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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Levamisole Powder

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of levamisole hydrochloride soluble powder in the drinking water of swine for the treatment of various internal parasites.

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: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, St. Joseph, MO 64503, filed ANADA 200-313 for Levamisole Hydrochloride Soluble Pig Wormer used to make medicated drinking water for the treatment of various internal parasites. Phoenix Scientific, Inc.'s Levamisole Hydrochloride Soluble Pig Wormer is approved as a generic copy of Schering-Plough Animal Health's TRAMISOL (levamisole hydrochloride) Soluble Pig Wormer, approved under NADA 112-049. The ANADA is approved as of October 25, 2002, and the regulations are amended in 21 CFR

cv0273

ANADA 200-313

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520.1242a 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 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:

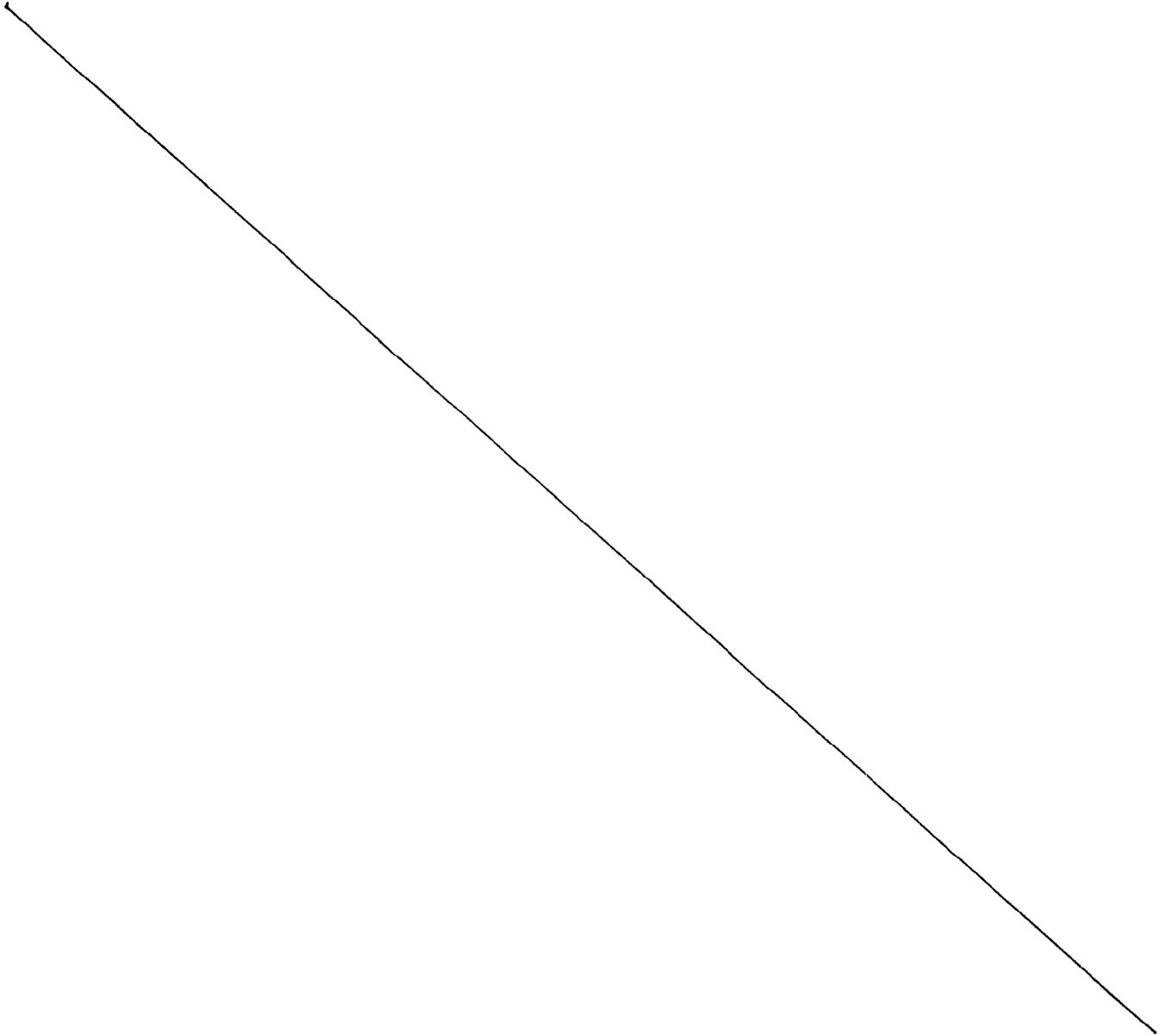
Authority: 21 U.S.C. 360b.

2. Section 520.1242a is amended by adding paragraph (b)(4) to read as follows:

§ 520.1242a Levamisole hydrochloride drench and drinking water.

* * * * *

(b) * * *



(4) See No. 059130 for use of 18.15-gram packages as in paragraph (d)(3) of this section.

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Dated: 1/6/03
January 6, 2003.

S F Sundlof

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.
[FR Doc. 03-00000 Filed 01-06-03; 8:45 am]

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COPY OF THE ORIGINAL

[Signature]