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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 12-13-04
Publication Date 12-14-04
Certifier [Signature]

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Furosemide

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

2010 MAR 18 09:17 AM '07

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 veterinary prescription use of furosemide syrup in dogs by oral administration for treatment of edema associated with cardiac insufficiency and acute noninflammatory tissue edema.

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: *lonnie.luther@fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Ter., St. Joseph, MO 64503, filed ANADA 200-382 for veterinary prescription use of Furosemide Syrup 1% in dogs by oral administration for treatment of edema associated with cardiac insufficiency and acute noninflammatory tissue edema. Phoenix Scientific's Furosemide Syrup 1% is approved as a generic copy of Intervet, Inc.'s LASIX (furosemide) Syrup 1%, approved under NADA 102-380. The ANADA is approved as of November 18, 2004, and the regulations

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200-382

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are amended in 21 CFR 520.1010 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.

FDA 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 520.1010 is amended by adding paragraph (b)(4) to read as follows:

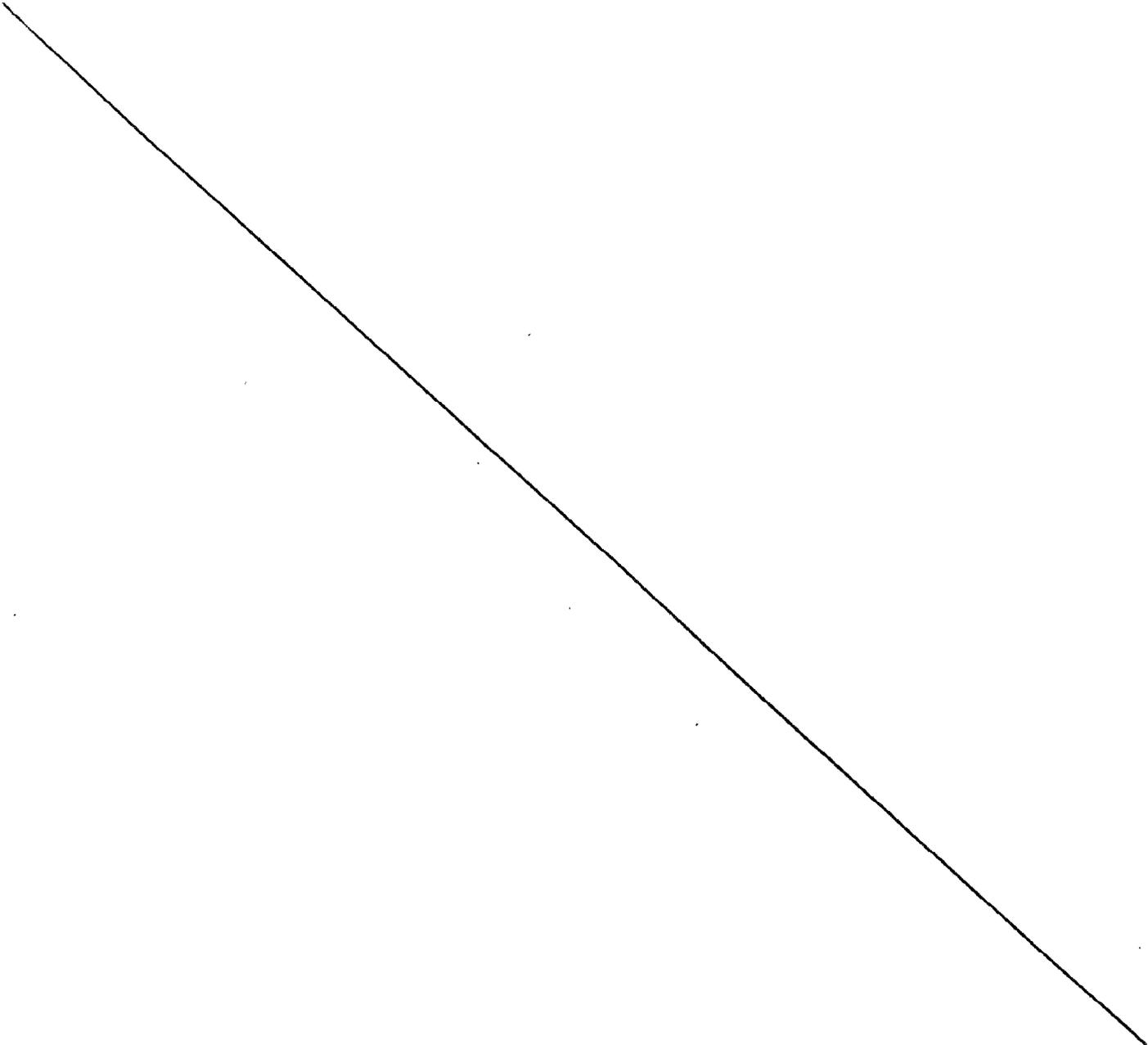
§ 520.1010 Furosemide.

* * * * *

(b) * * *

(4) No. 059130 for use of syrup in paragraph (a)(4) of this section for conditions of use in paragraph (d)(2)(i) and (d)(2)(ii)(A) of this section.

* * * * *



Dated: 12/6/04
December 6, 2004.

SF SJA

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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