under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS.

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9K, Airspace Designations and Reporting Points, dated August 31, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Needles Airport, CA [Revised]

Needles Airport, CA
(Lat.34°45′58″ N, long. 114°37′24″ W)
Needles VORTAC
(Lat. 34°45′58″ N, long. 114°28′27″ W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Needles Airport; and that airspace extending upward from 1200 feet above the surface within 7.8 miles south and 11.3 miles north of the Needles VORTAC 092° and 272° radials, extending from 9.6 miles west to 20.9 miles east of the Needles VORTAC.

* * * * *

Issued in Los Angeles, California, on October 24, 2002.

John Clancy,

Manager, All Traffic Division, Western-Pacific Region.

[FR Doc. 02–28829 Filed 11–12–02; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Gonadorelin Diacetate Tetrahydrate

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of gonadorelin diacetate tetrahydrate solution by injection in dairy cattle for the treatment of ovarian cysts.

DATES: This rule is effective November 13, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–069 that provides for veterinary prescription use of FERTELIN (gonadorelin diacetate tetrahydrate) Injection by intramuscular or intravenous injection in dairy cattle for the treatment of ovarian cysts. Phoenix's FERTELIN Injection is approved as a generic copy of Merial, Ltd.'s CYSTORELIN, approved under NADA 98–379. ANADA 200–069 is approved as of August 26, 2002, and the regulations are amended in § 522.1078 (21 CFR 522.1078) to reflect the approval. Section 522.1078 is also being revised to reflect a current format. 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.

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 Subject 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 522.1078 is revised to read as follows:

§ 522.1078 Gonadorelin diacetate tetrahydrate.

(a) *Specifications.* Each milliliter of solution contains 50 micrograms (µg) of gonadorelin diacetate tetrahydrate.

(b) *Sponsors.* See Nos. 050604, 057926, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle.* It is used as follows:

(1) *Amount.* 100 µg per cow as a single intramuscular or intravenous injection.

(2) *Indications for use.* For the treatment of ovarian cysts in dairy cattle.

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

Dated: October 28, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–28716 Filed 11–12–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Deracoxib

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 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