

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Submission Date	4-13-06
Publication Date	9-14-06
Control No.	L. CLAWSON
	DDM

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 minor changes to the labeling of over-the-counter fenbendazole granules, used for the treatment and control of certain internal parasites in dogs.

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, e-mail: *melanie.berson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed a supplement to NADA 121-473 that provides for over-the-counter use in dogs of SAFE-GUARD (fenbendazole) Canine, orally administered granules used for the treatment and control of certain internal parasites. The supplemental NADA provides for minor changes to product labeling. The supplemental NADA is approved as of March 17, 2006, and the regulations are amended in 21 CFR 520.905b to reflect the approval.

cv0620

NADA 121.473

NFR5

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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.

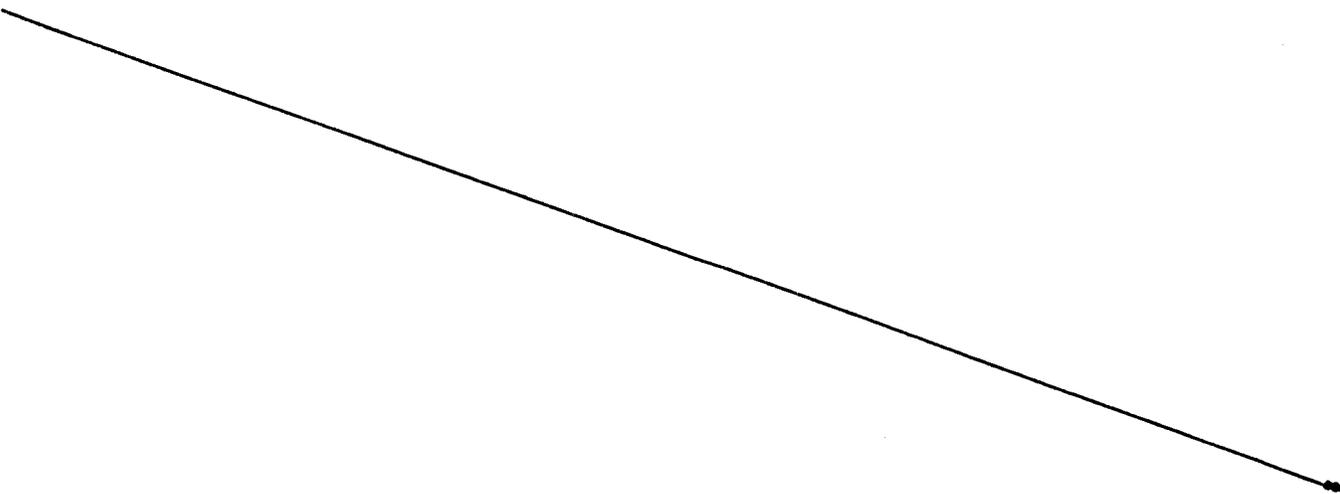
■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

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.

§ 520.905b [Amended]



■ 2. In paragraph (d)(2)(ii) of § 520.905b, remove the word “removal” and add, in its place, the words “treatment and control”.

Dated: April 6, 2006
April 6, 2006.

Steven D. Vaughn

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

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