

**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 Novartis Animal Health US, Inc. The NADA provides for the veterinary prescription use of deracoxib tablets for the control of postoperative pain and inflammation associated with orthopedic surgery in dogs.

**DATES:** This rule is effective November 13, 2002.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: mberson@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed NADA 141-203 that provides for the veterinary prescription use of DERAMAXX (deracoxib) Chewable Tablets for the control of postoperative pain and inflammation associated with orthopedic surgery in dogs weighing four or more pounds (1.8 kilograms). The NADA is approved as of August 21, 2002, and the regulations are amended in 21 CFR part 520 by adding new § 520.538 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)(i) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning August 21, 2002.

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 520

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 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.

2. Section 520.538 is added to read as follows:

#### § 520.538 Deracoxib.

(a) *Specifications.* Each chewable tablet contains 25 or 100 milligrams (mg) deracoxib.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs—(1) Amount.* 3 to 4 mg per kilogram (kg) (1.4 to 1.8 mg per pound) of body weight once daily for 7 days, given orally.

(2) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery in dogs weighing 4 or more pounds (1.8 kg).

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

Dated: October 25, 2002.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 02-28714 Filed 11-12-02; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 165

[COTP San Juan 02-133]

RIN 2115-AA97

#### Security Zones; St. Thomas, United States Virgin Islands

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule; request for comments.

**SUMMARY:** The Coast Guard is establishing temporary security zones 50 yards around all cruise ships in the Port of Charlotte Amalie, St. Thomas, United States Virgin Islands. These security zones are needed to protect the public and the Port of Charlotte Amalie from potential subversive acts.

**DATES:** This regulation becomes effective at 6 p.m. on November 4, 2002 and will terminate at 11:59 p.m. on June 15, 2003.

**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 [COTP San Juan 02-133] and are available for inspection or copying at Marine Safety Office San Juan, RODVAL Bldg., San Martin St. #90 Ste 400, Guaynabo, PR 00968, between 7 a.m. and 3:30 p.m. Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LCDR Michael Roldan, Marine Safety Office San Juan, Puerto Rico at (787) 706-2440.

#### 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 a NPRM. Publishing a NPRM and delaying the rule's effective date would be contrary to the public interest since immediate action is needed to protect the public, ports and waterways of the United States. The Coast Guard will issue a broadcast notice to mariners and a Marine Safety Information Bulletin via facsimile and electronic mail to advise mariners of the restriction.

For the same reasons, 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**.

##### Request for Comments

Although the Coast Guard has good cause to implement this regulation without a notice of proposed rulemaking, we want to afford the public the opportunity to participate in this rulemaking by submitting comments and related material regarding the size and boundaries of these security zones in order to minimize unnecessary burdens. If you do so, please include your name and address, identify the docket number for this rulemaking [COTP San Juan 02-133] 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 temporary final rule in view of them.

### Background and Purpose

Based on the September 11, 2001, terrorist attacks on the World Trade Center buildings in New York and the Pentagon in Arlington, Virginia, there is an increased risk that subversive activity could be launched by vessels or persons in close proximity to the Port of Charlotte Amalie, USVI against cruise ships in the Port. The President has continued the national emergencies he declared following the September 11, 2001 terrorist attacks (67 FR 58317 (Sept. 13, 2002) (continuing national emergency with respect to terrorist attacks), 67 FR 59447 (Sept. 20, 2002) (continuing national emergency with respect to persons who commit, threaten to commit or support terrorism)). The President also has found pursuant to law, including the Magnuson Act (50 U.S.C. 191 *et seq.*), that the security of the United States is and continues to be endangered following the attacks (E.O. 13,273, 67 FR 56215 (Sept. 3, 2002) (security endangered by disturbances in international relations of U.S and such disturbances continue to endanger such relations)).

On February 1, 2002 the Coast Guard published a temporary final rule in the **Federal Register** (CGD07-01-136) that established temporary moving and fixed security zones 50 yards around all cruise ships entering, departing or moored in the Port of Charlotte Amalie (67 FR 4909). That rule expired on June 15, 2002. The Captain of the Port has determined that this rule is necessary to protect the Port of Charlotte Amalie from subversive activity. The Captain of the Port intends to issue a notice of proposed rulemaking in a separate document to be published in the **Federal Register** proposing to create permanent security zones around cruise ships in the Port of Charlotte Amalie.

Due to the number of passengers onboard cruise ships moored in the Port of Charlotte Amalie, USVI, there is a risk that they are a target for subversive activity or a terrorist attack. The Captain of the Port San Juan is reducing this risk by prohibiting all vessels from coming within 50 yards of cruise ships while entering, departing, moored at any pier, or anchored in any anchorage in the Port of Charlotte Amalie, St. Thomas, USVI unless prior authorization is given by the Captain of the Port of San Juan.

