

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Paste

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 ivermectin oral paste for the treatment and control of various species of harmful gastrointestinal parasites in horses.

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-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-286 that provides for use of PHOENECTIN™ (ivermectin) Paste 1.87%. The ANADA provides for oral use of ivermectin paste for the treatment and control of various species of harmful gastrointestinal parasites in horses. The ANADA is approved as a generic copy of Merial Ltd.'s NADA 134-314 for EQVALAN® (ivermectin) Paste for Horses. ANADA 200-286 is approved as of September 20, 2000, and the regulations are amended in 21 CFR 520.1192 to reflect the approval. The basis for 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

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 520.1192 is amended by revising paragraphs (a) and (b), by redesignating paragraph (c) as paragraph (d), and by adding new paragraph (c) to read as follows.

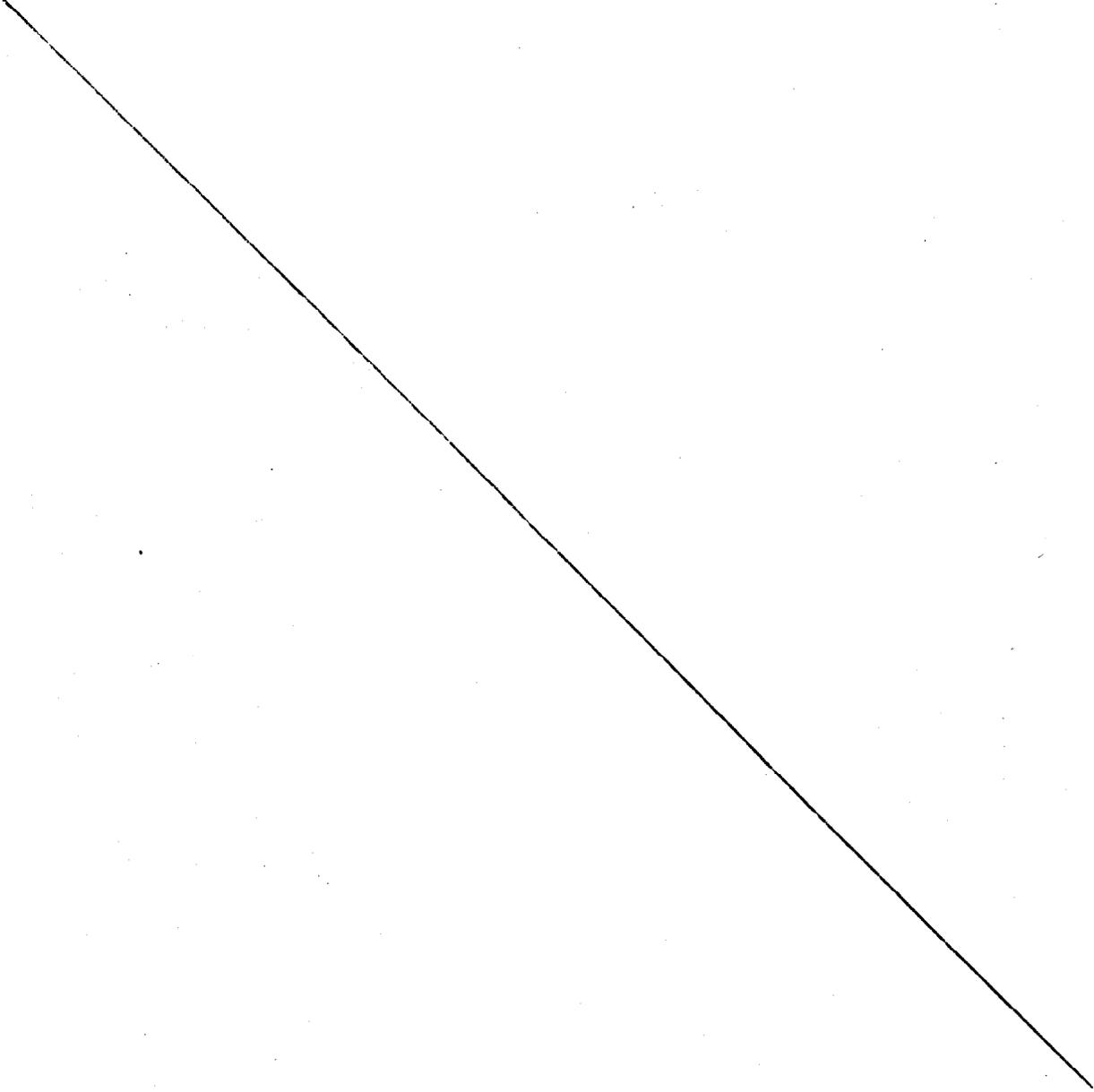
§ 520.1192 Ivermectin paste.

(a) *Specifications.* Each milligram of paste contains 0.0187 milligram (1.87 percent) or 0.00153 milligram (0.153 percent) of ivermectin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter, as follows:

(1) No. 050604 for use of a 1.87 percent paste as in paragraph (d)(1) of this section and a 0.153 percent paste as in paragraph (d)(2) of this section.

(2) No. 059130 for use of a 1.87 percent paste as in paragraph (d)(1) of this section.



(c) *Related tolerances.* See § 556.344 of this chapter.

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Dated: 10/16/00
October 16, 2000

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Stephen F. Sundlof
Director
Center for Veterinary Medicine

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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