

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DWB

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21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Tiamulin and Chlortetracycline

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 new animal drug application (NADA) filed by Boehringer Ingelheim Vetmedica, Inc. The supplemental NADA provides for an additional source of chlortetracycline (CTC) Type A medicated articles used to make Type B and C medicated swine feeds containing tiamulin and CTC.

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 Pi., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc. (BIV), 2621 North Belt Hwy., St. Joseph, MO 64506-2002, has filed supplemental NADA 141-011 that provides for using an additional source of CTC Type A medicated articles (Pennfield Oil Co.'s Pennchlor®) for the feed-mixed combination use with tiamulin Type A medicated articles (BIV's Denagard®) to make tiamulin/CTC Type B or C medicated swine feeds for use as described in § 558.600(c)(4) (21 CFR 558.600(c)(4)). The supplemental NADA is approved as of August 6, 1998, and the regulations are amended in § 558.600(c)(4)(ii) to reflect the approval.

Approval of this supplemental NADA does not require additional safety or effectiveness data. A freedom of information summary as provided under 21 CFR part 20 and 514.110 is not required.

The agency has determined under 21 CFR 25.33(a)(3) 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 558

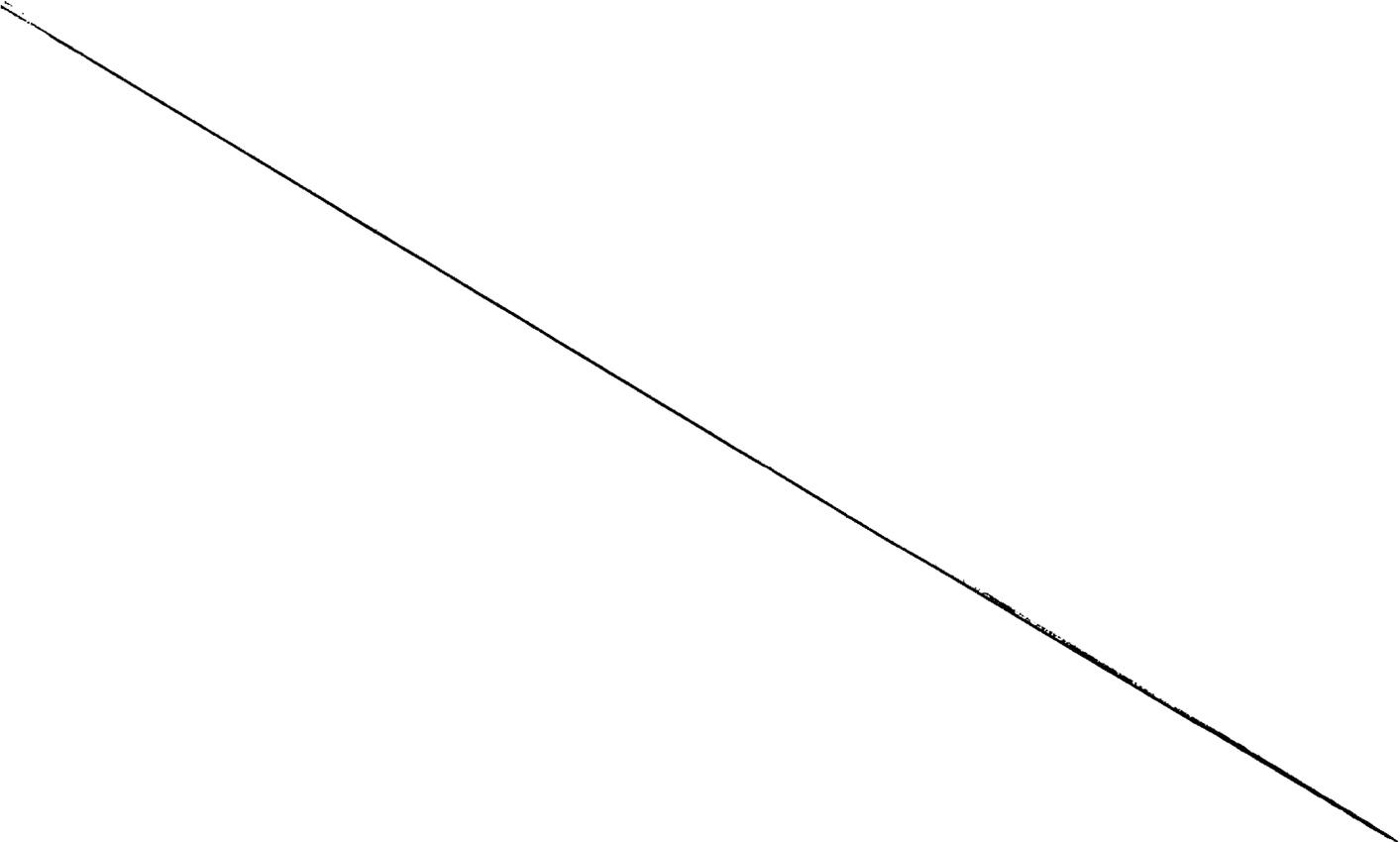
Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558-NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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



§ 558.600 [Amended]

2. Section **558.600 Tiamulin** is amended in paragraph (c)(4)(ii) by removing ‘ ‘046573 and 063238” and adding in its place “046573, 053389, and 063238”.

Dated: Sept 20, 1998

September 20, 1998

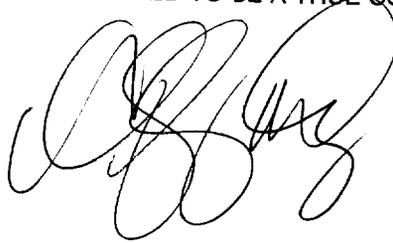
Margaret Ann Miller

Margaret Ann Miller
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

A large, stylized handwritten signature in black ink, appearing to be the signature of Margaret Ann Miller, is written over the certification text.