

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. Add § 520.852 to read as follows:

§ 520.852 Estriol.

(a) *Specifications.* Each tablet contains 1 milligram (mg) estriol.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer at an initial dose of 2 mg per dog per day. The dosage may be titrated to as low as 0.5 mg per dog every second day, depending on response.

(2) *Indications for use.* For the control of estrogen-responsive urinary incontinence in ovariohysterectomized female dogs.

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

Dated: December 9, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011-32214 Filed 12-15-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA-2011-N-0003]

Ophthalmic and Topical Dosage Form New Animal Drugs; Hydrocortisone Aceponate, Miconazole Nitrate, and Gentamicin Sulfate Otic Suspension

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 original new animal drug application (NADA) filed by Virbac AH, Inc. The NADA provides for the veterinary prescription use of a hydrocortisone aceponate, miconazole nitrate, and gentamicin sulfate suspension for the treatment of otitis externa in dogs.

DATES: This rule is effective December 16, 2011.

FOR FURTHER INFORMATION CONTACT: Lisa M. Troutman, Center for Veterinary Medicine (HFV-116), Food and Drug Administration, 7500 Standish Pl.,

Rockville, MD 20855, (240) 276-8322, email: lisa.troutman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Fort Worth, TX 76137, filed NADA 141-330 for the veterinary prescription use of EASOTIC (hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate) Suspension for the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*). The NADA is approved as of October 31, 2011, and 21 CFR part 524 is amended to reflect the approval.

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.

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 qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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. Add § 524.1132 to read as follows:

§ 524.1132 Hydrocortisone aceponate, miconazole nitrate, gentamicin sulfate otic suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains 1.11 milligrams (mg) of hydrocortisone aceponate, 15.1 mg of miconazole nitrate, and 1,505 micrograms of gentamicin sulfate.

(b) *Sponsor.* See No.051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Instill 1.0 mL in the affected ear once daily for 5 days.

(2) *Indications for use.* For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

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

Dated: December 13, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011-32226 Filed 12-15-11; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1980

[Docket Number OSHA-2011-0126]

RIN 1218-AC53

Procedures for the Handling of Retaliation Complaints Under Section 806 of the Sarbanes-Oxley Act of 2002, as Amended; Correction

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Interim final rule; correction.

SUMMARY: The Occupational Safety and Health Administration is correcting an interim final rule on the procedures for the handling of retaliation complaints under Section 806 of the Sarbanes-Oxley Act of 2002, As Amended, published in the **Federal Register** of November 3, 2011 (76 FR 68084).

DATES: Effective December 16, 2011.

FOR FURTHER INFORMATION CONTACT: Sandra Dillon, Acting Director, Office of the Whistleblower Protection Program, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3610, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693-2199.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011-28274 on page 68084 in the **Federal Register** of Thursday,

November 3, 2011, an incorrect amendatory instruction published inadvertently creating duplicate paragraphs (b)(1)(ii) in § 1980.102. This document corrects that error.

Therefore, OSHA amends 29 CFR part 1980 by making the following correcting amendment:

PART 1980—PROCEDURES FOR THE HANDLING OF RETALIATION COMPLAINTS UNDER SECTION 806 OF THE SARBANES-OXLEY ACT OF 2002, AS AMENDED

■ 1. The authority citation for part 1980 continues to read as follows:

Authority: 18 U.S.C. 1514A, as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, Pub. L. 111–203 (July 21, 2010); Secretary of Labor’s Order No. 4–2010 (Sept. 2, 2010), 75 FR 55355 (Sept. 10, 2010); Secretary of Labor’s Order No. 1–2010 (Jan. 15, 2010), 75 FR 3924 (Jan. 25, 2010).

§ 1980.102 [Corrected]

■ 2. In § 1980.102, redesignate the second paragraph (b)(1)(ii) as paragraph (b)(1)(iii).

Signed at Washington, DC on December 9, 2011.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2011–32095 Filed 12–15–11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2011–1078]

RIN 1625–AA08

Special Local Regulations; Boca Raton Holiday Boat Parade, Intracoastal Waterway, Boca Raton, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing special local regulations on the waters of the Intracoastal Waterway in Boca Raton, Florida during the Boca Raton Holiday Boat Parade on Saturday, December 17, 2011. The marine parade will consist of approximately 60 vessels. The marine parade will begin at C–15 Canal then head south on the Intracoastal Waterway to the Hillsborough Bridge, where the marine parade will conclude. These special local regulations are necessary to

provide for the safety of life on navigable waters of the United States during the marine parade. The special local regulations consist of a series of moving buffer zones around participant vessels as they transit from C–15 Canal to the Hillsborough Bridge. Persons and vessels that are not participating in the marine parade are prohibited from entering, transiting through, anchoring in, or remaining within any of the buffer zones unless authorized by the Captain of the Port Miami or a designated representative.

DATES: This rule is effective from 6 p.m. until 9 p.m. on December 17, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–1078 and are available online by going to <http://www.regulations.gov>, inserting USCG–2011–1078 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 final rule, call or email Lieutenant Jennifer S. Makowski, Sector Miami Prevention Department, Coast Guard; telephone (305) 535–8724, email Jennifer.S.Makowski@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 the Coast Guard did not receive necessary information about this year’s Boca Raton Holiday Boat Parade until November 7, 2011. As a result, the Coast Guard did not have sufficient time to publish an NPRM and to receive public comments prior to the event. Any delay in the

effective date of this rule would be contrary to the public interest because immediate action is needed to minimize potential danger to marine parade participants, participant vessels, spectators, and the general public.

For the same reason discussed above, 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**.

Basis and Purpose

The legal basis for the rule is the Coast Guard’s authority to establish special local regulations: 33 U.S.C. 1233.

The purpose of the rule is to insure safety of life on navigable waters of the United States during the Boca Raton Holiday Boat Parade.

Discussion of Rule

On December 17, 2011, the City of Boca Raton is hosting the Boca Raton Holiday Boat Parade on the Intracoastal Waterway in Boca Raton, Florida. The marine parade will consist of approximately 60 vessels. The marine parade will begin at C–15 Canal and transit south on the Intracoastal Waterway to the Hillsborough Bridge. Although this event occurs annually, and special local regulations have been promulgated in the Code of Federal Regulations at 33 CFR 100.701, the date of the marine parade does not correspond with the date published in the Code of Federal Regulations, and the special local regulations have been modified. Therefore, the special local regulations set forth in 33 CFR 100.701 are inapplicable for this year’s Boca Raton Holiday Boat Parade.

The special local regulations consist of a series of buffer zones around vessels participating in the Boca Raton Holiday Boat Parade. These buffer zones are as follows: (1) All waters within 75 yards of the lead marine parade vessel; (2) all waters within 75 yards of the last marine parade vessel; and (3) all waters within 50 yards of all other marine parade vessels. Notice of the special local regulations, including the identities of the lead marine parade vessel and the last marine parade vessel, will be provided prior to the marine parade by Local Notice to Mariners and Broadcast Notice to Mariners. These special local regulations will be enforced from 6 p.m. until 9 p.m. on December 17, 2011. Persons and vessels are prohibited from entering, transiting through, anchoring, or remaining within the buffer zones unless authorized by the Captain of the Port Miami or a designated representative. Persons and