susceptible strains of yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius).

The NADA is approved as of November 23, 2009, and the regulations are amended in 21 CFR part 524 by adding new 21 CFR 524.1445 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.

FDA 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:


2. Add §524.1445 to read as follows:

§524.1445 Miconazole, polymixin B, and prednisolone suspension.

(a) Specifications. Each milliliter of suspension contains 23 milligrams (mg) miconazole nitrate, 0.5293 mg polymixin B sulfate, and 5 mg prednisolone acetate.

(b) Sponsor. See No. 012578 in 510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Instill five drops in the ear canal twice daily for 7 consecutive days.

(2) Indications for use. For the treatment of canine otitis externa 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: January 22, 2010.

Bernadette Dunham,

Director, Center for Veterinary Medicine.