

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Tiamulin Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

Date	3-17-05
Publication Date	3-18-05
Director	L. CLAWSON
	DDM

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 soluble powder 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 a supplement to ANADA 200-344 that provides for use of Tiamulin Soluble Antibiotic to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia. Phoenix Scientific, Inc.'s Tiamulin Soluble Antibiotic is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s DENAGARD (tiamulin) Soluble Antibiotic approved under NADA 134-644. The ANADA is approved as of February 16, 2005, and the regulations are amended in 21 CFR 520.2455 to

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

FDA is also amending the regulations in 21 CFR 520.2455 to reflect a more recent genus name for the causative pathogen for swine dysentery and in the tables in 21 CFR 510.600(c) to reflect accepted style for the sponsor's street address. These actions are 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

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.

§ 510.600 [Amended]

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) in the entry for “Phoenix Scientific, Inc.” and in the table in paragraph (c)(2) in the entry for “059130” by removing “St. Terrace” and by adding in its place “Street Ter.”.

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.

§ 520.2455 [Amended]

■ 4. Section 520.2455 is amended in paragraph (b) by removing “*Sponsor*. See No. 000010” and by adding in its place “*Sponsors*. See Nos. 000010 and 059130”; and in paragraph (d)(1)(i) by removing “*Treponema*” and by adding in its place “*Brachyspira*”.

Dated: 3/9/05
March 9, 2005.

SFS/A

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

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