

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

#### New Animal Drugs for Use in Animal Feeds; Tiamulin and Chlortetracycline

**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 an abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. The ANADA provides for the use of single-ingredient Type A medicated articles containing tiamulin hydrogen fumarate and chlortetracycline hydrochloride to make two-way combination drug Type B and Type C medicated feeds for swine.

**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 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed ANADA 200-356 for use of PENNCHLOR (chlortetracycline hydrochloride) and DENAGARD (tiamulin hydrogen fumarate) Type A medicated articles to make two-way combination drug Type B and Type C medicated feeds for swine. Pennfield Oil Co.'s ANADA 200-356 is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s NADA 141-011. The ANADA is approved as of April 6, 2004, and the regulations are amended

in 21 CFR 558.600 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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 Division of Dockets Management (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)(2) 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 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 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 is amended in the table in paragraph (e)(1)(iii) in the “Sponsor” column by numerically adding “ 053389”.

Dated: May 18, 2004.

**Andrew J. Beaulieu,**

*Acting Director, Center for Veterinary Medicine.*

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