

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

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Food and Drug Administration

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 Pennfield Oil Co. The supplemental ANADA provides for a zero-day preslaughter withdrawal time for use of oxytetracycline hydrochloride (HCl) soluble powder in the drinking water of 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-101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed a supplement to ANADA 200-026 that provides for use of PENNOX 343 (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 preslaughter withdrawal time after the use of the product in the drinking water of swine. The supplemental ANADA is approved as of April 10, 2002, and 21 CFR 520.1660d is amended 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 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support

cv01103

**ANADA 200-026**

**NAR-1**

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 had 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 Subject in 21 CFR Part 520**

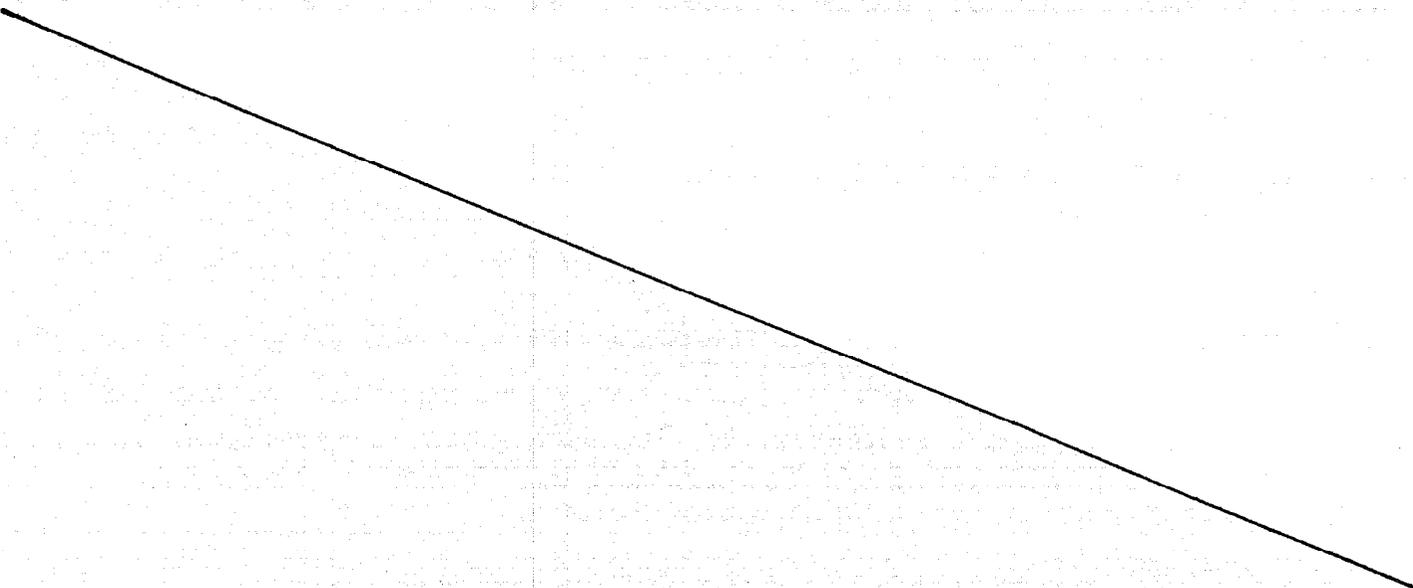
Animal drugs.

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 revising the last sentence in paragraph (d)(1)(iii)(C) to read as follows:

