4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2011-N-0003]

Oral Dosage Form New Animal Drugs; Phenylpropanolamine

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 original new animal drug application (NADA) filed by Pegasus Laboratories, Inc. The NADA provides for the veterinary prescription use of phenylpropanolamine hydrochloride chewable tablets for the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

Lisa M. Troutman,

Center for Veterinary Medicine (HFV-116),

Food and Drug Administration,

7500 Standish Pl.,

Rockville, MD 20855,

240-276-8322,

email: lisa.troutman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514, filed NADA 141-324 that provides for the veterinary prescription use of PROIN (phenylpropanolamine hydrochloride) Chewable Tablets for the control of urinary incontinence due to urethral sphincter hypotonus in dogs. The NADA is approved as of August 4, 2011, and the regulations are amended in 21 CFR part 520 to reflect the approval.

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 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning on the date of approval.

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. Add § 520.1760 to read as follows:

§ 520.1760 Phenylpropanolamine.

(a) Specifications. Each chewable tablet contains 25, 50, or 75 milligram (mg) phenylpropanolamine hydrochloride.

(b) Sponsors. See No. 055246 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs--(1) Amount. Administer 2 mg/kg of body weight twice daily.

(2) Indications for use. For the control of urinary incontinence due to urethral sphincter hypotonus in dogs.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: March 14, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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