

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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Oral Dosage Form New Animal Drugs; Ponazuril

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 a new animal drug application (NADA) filed by Bayer Corp., Agriculture Division, Animal Health. The NADA provides for veterinary prescription use of ponazuril paste for the treatment of protozoal myeloencephalitis in horses.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540.

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed NADA 141-188 that provides for veterinary prescription use of Marquis™ (ponazuril) EPM Paste for the treatment of equine protozoal myeloencephalitis caused by *Sarcocystis neurona*. The NADA is approved as of July 19, 2001, and the regulations are amended in 21 CFR part 520 by adding § 520.1855 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 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.

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Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning July 19, 2001, because no active ingredient (including any ester or salt of the drug) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(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 520.1855 is added to read as follows:

§ 520.1855 Ponazuril.

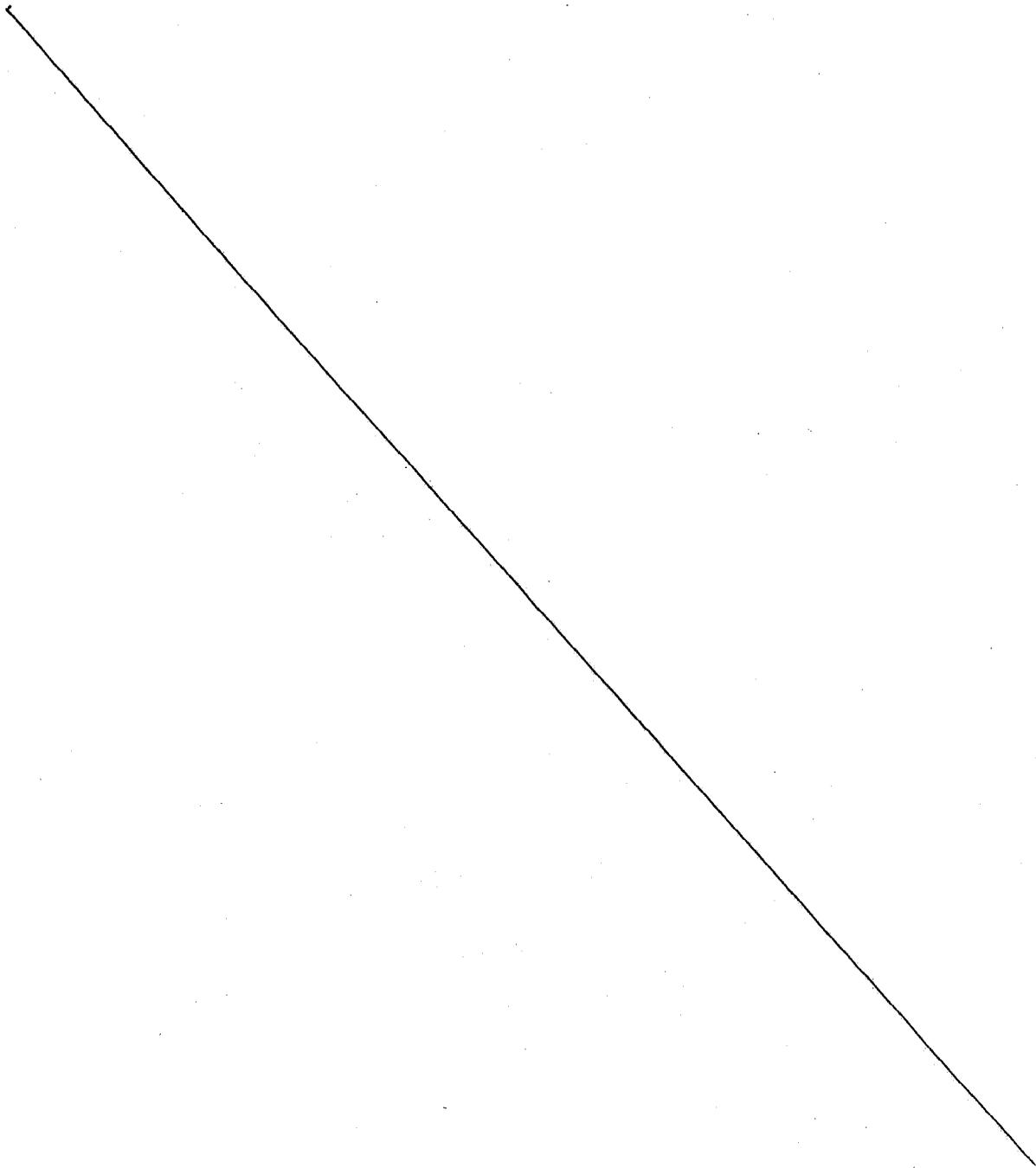
(a) *Specifications.* Each gram of paste contains 150 milligrams (mg) ponazuril.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* 5 mg per kilogram body weight, daily for 28 days.

(2) *Indications for use.* For the treatment of equine protozoal myeloencephalitis caused by *Sarcocystis neurona*.

(3) *Limitations.* Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.



Dated: 8/1/01

August 1, 2001.

L Tollefson

Linda Tollefson,
Deputy Director,

~~Office of New Animal Drug Evaluation,~~

Center for Veterinary Medicine,

[FR Doc. 01-~~????~~ Filed ~~??-??-01~~; 8:45 am]

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