will have a significant impact on a substantial number of small businesses and not-for-profit organizations that are not dominant in their respective fields, and governmental jurisdictions with populations less than 50,000. The Coast Guard certifies under section 605(b) that this temporary final rule will not have a significant economic impact on a substantial number of small entities for the following reason: this rule will be in effect for one hour. Before the effective period, we will issue maritime advisories widely available to users of the waterway.

Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), the Coast Guard wants to assist small entities in understanding this rule so that they can better evaluate its effectiveness and participate in the rulemaking process. If your small business or organization is affected by this rule, and you have questions concerning its provisions or options for compliance, please contact the office listed in **ADDRESSES** in this preamble.

Collection of Information

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

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 or more in any one year. Though this rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 13132 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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 rule is not an economically significant rule and does not concern 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. A rule with tribal implications has a substantial direct effect on one or more Indian tribe, 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.

Environment

The Coast Guard has considered the environmental impact of this regulation and concluded that, under figure 2-1, paragraph 34(g) of Commandant Instruction M16475.1C, this rule is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping

requirements, Security measures, Waterways.

For the reasons set out 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.1231; 50 U.S.C. 191, 33 CFR 1.05–1(g), 6.04–1, 6.04–6, 160.5; 49 CFR 1.46.

2. A new temporary § 165.T09–958 is added to read as follows:

§ 165.T09–958 Safety Zone; Lake Erie, Cleveland Harbor, Ohio.

(a) *Location.* The Safety Zone encompasses the navigable waters of Cleveland Harbor and Lake Erie beginning at coordinates 41°30'50" N, 081°41'33" W (the northwest corner of Burke Lakefront Airport); continuing northwest to coordinates 41°31'11" N, 081°41'55" W; thence southwest to 41°30'48" N, 081°42'34" W; then southeast to 41°30'27" N, 081°42'13" W (the northwest corner of dock 28 at the Cleveland Port Authority). All coordinates are based on North American Datum 1983 (NAD83).

(b) *Effective dates.* This section is effective from 9 p.m. until 10 p.m. on July 28, 2001.

(c) *Regulations.* In accordance with the general regulations in § 165.23, entry into, transit through, or anchoring within this Safety Zone is prohibited unless authorized by the Captain of the Port, Cleveland or his representative on the Coast Guard vessel on scene. The Coast Guard Patrol Commander may be contacted on VHF Channel 16.

Dated: June 26, 2001.

R.J. Perry,

Commander, U.S. Coast Guard, Captain of the Port, Cleveland, Ohio.

[FR Doc. 01–16997 Filed 7–6–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD13–01–015]

RIN 2115–AA97

Security Zones; Naval Submarine Base Bangor and Naval Submarines, Puget Sound and Strait of Juan De Fuca, WA

AGENCY: Coast Guard, DOT.

ACTION: Interim final rule; request for comments.

SUMMARY: The Coast Guard is establishing a fixed security zone around Naval Submarine Base Bangor, and moving security zones around Naval submarines while underway on Puget Sound, and the Strait of Juan De Fuca, Washington, and adjoining waters. These zones would safeguard U.S. Naval Submarine Base Bangor, and U.S. Naval submarines from sabotage, other subversive acts, or accidents, and otherwise protect Naval assets vital to national security.

DATES: This rule becomes effective at 6 p.m. PDT, June 20, 2001. Comments and related material must reach the Coast Guard on or before September 7, 2001.

ADDRESSES: Coast Guard Marine Safety Office Puget Sound maintains the public docket for this rulemaking. You may mail comments and related material to the address below. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at U.S. Coast Guard Marine Safety Office Puget Sound, 1519 Alaskan Way South, Building 1, Seattle, Washington 98134. Normal office hours are between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LT P. M. Stocklin, Jr., c/o Captain of the Port Puget Sound, 1519 Alaskan Way South, Seattle, WA 98134, (206) 217–6232.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM and for making this rule effective less than 30 days after publication in the **Federal Register**. Publishing a NPRM would be contrary to public interest since immediate action is necessary to safeguard U.S. Naval bases and submarines from sabotage, other subversive acts, or accidents, and otherwise protect Naval assets vital to national security. The attack on USS COLE precipitated U.S. Navy security reviews, which have determined that immediate threats exist to Naval bases and submarines in Puget Sound. If normal notice and comment procedures were followed, this rule would not become effective soon enough to provide immediate protection to Naval assets from the threats posed by hostile entities. The security zones in this regulation have been carefully designed to minimally impact the

public while providing a reasonable level of protection for Naval assets. For these reasons, following normal rulemaking procedures in this case would be impracticable, unnecessary, and contrary to the public interest.

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD 13–01–015), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this interim final rule in view of them.

Public Meeting

We do not plan to hold a public meeting. However, you may submit a request for a meeting by writing to the person identified in the **FOR FURTHER INFORMATION CONTACT** section, or to the address under **ADDRESSES** explaining why a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Coast Guard is establishing a fixed security zone around Naval Submarine Base Bangor, and moving security zones around Naval submarines while underway on Puget Sound, and the Strait of Juan De Fuca, WA, and adjoining waters. The Coast Guard has determined it is necessary to prevent access in order to safeguard this U.S. Naval base and submarines from sabotage, other subversive acts, or accidents, and otherwise protect Naval assets vital to national security. Recent events such as the bombing of the USS COLE highlight the fact that there are hostile entities operating with the intent to harm U.S. National Security by attacking or sabotaging Naval assets including those in Puget Sound. It would be contrary to the public interest to disclose the exact nature of the current threats to U.S. Naval assets, as this information is highly classified, and if divulged would greatly damage U.S. intelligence sources and security postures. However, the threat to the security of U.S. Naval assets is real,