PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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.

FOR FURTHER INFORMATION CONTACT: Lisa Troutman, Center for Veterinary Medicine, 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 acetate, 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(h)(2)(i), 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.


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.


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:

2. Add § 524.1132 to read as follows:

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

(a) Specifications. Each milliliter (mL) of suspension contains 1.11 milligrams (mg) of hydrocortisone acetate, 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.

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1980

[Docket Number OSHA–2011–0126]

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.

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,