

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.

§ 520.1660d [Amended]

2. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraph (a)(9) by adding “3.09 and ” after “pails:”; in paragraphs (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), and (d)(1)(ii)(C)(3) by removing “and 053389” and by adding in its place “, 053389, and 061133”; and in paragraph (d)(1)(iii)(C) by removing “No. 046573” and by adding in its place “Nos. 046573 and 061133.”

Dated: November 8, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Fenbendazole

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction; technical amendment.

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 November 26, 2001.

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>Hyostrogylus 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
(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.	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.	046573
.....	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> .	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.	

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

¹The 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 (subfamily 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

Species/Class	Amount fenbendazole	Indications for use	Limitations	Sponsor
(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

Dated: November 9, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 4, 19, 24, 194, 250 and 251

[T.D. ATF-470 RE: T.D. ATF-398, Notice No. 859, Notice No. 869, T.D. ATF-418, Notice No. 881 and T.D. ATF-430]

RIN 1512-AB71

Hard Cider, Semi-Generic Wine Designations, and Wholesale Liquor Dealers' Signs (97-2523)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule (Treasury decision).

SUMMARY: This rule finalizes temporary regulations related to semi-generic designations on wine labels and wholesale liquor dealers' signs. This rule also finalizes some of the temporary regulations concerning hard cider, and amends others.

DATES: *Effective date:* January 25, 2002.

Compliance date: Compliance with the amendments to hard cider labeling requirements in 27 CFR 4.21 and 24.257(a) is not mandatory until May 27, 2002.

FOR FURTHER INFORMATION CONTACT: Marjorie D. Ruhf, Regulations Division, 650 Massachusetts Avenue, NW., Washington, DC 20226; (202) 927-8202; or mdruhf@atfhq.atf.treas.gov.

SUPPLEMENTARY INFORMATION:

Background

This final rule implements some of the provisions of the Taxpayer Relief Act of 1997, Pub. L. 105-34, specifically the sections that amended the Internal Revenue Code (26 U.S.C., "the IRC") to:

—Create a wine excise tax category for hard cider (sec. 908),

—List semi-generic designations for wine (sec. 910), and

—Repeal the requirement for wholesale dealers in liquors to post signs (sec. 1415).

The definition of hard cider in Public Law 105-34 was amended by section 6009 of the Internal Revenue Service Restructuring and Reform Act of 1998, Pub. L. 105-206, as we will discuss later.

On August 21, 1998, ATF issued a temporary rule, T.D. ATF-398 (63 FR 44779), to implement various sections of Public Law 105-34. On the same day, ATF issued a notice of proposed rulemaking, Notice No. 859 (63 FR 44819), inviting comments on this temporary rule for a 60 day period. In response to requests from the industry, ATF reopened the comment period for an additional 30 days on November 6, 1998, by Notice No. 869 (63 FR 59921). We will discuss our proposals, the public comments, and our decisions below.

Temporary Rule, Comments and Decision on Semi-generic Designations

Section 910 of Public Law 105-34 amended 26 U.S.C. 5388 by adding a new subsection (c), Use of semi-generic designations, which generally parallels the language of 27 CFR 4.24 on the same subject, but places the existing list of semi-generic designations outside the discretion of the Secretary.

Since the IRC regulations concerning wine labeling appear in 27 CFR 24.257, we amended that regulation to incorporate the wording of 26 U.S.C. 5388, concerning the use of semi-generic wine designations. Additionally, we incorporated the standards of identity for wines under 27 U.S.C. 205 by reference in this section. Finally, we placed a cross-reference to this new rule in § 4.24.

Since the rules for use of semi-generic designations have been made part of the IRC, the rules apply to all wines, including wines that contain less than 7 percent alcohol by volume and to wines sold only in intrastate commerce.

The use of semi-generic designations on wine labels was the subject of two comments. Peter M. Brody of Ropes & Gray, writing on behalf of the Institut National des Appellations d'Origine (INAO) objected to "entrenching" the

U.S. policy of allowing use of the names champagne, chablis, burgundy and sauternes, on wines made outside France. Jean-Christophe Paille, Counselor for Agriculture of the Ambassade de France aux Etats-Unis, made the same objection. However, these objections were to the underlying statute and not to the regulatory changes made as a result. Therefore, we are adopting the language of the temporary rule in this final regulation.

Temporary Rule, Comments and Decision on Wholesale Dealers' Signs

Section 1415 of Public Law 105-34 repealed the requirement for wholesale dealers in liquor to post signs identifying their premises and made conforming changes to sections of the law which referenced that requirement. In the temporary rule, ATF amended the Liquor Dealers' regulations by removing §§ 194.239 through 194.241, which relate to this requirement. This change received no comments, so we are adopting the language of the temporary rule in this final regulation.

Hard Cider

The Taxpayer Relief Act of 1997, Pub. L. 105-34, was enacted on August 5, 1997. Section 908 added a new tax class (6) for wine, called "hard cider," to 26 U.S.C. 5041 and imposed a new rate of tax on hard cider as follows:

On hard cider [which is a still wine] derived primarily from apples or apple concentrate and water, containing no other fruit product, and containing at least one-half of 1 percent and less than 7 percent alcohol by volume, 22.6 cents per wine gallon.

The phrase in brackets was added by section 6009 of the Internal Revenue Service Restructuring and Reform Act of 1998, Pub. L. 105-206, enacted July 22, 1998, and effective as if it were part of Pub. L. 105-34.

In the temporary rule, ATF added a definition of hard cider to the wine regulations and made other changes to the wine production and labeling regulations. In associated Notice Number 859, ATF invited comments on the definition of hard cider established in the temporary rule. We noted there were numerous traditional ways of making fermented cider, some of which