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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Sulfachlorpyridazine Powder

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 supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, A Division of Wyeth Holdings Corp. The supplemental NADA provides for a revised food safety warning statement for oral use of sulfachlorpyridazine in the milk or milk replacer of ruminating calves.

DATES: This rule is effective June 24, 2008.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: *cindy.burnsteel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, A Division of Wyeth Holdings Corp., P.O. Box 1339, Fort Dodge, IA 50501, filed a supplement to NADA 33–373 for VETISULID (sulfachlorpyridazine sodium) Powder, approved for oral use in calves and swine for the treatment of diarrhea caused or complicated by *Escherichia coli* (colibacillosis). The supplemental NADA provides for a revised food safety warning statement for oral use of sulfachlorpyridazine in the milk or milk replacer of ruminating calves. The supplemental application is approved as of May 19, 2008, and the regulations are amended in 21 CFR 520.2200b to reflect the approval and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency 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 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. Revise § 520.2200b to read as follows:

§ 520.2200b Sulfachlorpyridazine powder.

(a) *Specifications.* Sodium sulfachlorpyridazine powder.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.630 of this chapter.

(d) *Conditions of use.* It is used as follows:

(1) *Calves*—(i) *Amount.* Administer 30 to 45 milligrams per pound (mg/lb) body weight per day in milk or milk replacer for 1 to 5 days in 2 divided doses twice daily.

(ii) *Indications for use.* For the treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(iii) *Limitations.* Treated, ruminating calves must not be slaughtered for food during treatment or for 7 days after the last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Swine*—(i) *Amount.* Administer 20 to 35 mg/lb body weight per day for 1 to 5 days in 2 divided doses twice daily:

(A) In drinking water; or

(B) For individual treatment, in an oral suspension containing approximately 42 mg sulfachlorpyridazine per milliliter in divided doses twice daily.

(ii) *Indications for use.* For the treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(iii) *Limitations.* Treated swine must not be slaughtered for food during treatment or for 4 days after the last treatment.

Dated: June 9, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–14291 Filed 6–23–08; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 292

RIN 1076–AE81

Gaming on Trust Lands Acquired After October 17, 1988; Correction

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule; correction and stay of effective date.

SUMMARY: This document contains a correction to a final rule that was published May 20, 2008 (73 FR 29354). The regulation relates to gaming on trust lands acquired after October 17, 1988.

DATES: The effective date of this correction is June 24, 2008. In rule FR Document E8–11086 published on May 20, 2008 (73 FR 29353), the effective date of the rule is stayed until August 25, 2008.

FOR FURTHER INFORMATION CONTACT: Paula Hart, Acting Director, Office of Indian Gaming, (202) 219–4066.

SUPPLEMENTARY INFORMATION: The Bureau of Indian Affairs published on May 20, 2008, a final rule relating to gaming on trust lands acquired after October 17, 1988. The preamble to this