

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Tiamulin Liquid Concentrate

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 Phoenix Scientific, Inc. The ANADA provides for use of tiamulin concentrate solution to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia.

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

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223, e-mail: daniel.benz@fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed ANADA 200-360 that provides for use of Tiamulin Liquid Concentrate to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia. Phoenix Scientific, Inc.'s Tiamulin Liquid Concentrate is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s DENAGARD (tiamulin) Liquid Concentrate approved under NADA 140-916. The ANADA is approved as of June 24, 2005, and the regulations are amended in § 520.2456 (21 CFR 520.2456) to reflect

the approval. The basis of approval is discussed in the freedom of information summary.

The regulations are also amended in § 520.2456 to reflect a more recent genus name for the causative pathogen for swine dysentery. This action is being taken to improve the accuracy of the regulations.

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.

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.

§ 520.2456 [Amended]

■ 2. Section 520.2456 is amended in paragraph (b) by removing “*Sponsor. See 000010*” and by adding in its place “*Sponsors. See Nos. 000010 and 059130*”, and in paragraph (d)(2) by removing “*Treponema*” and by adding in its place “*Brachyspira*”.

Dated: July 11, 2005.

Linda Tollefson,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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