ANADA 200–376 that provides for use of SULFAMED–G (sulfadimethoxine) Soluble Powder to create a solution administered as a drench to cattle or in the drinking water of chickens, turkeys, or cattle for the treatment of coccidiosis or various bacterial diseases. Cross Vetpharm Group Ltd.'s SULFAMED–G Soluble Powder is approved as a generic copy of Pfizer, Inc.'s ALBON (sulfadimethoxine) Soluble Powder, approved under NADA 46–285. The ANADA is approved as of November 14, 2005, and the regulations are amended in 21 CFR 520.2220a 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 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(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 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 520.2220a is amended by revising paragraphs (a)(2) and (b); and by adding two sentences at the end of paragraph (d)(3)(iii) to read as follows:

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

(a) * * *

(2) For soluble powder, each 107 grams contain the equivalent of 94.6 grams of sulfadimethoxine (as the sodium salt); see Nos. 000069, 051259, 057561, 059130, and 061623 in § 510.600(c) of this chapter.

(b) *Special considerations.* Federal law prohibits the extralabel use of this product in lactating dairy cattle.

* * * * *

(d) * * *

(3) * * *

(iii) * * * A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: November 30, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–23813 Filed 12–8–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Miconazole Nitrate Cream; Miconazole Nitrate Lotion; Miconazole Nitrate Spray

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 First Priority, Inc. The ANADA provides for topical use of miconazole nitrate as a spray or lotion on dogs and cats for the treatment of certain fungal infections.

DATES: This rule is effective December 9, 2005.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1069, e-mail: *linda.wilmot@fda.gov*.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–362 for PRICONAZOLE (miconazole nitrate) Lotion 1% and PRICONAZOLE (miconazole nitrate) Spray 1% for topical use on dogs and cats for the treatment of certain fungal infections. First Priority's PRICONAZOLE Lotion 1% and PRICONAZOLE Spray 1% are approved as generic copies of Schering-Plough Animal Health Corp.'s CONOFITE Lotion 1% and Spray 1%, approved under NADA 95–184. The ANADA is approved as of November 14, 2005, and 21 CFR 524.1443 is amended 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 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(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 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.

§ 524.1443 [Amended]

■ 2. Section 524.1443 is amended in paragraph (b) by removing ''No. 051259'' and by adding in its place ''Nos. 051259 and 058829''.

Dated: November 30, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–23811 Filed 12–8–05; 8:45 am]

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