

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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Certifier A. Corbin

**Oral Dosage Form New Animal Drugs; Fenbendazole Paste**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADAs) filed by Intervet, Inc. The supplemental NADAs provide for a revised human food safety warning for fenbendazole paste, used for the control of various internal parasites in horses and cattle.

**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](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Intervet, Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed a supplement to NADA 120-648 that provides for use of PANACUR (fenbendazole) Paste in horses for the control of various internal parasites, and to NADA 132-872 that provides for use of SAFE-GUARD (fenbendazole) Paste in cattle for the control of various internal parasites. The supplemental NADAs provide for a revised human food safety warning on product labeling. The supplemental NADAs are approved as of February 8, 2007, and the regulations are amended in 21 CFR 520.905c to reflect the approval and a current format.

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

FDA 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 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.

■ 2. Amend § 520.905c as follows:

- a. Revise paragraph (a);
- b. Redesignate paragraph (d) as paragraph (e);
- c. Add new paragraph (d); and
- d. Revise newly redesignated paragraph (e).

The revisions, redesignation, and addition read as follows:

§ 520.905c Fenbendazole paste.

(a) *Specifications.* Each gram of paste contains 100 milligrams (mg) fenbendazole (10 percent).

\* \* \* \* \*

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

(e) *Conditions of use*—(1) *Horses*—(i) *Indications for use and amounts*—

(A) For control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*): 2.3 mg per pound (/lb) of body weight, or for foals and weanlings (less than 18 months of age), 4.6 mg/lb of body weight. Retreatment at intervals of 6 to 8 weeks may be required.

(B) For control of arteritis caused by the fourth-stage larvae of *S. vulgaris*: 4.6 mg/lb of body weight daily for 5 days. Treatment should be initiated in the spring and repeated in 6 months.

(C) For treatment of encysted mucosal cyathostome (small strongyle) larvae including early third-stage (hypobiotic), late third-stage, and fourth-stage larvae: 4.6 mg/lb of body weight daily for 5 consecutive days.

(D) Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in paragraph (e)(1)(i)(A) of this section and for treating infections of stomach bots as provided in § 520.2520.

(ii) *Limitations.* Do not use in horses intended for human consumption.

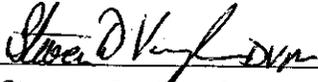
(2) *Cattle*—(i) *Amount.* 2.3 mg/lb of body weight. Re-treatment may be needed after 4 to 6 weeks.

(ii) *Indications for use.* For the removal and control of lungworms (*Dictyocaulus viviparus*), stomach worms (*Haemonchus contortus*, *Ostertagia ostertagi*, *Trichostrongylus axei*), and intestinal worms (*Bunostomum*

*phlebotomum*, *Nematodirus helvetianus*, *Cooperia punctata*, *C. oncophora*, *Trichostrongylus colubriformis*, and *Oesophagostomum radiatum*).

(iii) *Limitations*. Cattle must not be slaughtered within 8 days following last treatment.

Dated: February 28, 2007  
February 28, 2007.



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