

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

DMIB

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Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 Bimeda, Inc., that provides for a revised withdrawal time for use of oxytetracycline hydrochloride soluble powder in the drinking water of turkeys and swine. The regulations are also being amended to reflect approval of an additional pail size, which was approved under ANADA 200-144 on June 26, 1995; however, inadvertently this change has not yet been made in title 21 CFR. This document corrects that omission and improves the accuracy of the regulations.

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

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Bimeda, Inc., 288 County Rd. 28, LeSueur, MN 56058-9322, filed a supplement to ANADA 200-144 that provides for use of TETROXY® (oxytetracycline HCl) Soluble Powder for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental ANADA provides for a zero-day withdrawal time after the use of the product in the drinking water of turkeys and swine. The ANADA is approved as of September 17, 2001, and the regulations are amended in 21 CFR 520.1660d to reflect the approval.

Section 520.1660d is also being amended to reflect approval of a 3.09-pound pail size, which was approved under ANADA 200–144 on June 26, 1995.

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.

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

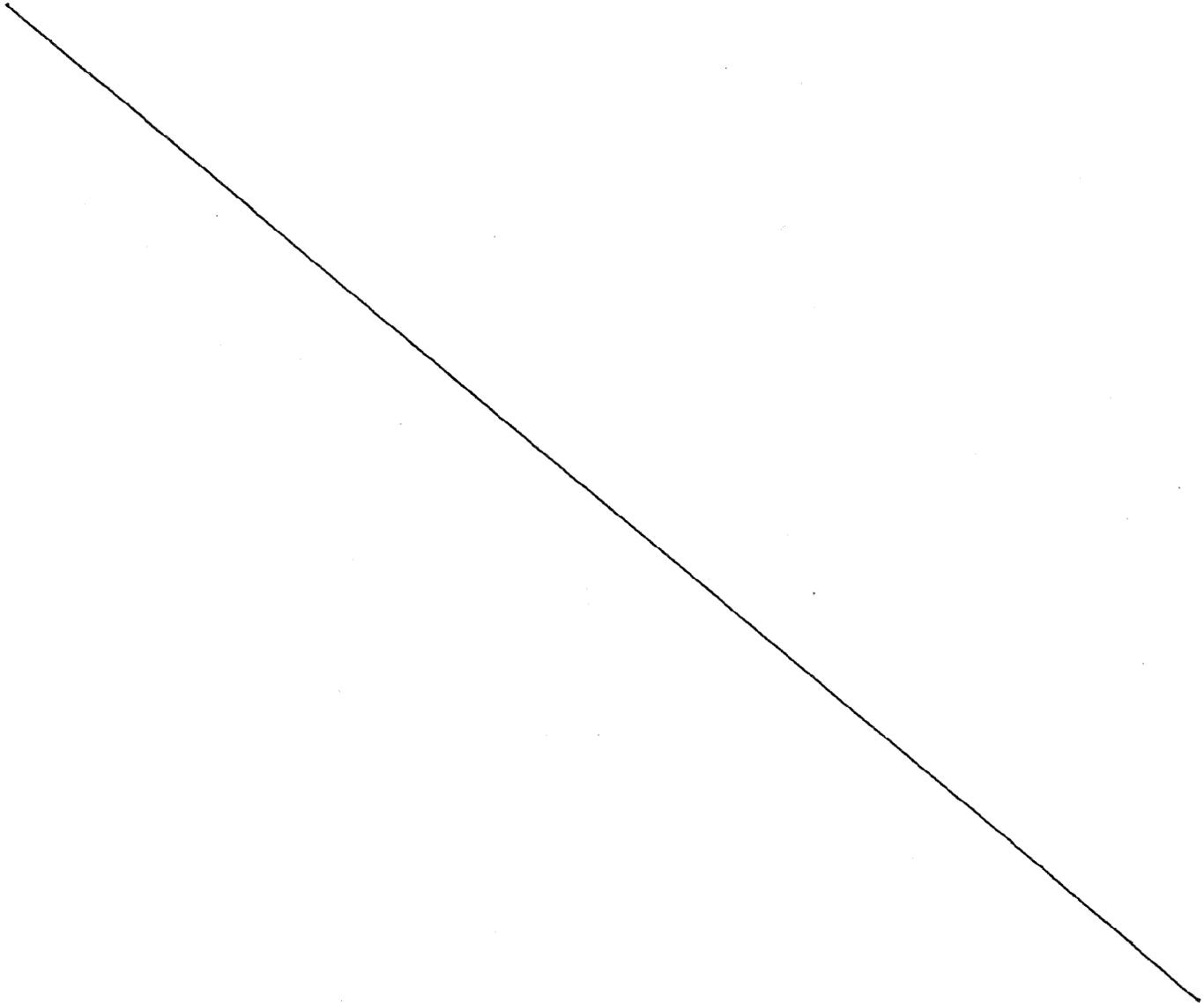
1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1660d [Amended]

2. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraph (a)(9) by adding “3.09 and ” after “pails:”; in paragraphs (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), and

(d)(1)(ii)(C)(3) by removing “and 053389” and by adding in its place “, 053389, and 061133”;
and in paragraph (d)(1)(iii)(C) by removing “No. 046573” and by adding in its place “Nos. 046573
and 061133.”



Dated: 11/08/01
November 8, 2001.

Claire M. Lathers

Claire M. Lathers,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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Suzette K. Reese