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**DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

**Food and Drug Administration**

**21 CFR Parts 520 and 558**

**Animal Drugs, Feeds, and Related Products; Chlortetracycline Powder, Etc.;**  
**Technical Amendments**

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

**ACTION:** Final rule; technical amendments.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to correct errors concerning the sponsor of oral chlortetracycline powder, oral tetracycline powder, and interim use of certain medicated feeds. The amendments are required because the regulations did not reflect a change of sponsor from Fermenta Animal Health to Boehringer Ingelheim Vetmedica.

**EFFECTIVE DATE:** *(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:** In the **Federal Register** of June 30, 1997 (62 FR 35075 through 35077), FDA published a document reflecting the change of sponsor of several new animal drug applications from Fermenta Animal Health Co. to Boehringer Ingelheim Vetmedica, Inc. (at that time known as Boehringer Ingelheim Animal Health, Inc.). In 21 CFR 520.445b(d)(4)(iii)(C) and 520.2345d(a)(1) the regulations failed to reflect the change from "054273" to "000010". Also, in 21 CFR 558.15(g)(1) and (g)(2), the regulation failed to reflect the change from "Fermenta Animal Health" to "Boehringer Ingelheim Vetmedica." At this time, the regulations in 21 CFR parts 520 and 558 are amended to reflect the change of sponsor.

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 520*

Animal drugs.

#### *21 CFR Part 558*

Animal drugs, Animal feeds.

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 520 and 558 are 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.

#### **§ 520.445b [Amended]**

2. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraph (d)(4)(iii)(C) by removing “012286, 053389, and 054273” and adding in its place “000010, 012286, and 053389”.

#### **§ 520.2345d [Amended]**

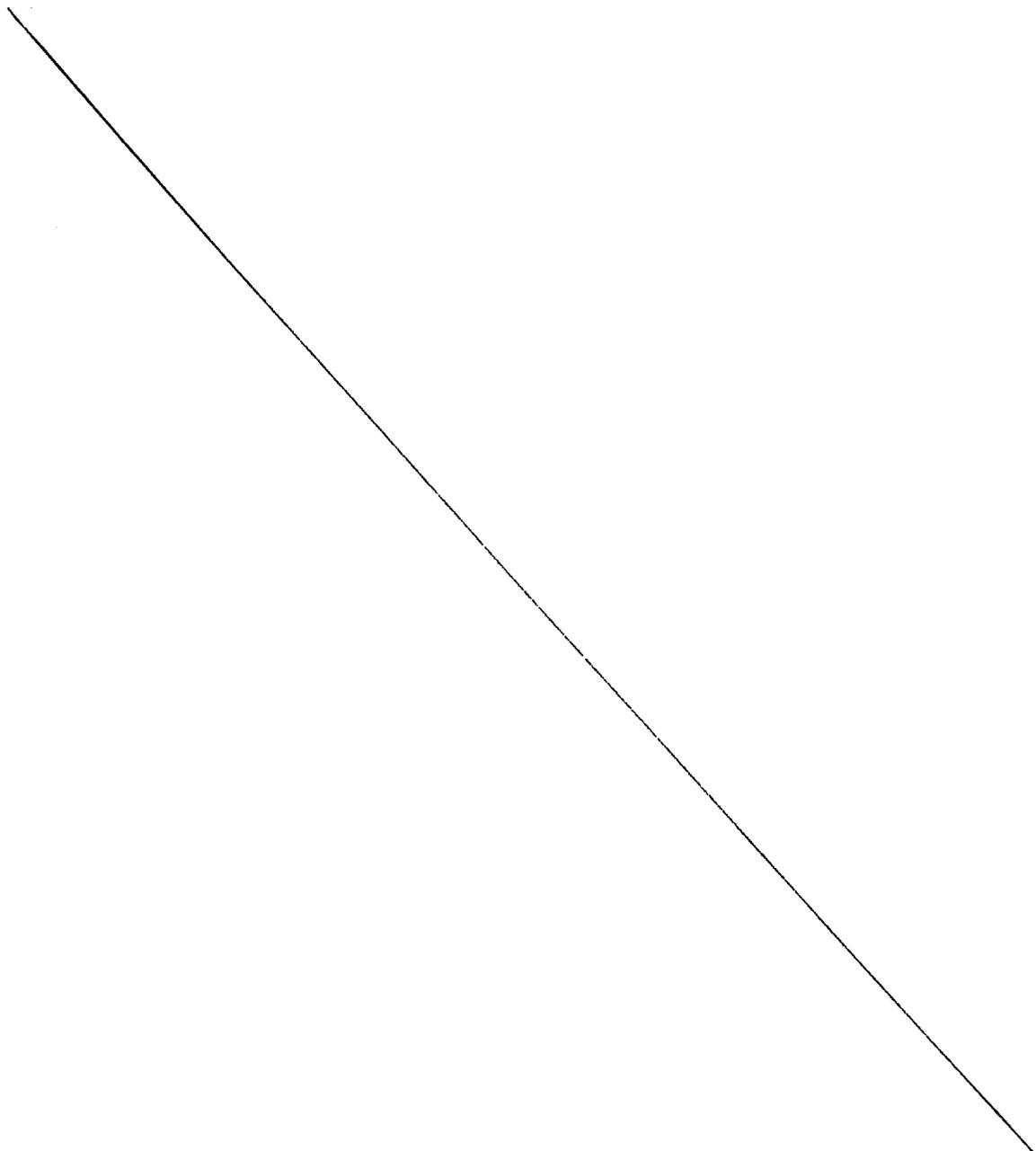
3. Section 520.2345d *Tetracycline hydrochloride soluble powder* is amended in paragraph (a)(1) by removing “054273,” and adding “000010,” before “046573”.

**PART 558— NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

4. The authority citation for 21 CFR part 558 continues to read as follows:

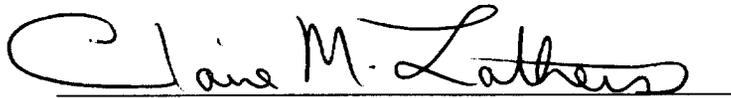
**Authority:** 21 U.S.C. 360b, 371.

**§ 558.15 [Amended]**



5. Section 558.15 *Antibiotic, nitrofurans, and sulfonamide drugs in the feed of animals* is amended in paragraphs (g)(1) and (g)(2) by removing “Fermenta Animal Health Co.” and adding in its place “Boehringer Ingelheim Vetmedica, Inc.”

Dated: 6/28/99  
June 28, 1999



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Office of New Animal Drug Evaluation  
Center for Veterinary Medicine

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