

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DMB  
Display Date 6-9-03  
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Certifier N. Hawkins

**New Animal Drugs for Use in Animal Feeds; Fenbendazole.**

**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 a supplemental new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA provides for use of an approved fenbendazole Type A medicated article to make Type B and Type C medicated feeds used for the control of gastrointestinal worms 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, e-mail: mberson@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed a supplement to NADA 131-675 that provides for the use of SAFE-GUARD (fenbendazole) 20% Type A medicated article to make Type B and Type C medicated horse feeds. The medicated feeds are used for the control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*, *Triodontophorus* spp.), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*) in horses. The NADA is approved as of March 14, 2003, and the

regulations are amended in 21 CFR 558.258 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning March 14, 2003.

The agency has determined under § 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 558**

Animal drugs, Animal feeds.

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 558 is amended as follows:

#### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.258 is amended by redesignating paragraph (e)(4) as paragraph (e)(5) and by adding new paragraph (e)(4) to read as follows:

§ 558.258 Fenbendazole.

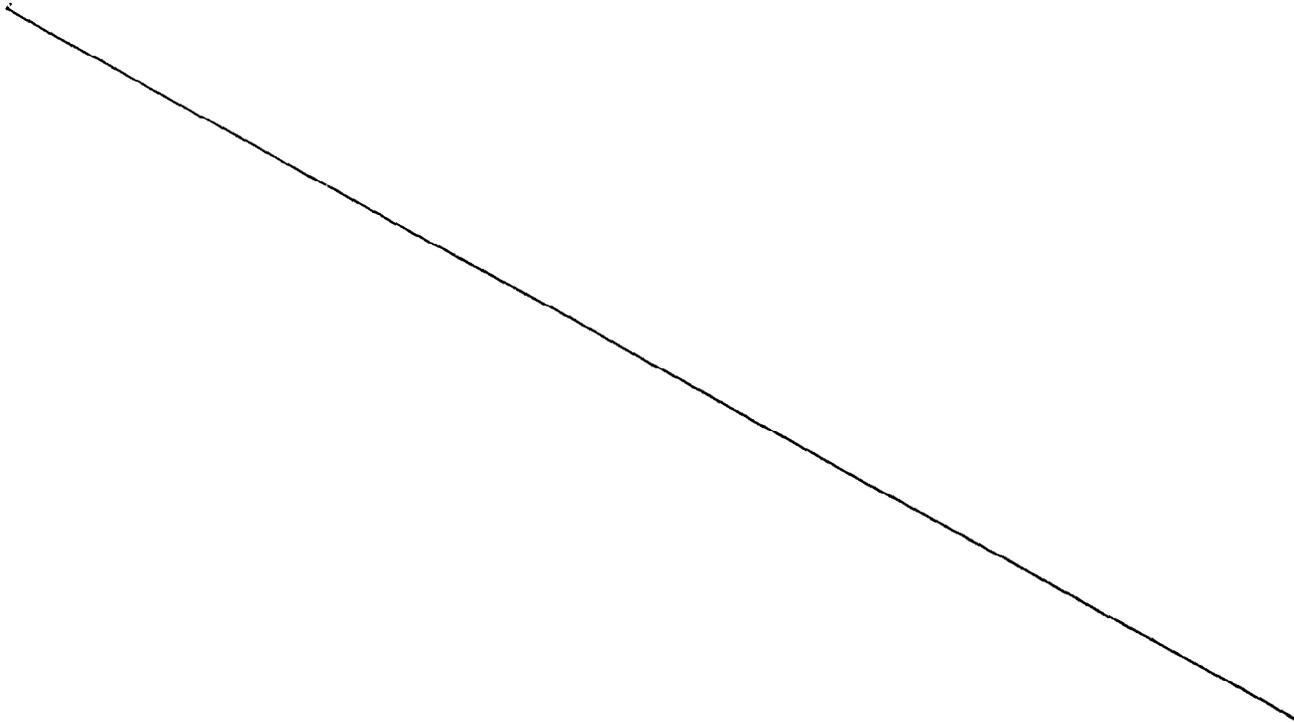
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(e) \* \* \*

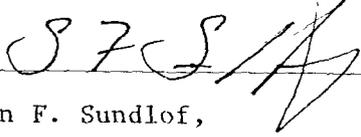
(4) Horses.

Amount fenbendazole in grams per ton	Indications for use	Limitations	Sponsor
(i) 4,540	5 mg/kg body weight (2.27 mg/lb) for the control of large strongyles ( <i>Strongylus edentatus</i> , <i>S. equinus</i> , <i>S. vulgaris</i> , <i>Triodontophorus</i> spp.), small strongyles ( <i>Cyathostomum</i> spp., <i>Cylicocycclus</i> spp., <i>Cylicostephanus</i> spp.), and pinworms ( <i>Oxyuris equi</i> ); 10 mg/kg body weight (4.54 mg/lb) for the control of ascarids ( <i>Parascaris equorum</i> ).	Feed at the rate of 0. 1lb of feed per 100 lb of body weight to provide 2.27 mg fenbendazole/lb of body weight in a 1-day treatment or 0.2 lb of feed per 100 lb of body weight to provide 4.54 mg fenbendazole/lb of body weight in a 1-day treatment. All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed. Regular deworming at intervals of 6 to 8 weeks may be required due to the possibility of reinfection. Do not use in horses intended for food.	057926
(ii) [Reserved]			

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Dated: 5/27/03  
May 27, 2003.



Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.  
[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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Dawn P. Hawkins