

## 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]

**BILLING CODE 4160–01–P**

## 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](mailto: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,