

DMS

Display Date	8/21/00
Publication Date	8/22/00
Certifier	Jan Windsor

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 556 and 558**

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

**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 Hoechst Roussel Vet. 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 removal and control of gastrointestinal worms in growing turkeys. Also, tolerances for fenbendazole residues in turkey liver and muscle are being established.

**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-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

**SUPPLEMENTARY INFORMATION:** Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809-4010, 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 feeds for cattle, swine, and zoo and wildlife animals. The supplemental NADA provides for the use of the approved fenbendazole Type A medicated article to make Type B and Type C medicated feeds used for the removal and control of gastrointestinal worms: Round worms, adult and larvae (*Ascaridia dissimilis*) and cecal worms, adult and larvae (*Heterakis gallinarum*),

an important vector of *Histomonas meleagridis* (Blackhead) in growing turkeys. Also, tolerances for fenbendazole sulfone in turkey liver and muscle are established. The supplemental NADA is approved as of July 3, 2000, and the regulations are amended in §§ 556.275 and 558.258 (21 CFR 556.275 and 558.258) to reflect the approval.

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 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 Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning on July 3, 2000, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new species for which the supplemental application was approved.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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***21 CFR Part 556*

Animal drugs, Food.

*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 parts 556 and 558 are amended as follows:

**PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD**

1. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

2. Section 556.275 is amended by redesignating paragraph (b)(3) as paragraph (b)(4) and by adding new paragraph (b)(3) to read as follows:

**§ 556.275 Fenbendazole.**

\* \* \* \* \*

(b) \* \* \*

(3) *Turkeys*—(i) *Liver (the target tissue)*. The tolerance for fenbendazole sulfone (the marker residue) is 6 ppm.

(ii) *Muscle*. The tolerance for fenbendazole sulfone (the marker residue) is 2 ppm.

\* \* \* \* \*

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

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

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

4. Section 558.258 is amended by redesignating paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) as paragraphs (d)(2), (d)(3), (d)(4), and (d)(5) and by adding new paragraph (d)(1) to read as follows:

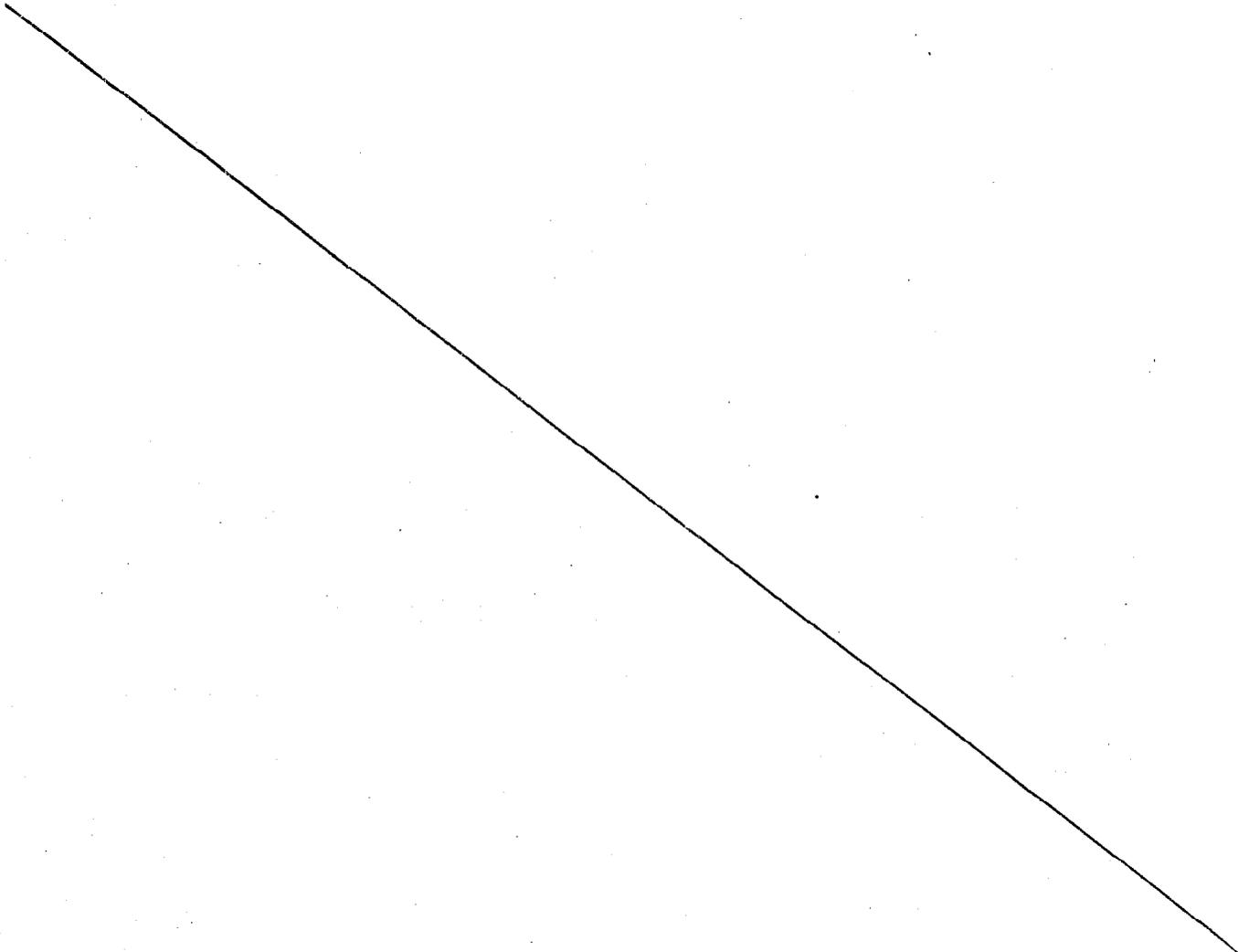
**§ 558.258 Fenbendazole.**

\* \* \* \* \*

(d) \* \* \*

(1) *Turkeys*—(i) *Amount*. Fenbendazole, 14.5 grams per ton (16 parts per million).

(A) *Indications for use*. For the removal and control of gastrointestinal worms: Round worms, adult and larvae (*Ascaridia dissimilis*); cecal worms, adult and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead).



(B) *Limitations.* Feed continuously as the sole ration for 6 days. For growing turkeys only.

\* \* \* \* \*  
(2) [RESERVED]  
Dated: 7/25/00  
July 25, 2000

OKA  
8/18/00

S F Sundlof

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

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

Jan Windsor