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

\* \* \* \* \*

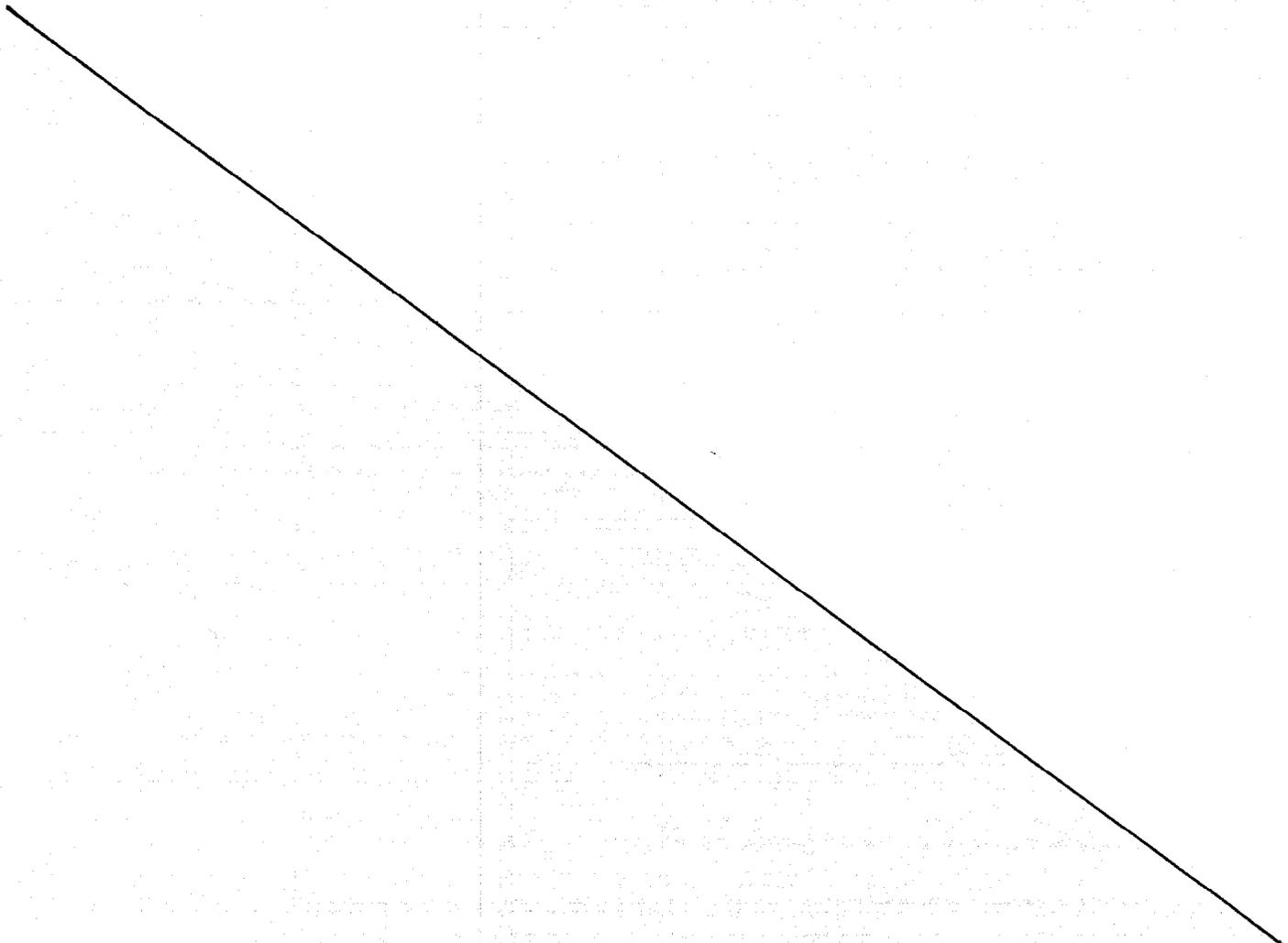
(d) \* \* \*

(1) \* \* \*

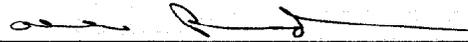
(iii) \* \* \*

(C) \* \* \* Administer up to 5 days; do not use for more than 5 consecutive days; withdraw zero days prior to slaughter those products sponsored by Nos. 046573, 053389, 057561, and 061133.

\* \* \* \* \*



Dated: July 17, 2002.

 7/17/02

Alan Rudman,  
Acting Director,  
Office of New Animal Drug Evaluation,  
Center for Veterinary Medicine.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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