

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2009-N-0665]

Oral Dosage Form New Animal Drugs; Tiamulin

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 Novartis Animal Health US, Inc. The supplemental NADA provides for removal of a 250-pound weight restriction and the addition of a reproductive caution statement to labeling of tiamulin concentrate solution used in drinking water for the treatment of certain bacterial respiratory and enteric diseases in swine.

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

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: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to NADA 140-916 for DENAGARD (tiamulin) Liquid Concentrate used for the treatment of certain bacterial respiratory and enteric diseases in swine. The supplemental NADA provides for removal of a 250-pound weight restriction and the addition of a reproductive caution statement to labeling. The supplemental NADA is

approved as of January 27, 2009, and 21 CFR 520.2455 is amended to reflect the approval.

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(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 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. In § 520.2455, remove paragraph (d), redesignate paragraph (e) as paragraph (d), and revise newly redesignated paragraph (d)(2) to read as follows:

§ 520.2455 Tiamulin.

* * * * *

(d) * * *

(2) *Limitations.* Use as only source of drinking water. Prepare fresh medicated water daily. Withdraw medication 3 days before slaughter following treatment at 3.5 mg/lb and 7 days before slaughter following treatment at 10.5 mg/lb of body weight. Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramycin) as adverse reactions may occur. The effects of tiamulin on swine reproductive performance, pregnancy, and lactation have not been determined.

Dated: February 10, 2009.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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