These temporary security zones are activated when cruise ships pass: St. Thomas Harbor green lighted buoy #3 in approximate position 18°19'19" North, 64°55'40" West when entering the port

using St. Thomas Channel; red buoy #2 in approximate position 18°19'15" North, 64°55'59" West when entering the port using East Gregorie Channel; and red lighted buoy #4 in approximate position 18°18'16" North, 64°57'30" West when entering the port using West Gregorie Channel. These zones are deactivated when the vessel passes any of these buoys on its departure from port. United States Coast Guard and territorial law enforcement personnel will be on-scene to notify the public of these security zones.

### 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 Transportation (DOT) (44 FR 11040; February 26, 1979) because the zones are narrow in scope and are only in effect for limited periods of time when a cruise ship is in Port.

### Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), the Coast Guard considered whether this rule would have a significant economic effect upon a substantial number of small entities. "Small entities" include 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 because the zones are narrow in scope and are only in effect for limited periods of time when a cruise ship is in Port. Moreover, vessels may be allowed to enter the zones on a case-by-case basis with the permission of the Captain of the Port of San Juan.

### Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 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. If the rule will affect your small business, organization, or government jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under

**FOR FURTHER INFORMATION CONTACT** for assistance in understanding this rule.

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 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 requirements under the Paperwork Reduction Act (44 U.S.C. 3501-3520).

### Federalism

A rule has implication 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 or more in any one year. Although 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 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.

### Environmental

The Coast Guard has considered the environmental impact of this rule and concluded that under figure 2-1, paragraph 34(g), of Commandant Instruction M14475.1D that this rule is categorically excluded from further

environmental documentation. A "Categorical Exclusion Determination" is available in the docket for inspection or copying where indicated under ADDRESSES.

### 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 relationships 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 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.

### 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. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new temporary section 165.T07–133 is added to read as follows:

### § 165.T–07–133 Security Zones; Charlotte Amalie Harbor, St. Thomas, USVI.

(a) *Regulated area.* Temporary moving security zones are established 50 yards around all cruise ships while they enter, depart, are moored at any pier or anchored in any anchorage in Charlotte Amalie Harbor. These temporary security zones are activated when cruise ships pass: St. Thomas Harbor green lighted buoy #3 in approximate position 18°19'19" North, 64°55'40" West when entering the port using St. Thomas Channel; red buoy #2 in approximate position 18°19'15" North, 64°55'59" West when entering the port using East Gregorie Channel; and red lighted buoy #4 in approximate position 18°18'16" North, 64°57'30" West when entering the port using West Gregorie Channel. These zones are deactivated when the cruise ship passes any of these buoys on its departure from port.

(b) *Regulations.* In accordance with the general regulations in § 165.33 of this part, no person or vessel shall enter or remain in this security zone unless specifically authorized by the Captain of the Port San Juan, or a Coast Guard commissioned, warrant, or petty officer designated by the Captain of the Port. The Captain of the Port will notify the public when a zone is activated and any changes in the status of the zones by Marine Safety Radio Broadcast on VHF Marine Band Radio, Channel 16 (157.1 Mhz) and by a Marine Safety Information Bulletin (MSIB) sent by facsimile and electronic mail.

(c) *Dates.* This section becomes effective at 6 p.m. on November 4, 2002 and will terminate at 11:59 p.m. on June 15, 2003.

Dated: November 4, 2002.

**W.J. Uberti,**

*Captain, U.S. Coast Guard, Captain of the Port.*

[FR Doc. 02–28837 Filed 11–12–02; 8:45 am]

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### DEPARTMENT OF TRANSPORTATION

#### Coast Guard

#### 33 CFR Part 165

[CGD 07–02–132]

RIN 2115–AA97

#### Security Zone; San Juan, Puerto Rico

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule; request for comments.

**SUMMARY:** The Coast Guard is extending the effective period for the temporary final rule creating temporary moving

security zones 50 yards around all cruise ships entering or departing the Port of San Juan. Temporary fixed security zones are also established 50 yards around all cruise ships that are moored in the Port of San Juan. These security zones are needed for national security reasons to protect the public, ports, and waterways from potential subversive acts. Entry into these zones is prohibited, unless specifically authorized by the Captain of the Port, San Juan, Puerto Rico or his designated representative.

**DATES:** This rule is effective from 11:59 p.m. on October 31, 2002 until 11:59 p.m. on April 30, 2003.

**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 [CGD 07–02–132] and are available for inspection or copying at Marine Safety Office San Juan, Rodval Bldg, San Martin St. #90 Ste 400, Guaynabo, PR 00969 between 7 a.m. and 3:30 p.m. Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Chip Lopez, Marine Safety Office San Juan, Puerto Rico at (787) 706–2444.

#### 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 a NPRM. Publishing a NPRM, which would incorporate a comment period before a final rule could be issued, would be contrary to the public interest since the Captain of the Port of San Juan has determined that immediate action is needed to protect the public, ports and waterways of the United States near San Juan.

For the same reasons, 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**. The Coast Guard will issue a broadcast notice to mariners and written information via facsimile and electronic mail to inform mariners of this regulation.

#### Request for Comments

Although the Coast Guard has good cause to implement this regulation without a notice of proposed rulemaking, we want to afford the public the opportunity to participate in this rulemaking by submitting comments and related material regarding the size and boundaries of