

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

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Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Fenbendazole Suspension

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 a change to over-the-counter marketing status for the oral use of fenbendazole suspension in goats for removal and control of stomach worms.

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

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; 301-827-7578; e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed a supplement to NADA 128-620 for the oral use of SAFE-GUARD (fenbendazole) Suspension 10% in goats for removal and control of stomach worms. The supplemental NADA is approved as of February 13, 2003, and the regulations are amended in 21 CFR 520.905a 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 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 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.

FDA has determined under 21 CFR 25.33(a)(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 520.905a is amended by revising paragraph (d)(4)(ii) and in paragraph (d)(4)(iii) by removing the last sentence to read as follows:

§ 520.905a Febendazole suspension.

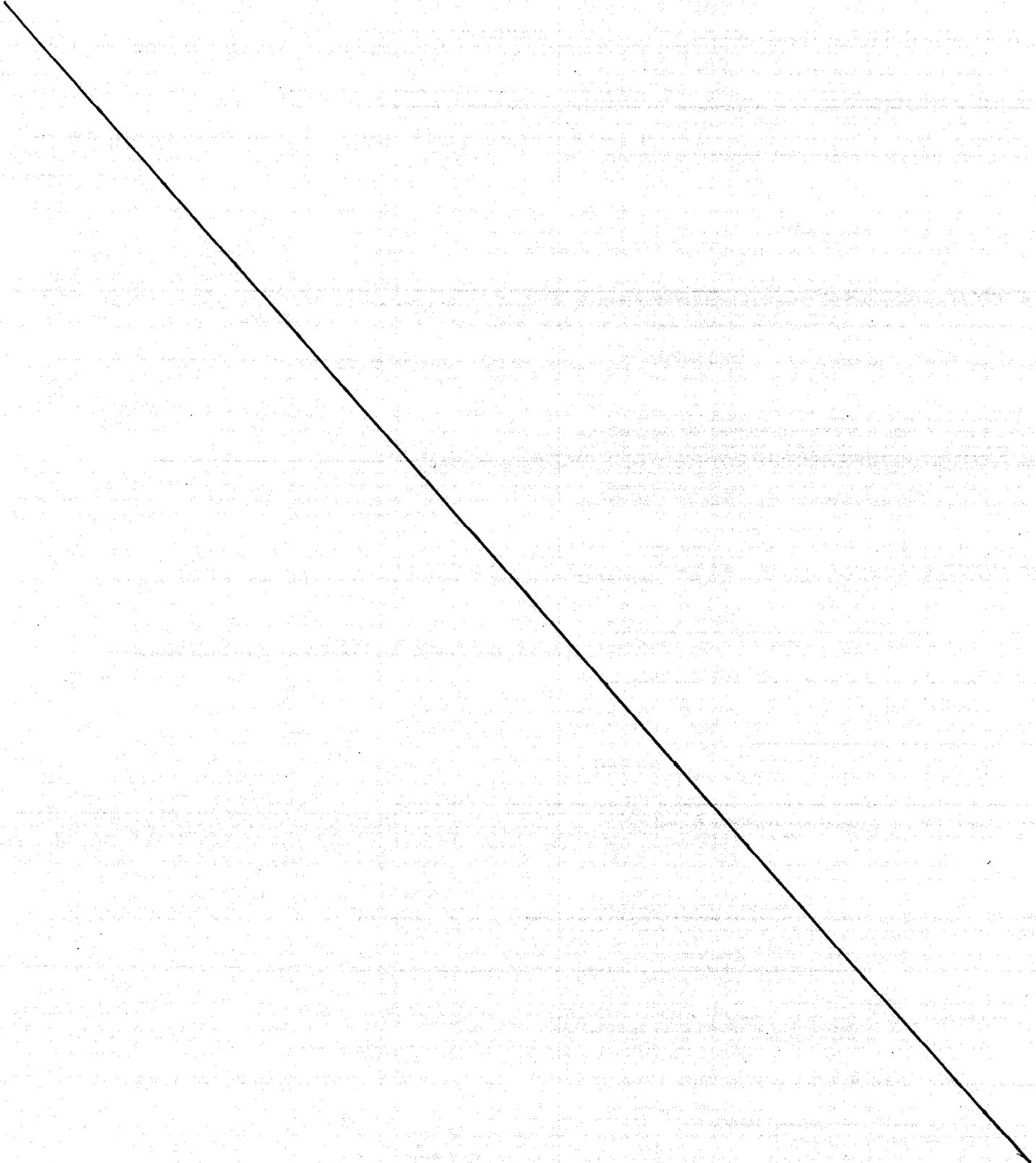
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(d) * * *

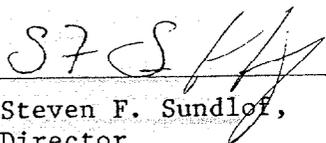
(4) * * *

(ii) *Indications for use.* For the removal and control of stomach worms
(adults) *Haemonchus contortus* and *Teladorsagia circumcincta*.

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Dated: 4/30/03
April 30, 2003.



Steven F. Sundlor,
Director,
Center for Veterinary Medicine.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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