

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Sulfadiazine/Pyrimethamine 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 a new animal drug application (NADA) filed by Animal Health Pharmaceuticals, LLC. The NADA provides for veterinary prescription use of an oral suspension of sulfadiazine and pyrimethamine for the treatment of equine protozoal myeloencephalitis (EPM).

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: melanie.berson@fda.gov.

SUPPLEMENTARY INFORMATION: Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506, filed NADA 141-240 for veterinary prescription use of REBALANCE (sulfadiazine/pyrimethamine) Antiprotozoal Oral Suspension for the treatment of EPM caused by *Sarcocystis neurona*. The NADA is approved as of November 5, 2004, and 21 CFR part 520 is amended by adding new § 520.2215 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Animal Health Pharmaceuticals, LLC, is not currently listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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 November 5, 2004.

The agency has determined under 21 CFR 25.33(d)(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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for “Animal Health Pharmaceuticals, LLC”; and in the table in paragraph (c)(2) by numerically adding an entry for “068718” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	*
Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506	068718
* * * * *	*

(2) * * *

Drug labeler code	Firm name and address
* * * * *	*
068718	Animal Health Pharmaceuticals, LLC, 1805 Oak Ridge Circle, suite 101, St. Joseph, MO 64506
* * * * *	*

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 360b.

- 4. Section 520.2215 is added to read as follows:

§ 520.2215 Sulfadiazine/pyrimethamine suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains 250 milligrams (mg) sulfadiazine (as the sodium salt) and 12.5 mg pyrimethamine.

(b) *Sponsor.* See No. 068718 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer orally 20 mg sulfadiazine per kilogram (kg) body weight and 1 mg/kg pyrimethamine daily.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona*.

(3) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: November 23, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S