

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DMB

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

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

**ACTION:** Final rule; correction; technical amendment.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to restore indications for fenbendazole medicated feeds for cattle that have been inadvertently deleted from the regulations. Changes to a table format are also being made. This action is being taken to correct these errors and to improve the accuracy of the regulations.

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

**FOR FURTHER INFORMATION CONTACT:** George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567, e-mail: ghaibel@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** FDA has discovered that an error has become incorporated into the agency's regulation for part 558 (21 CFR part 558). A portion of the list of indications for fenbendazole medicated feeds for cattle was inadvertently deleted as a publication error beginning with the April 1, 1996, edition of the CFR. At this time, the regulations are being amended in § 558.258 to correct this error, to format some portions of this section as a table, and to restructure other portions to more closely resemble similar regulations for free-choice medicated feeds for cattle. Indications for the control of certain swine parasites, inadvertently removed in a previous revision of the regulations in the **Federal Register** of November 20, 1990 (55 FR 48230), are also being added. The entire text of § 558.258 is being provided for the convenience of the reader.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

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 revised to read as follows:

#### **§ 558.258 Fenbendazole.**

(a) *Specifications.* Type A medicated articles: 4 percent (18.1 grams per pound (g/lb)), 8 percent (36.2 g/lb), and 20 percent (90.7 g/lb) fenbendazole.

(b) *Approvals.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.275 of this chapter.

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

## (e) Conditions of use—(1) Turkeys.

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
14.5 (16 parts per million) .....	.....	Growing turkeys: For the removal and control of gastrointestinal worms: round worms, adult and larvae ( <i>Ascaridia dissimilis</i> ); cecal worms, adult and larvae ( <i>Heterakis gallinarum</i> ), an important vector of <i>Histomonas meleagridis</i> (Blackhead).	Feed continuously as the sole ration for 6 days. For growing turkeys only.	057926

## (2) Swine.

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10 to 300 (to provide 9 milligrams per kilogram (mg/kg) of body weight) given over a 3- to 12-day period.	.....	For the removal and control of: Adult stage lungworms ( <i>Metastrongylus apri</i> and <i>M. pudendotectus</i> ); adult and larvae (L3, 4 stages—liver, lung, intestinal forms) large roundworms ( <i>Ascaris suum</i> ); adult stage nodular worms ( <i>Oesophagostomum dentatum</i> , <i>O. quadrispinulatum</i> ); adult stage small stomach worms ( <i>Hyostrongylus rubidus</i> ); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms ( <i>Trichuris suis</i> ); adult and larvae kidney worms ( <i>Stephanurus dentatus</i> ).	Feed as sole ration .....	057926
(ii) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 20 .....	As in paragraph (e)(2)(i) of this section; for increased rate of gain in growing-finishing swine.	Feed as sole ration. Do not feed to swine that weigh more than 250 pounds (lbs); lincomycin as provided by 000009 in § 510.600(c) of this chapter.	057926
(iii) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 40 .....	As in paragraph (e)(2)(i) of this section; for control of swine dysentery in animals on premises with a history of swine dysentery, but where symptoms have not yet occurred.	Feed as sole ration. Do not feed to swine that weigh more than 250 lbs.; lincomycin as provided by 000009 in § 510.600(c) of this chapter.	057926
(iv) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 100 .....	As in paragraph (e)(2)(i) of this section; for the treatment of swine dysentery.	Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 lbs.; lincomycin as provided by 000009 in § 510.600(c) of this chapter.	057926

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(v) 10 to 80 (to provide 9 mg/kg of body weight).	Lincomycin 200 .....	As in paragraph (e)(2)(i) of this section; for reduction in the severity of swine mycoplasmal pneumonia caused by <i>Mycoplasma hyopneumoniae</i> .	Feed as sole ration. Do not use within 6 days of slaughter. Do not feed to swine that weigh more than 250 pound (lb); lincomycin as provided by 000009 in § 510.600(c) of this chapter.	057926
(vi) 10 to 300 (to provide 9 mg/kg of body weight).	Bacitracin methylene disalicylate 10 to 30.	Growing/finishing swine: As in paragraph (e)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency.	Feed as sole ration. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	046573
(vii) 10 to 300 (to provide 9 mg/kg of body weight).	Bacitracin methylene disalicylate 250.	1. Growing/finishing swine: As in paragraph (e)(2)(i) of this section; for control of swine dysentery associated with <i>Treponema hyodysenteriae</i> on premises with a history of swine dysentery, but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.  2. Pregnant sows: As in paragraph (e)(2)(i) of this section; for control of clostridial enteritis in suckling pigs caused by <i>Clostridium perfringens</i> .	1. Growing/finishing swine: Feed as sole ration. Not for use in growing and finishing swine that weigh more than 250 lbs. Diagnosis of swine dysentery should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.  2. Pregnant sows: Feed as sole ration. Diagnosis of clostridial enteritis should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	046573

