

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Dms
Display Date 7-18-02
Publication Date 7-19-02
Certifier G. Bradley

Oral Dosage Form New Animal Drugs; Fenbendazole Granules

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 supplemental new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA provides for change from prescription to over-the-counter marketing status for the oral use in dogs of fenbendazole granules for removal of certain internal parasites.

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, mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed a supplement to NADA 121-473 that provides for oral use in dogs of PANACUR-C (fenbendazole) Granules 22.2% for removal of certain internal parasites. The supplemental NADA provides for change from prescription to over-the-counter marketing status. The supplemental NADA is approved as of March 19, 2002, and the regulations are amended in 21 CFR 520.905b to reflect the approval. The basis of approval is discussed in the freedom of information summary. Section 520.905b is also being revised to reflect a current format.

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

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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(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 520.905b is amended by redesignating paragraph (c) as paragraph (d); by adding new paragraph (c); by removing the last sentence in paragraphs (d)(1)(iii) and (d)(2)(iii); by revising paragraphs (a), ^{and newly designated} (d)(1)(i), (d)(2)(i), and (d)(3)(i) to read as follows:

§ 520.905b Fenbendazole granules.

(a) *Specifications.* Each gram of granules contains 222 milligrams (mg) fenbendazole.

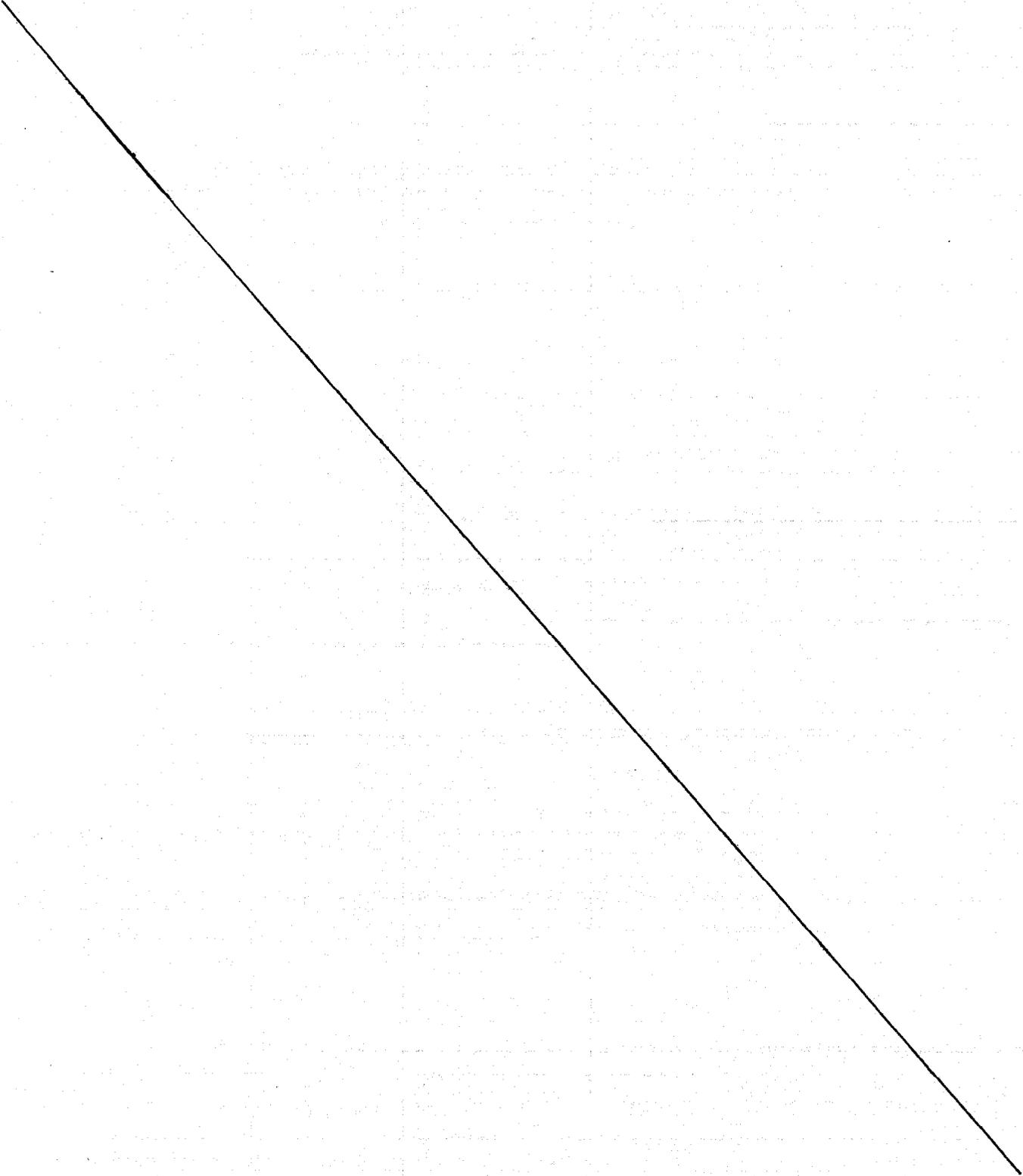
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(c) *Special considerations.* See § 500.25 of this chapter.

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(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 5 mg/kilogram (kg) for large strongyles, small strongyles, and pinworms; 10 mg/kg for ascarids.

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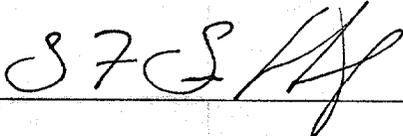
(2) *Dogs*—(i) *Amount*. 50 mg/kg daily for 3 consecutive days.

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(3) *Zoo and wildlife animals*—(i) *Amount*. 10 mg/kg per day for 3 days.

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Dated: 7/8/02
July 8, 2002.



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

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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