

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 520

**Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**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 Merial, Ltd. The supplemental ANADA provides for use of a larger package size of oxytetracycline hydrochloride soluble powder in the drinking water of chickens, turkeys, swine, cattle, 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:** Patricia D. Leinbach, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6965.

**SUPPLEMENTARY INFORMATION:** Merial, Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, filed supplemental ANADA 200-144 that provides for use of a larger package size of oxytetracycline hydrochloride soluble powder in the drinking water of chickens, turkeys, swine, cattle, and sheep for the treatment and control of various bacterial diseases. The supplemental ANADA is approved as of December 16, 1998, and the regulations are amended in 21 CFR 520.1660d(a) and (b) to reflect the approval.

Furthermore, the regulations had not been previously amended to reflect the sponsor change from Rhone Merieux Canada, Inc., to Merial, Ltd. The regulation in § 520.1660d(b) is amended at this time to reflect the sponsor change.

Approval of this supplemental ANADA does not require additional safety and effectiveness data. Therefore, a freedom of information summary for approval of this supplemental application 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.

**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 adding paragraphs (a)(9) and (b)(7), and by revising paragraph (b)(2) to read as follows:

**§ 520.1660d Oxytetracycline hydrochloride soluble powder.**

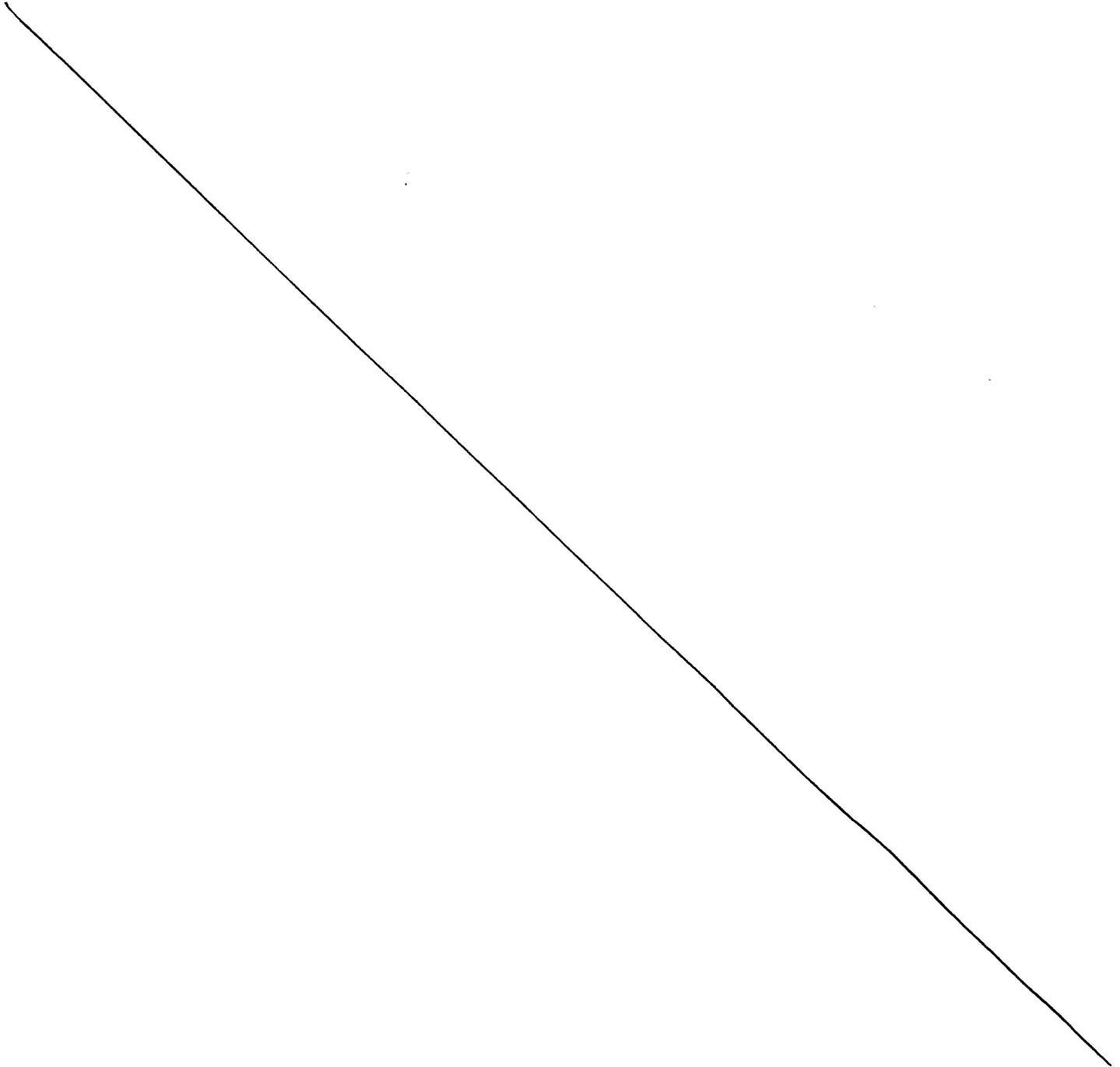
(a) \* \* \*

(9) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 9.87 and 19.75 oz; pails: 5 lb).

(b) \* \* \*

(2) No. 017144 for use of OTC HCl concentration in paragraph (a)(4) of this section in chickens, turkeys, and swine.

\* \* \* \* \*



(7) No. 050604 for use of OTC HCl concentration in paragraph (a)(9) of this section in chickens, turkeys, and swine.

\* \* \* \* \*

Dated: 2/24/99  
February 24, 1999

Woodrow M. Knight

Woodrow M. Knight  
Acting Director  
Office of New Animal Drug  
Evaluation  
Center for Veterinary Medicine

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

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*Obai Burdels*