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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble 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 abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for an additional package size of oxytetracycline hydrochloride soluble powder to be used to make a medicated drinking water for chickens, turkeys, cattle, swine, and sheep for control and/or treatment of various bacterial diseases.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: William G. Marnane, Center for Veterinary Medicine (HFV-140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6966.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed supplemental ANADA 200-146 that provides for use of 6.4 ounce (181.5 gram (g)) packet of oxytetracycline hydrochloride soluble powder (10 g oxytetracycline hydrochloride per packet) for use in making medicated drinking water for chickens, turkeys, cattle, swine, and sheep for treatment and/or control of various bacterial diseases. The

supplemental ANADA is approved as of July 26, 1999, and the regulations are amended in 21 CFR 520.1660d(a)(7) to reflect the approval.

This supplemental ANADA concerns an additional packet size of product to be used as currently approved. The safety and effectiveness of the product does not change. A freedom of information summary as described in 21 CFR part 20 and 514.11(e)(2)(ii) 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:

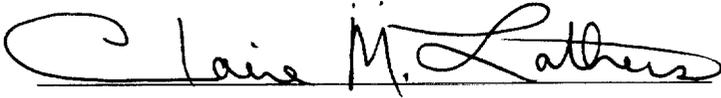
Authority: 21 U.S.C. 360b.

§ 520.1660d [Amended]

2. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraphs (a)(1) and (a)(2) by removing the semicolons at the end of the paragraphs and by adding periods

in their places, and in paragraph (a)(7) by adding at the beginning of the first parenthetical phrase the words "packet: 6.4 oz.;"

Dated: 8/24/99
August 24, 1999



Claire M. Lathers
Director
Office of New Animal Drug
Evaluation
Center for Veterinary
Medicine
[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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