(3) Cattle—(i) Conditions of use are as follows:

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(A) 5 mg/kg body weight (2.27 mg/lb).	.....	For the removal and control of lungworms ( <i>Dictyoacaulus viviparus</i> ); barberpole worms ( <i>Haemonchus contortus</i> ); brown stomach worms ( <i>Ostertagia ostertagi</i> ); small stomach worms ( <i>Trichostrongylus axei</i> ); hookworms ( <i>Bunostomum phlebotomum</i> ); thread-necked intestinal worms ( <i>Nematodirus helvetianus</i> ); small intestinal worms ( <i>Cooperia oncophora</i> and <i>C. punctata</i> ), bankrupt worms ( <i>Trichostrongylus colubriformis</i> ), and nodular worms ( <i>Oesophagostomum radiatum</i> ).	Feed as sole ration for one day. Do not use within 13 days of slaughter.	057926
(B) 5 mg/kg body weight (2.27 mg/lb) in a free-choice feed.	.....	As in paragraph (e)(3)(i)(A) of this section.	Formulate as specified in paragraph (e)(3)(ii) of this section. Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Do not slaughter within 13 days following last treatment.	057926

(ii) Formulate for use as a free-choice cattle feed as in paragraph (e)(3)(i)(B) of this section

as follows:

Ingredient <sup>1</sup>	Percent	International feed No.
(A) Ingredient: .....		
Copper sulfate .....	0.45	6-01-720
Dried Cane Molasses .....	3.12	4-04-695
Monosodium phosphate .....	31.16	6-04-288
Salt (sodium chloride) .....	59.00	6-04-152
Zinc sulfate .....	0.76	6-05-556
Fenbendazole Type A article (20%) .....	5.51	
(B) Ingredient: .....		
Dicalcium phosphate .....	32.31	6-00-080
Limestone .....	17.13	6-02-632
Magnesium oxide .....	9.79	6-02-756
Zinc sulfate .....	1.47	6-05-556
Copper sulfate .....	0.29	6-01-720
Potassium iodide .....	0.0098	6-03-759
Dried Cane Molasses .....	0.98	4-04-695
Selenium .....	0.0002	
Salt .....	35.93	6-04-152
Fenbendazole Type A article (20%) .....	2.09	

<sup>1</sup>The content of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium must comply with published regulations.

(4) Zoo and wildlife animals.

Species/Class	Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) Feral swine ( <i>Sus scrofa</i> ).	3 mg/kg/day for 3 days. ....	For the removal and control of kidney worm ( <i>Stephanurus dentatus</i> ), roundworm ( <i>Ascaris suum</i> ), nodular worm ( <i>Oesophagostomum dentatum</i> ).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	057926
(ii) Ruminants (sub-family Antilopinae, Hippotraginae, Caprinae).	2.5 mg/kg/day for 3 days. ....	For the removal and control of small stomach worm ( <i>Trichostrongylus</i> spp.), thread necked intestinal worm ( <i>Nematodirus</i> spp.), barberpole worm ( <i>Haemonchus</i> spp.), whipworm ( <i>Trichuris</i> spp.).	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	057926
(iii) Rocky mountain big-horn sheep ( <i>Ovis c. canadensis</i> ).	10 mg/kg/day for 3 days. ....	For the removal and control of <i>Protostrongylus</i> spp.	Use as complete feed. Prior withdrawal of feed or water is not necessary. Retreatment may be required in 6 weeks. Do not use 14 days before or during the hunting season.	057926

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