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Display Date	3.17.99
Publication Date	3.18
Category	CWSMS-DAY

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for oral use of oxytetracycline hydrochloride soluble powder in the drinking water of chickens, turkeys, cattle, swine, and sheep for the treatment and control of various bacterial diseases.

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

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0212.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-247 that provides for use of oxytetracycline hydrochloride soluble powder (343 grams of oxytetracycline hydrochloride per pound) in the drinking water of chickens, turkeys, cattle, swine, and sheep for the treatment and control of various bacterial diseases.

Approval of Phoenix Scientific, Inc.'s ANADA 200-247 oxytetracycline hydrochloride soluble powder-343 is as a generic copy of Pfizer, Inc.'s NADA 8-622 Terramycin-343 (oxytetracycline soluble powder). ANADA 200-247 is approved as of February 10, 1999, and the regulations are

amended in § 520.1660d (21 CFR 520.1660d) by revising paragraph (a)(7) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, § 520.1660d is amended by removing paragraph (c) and redesignating paragraphs (d) and (e) as paragraphs (c) and (d).

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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.

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. Section 520.1660d is amended by revising paragraph (a)(7), by removing paragraph (c), and by redesignating paragraphs (d) and (e) as paragraphs (c) and (d) to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

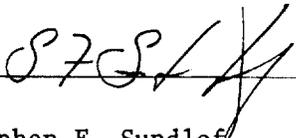
(a) * * *

(7) Each 18.1 grams of powder contains 1 gram of OTC HCl (pails: 2 and 5 lb), each 272.2 grams (9.6 oz) of powder contains 204.8 grams of OTC HCl, each 907.2 grams (2 lb) of powder contains 686 grams of OTC HCl, each 2.26 kilograms (5 lb) of powder contains 1,715 grams of OTC HCl.

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Dated: 2/26/99

February 26, 1999



Stephen F. Sundlof
Director, Center for Veterinary Medicine

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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