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; Pergolide

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 Boehringer Ingelheim Vetmedica, Inc. The NADA provides for the veterinary prescription use of pergolide mesylate tablets in horses for the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease).

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

FOR FURTHER INFORMATION CONTACT:

Amy L. Omer,

Center for Veterinary Medicine (HFV-114),

Food and Drug Administration,

7500 Standish Pl.,

Rockville, MD 20855,

240-276-8336,

email: amy.omer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002, filed NADA 141-331 for the veterinary prescription use in horses of PRASCEND (pergolide mesylate) Tablets for the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease). The NADA is approved as of September 7, 2011, and 21 CFR part 520 is amended to reflect the approval.

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.

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.

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.

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 § 520.1705 to read as follows:

§ 520.1705 Pergolide.

(a) Specifications. Each tablet contains 1 milligram (mg) pergolide mesylate.

(b) Sponsor. See No. 000010 in § 510.600(c) of this chapter.

(c) Conditions of use in horses--(1) Amount. Administer orally at a starting dose of 2 micrograms/kilograms (µg/kg) once daily. Dosage may be adjusted to effect, not to exceed 4 µg/kg daily.

(2) Indications for use. For the control of clinical signs associated with Pituitary Pars Intermedia Dysfunction (Equine Cushing's Disease).

(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.

[FR Doc. 2012-6544 Filed 03/16/2012 at 8:45 am; Publication Date: 03/19/2012]