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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2008-N-0039]

Display Date 10-7-08
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Certifier Spice

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 Intervet Inc. The supplemental NADA provides for use of a fenbendazole free choice, liquid Type C medicated feed in dairy and beef cattle for the removal and control of various internal parasites.

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

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8343, e-mail: *donald.prater@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed a supplement to NADA 131-675 for SAFE-GUARD (fenbendazole) 20% Type A medicated article. The supplemental NADA provides for manufacture of a fenbendazole free choice, liquid Type C medicated feed for use in dairy and beef cattle for the removal and control of various internal parasites. The supplemental NADA is approved as of September 5, 2008, and the regulations are amended in 21 CFR 558.258 to reflect the approval.

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2008-131-675

NFR

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 Division of Dockets Management (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 supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval. The 3 years of exclusivity apply only to the use of fenbendazole liquid Type C medicated feed for the removal and control of lungworms (*Dictyocaulus viviparus*), one of the parasite species for which the supplement is approved.

FDA has determined under 21 CFR 25.33(a) 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. In § 558.258, in the table in paragraph (e)(1), in the “Indications for use” column, remove “round worms” and in its place add “roundworms”; and revise paragraph (e)(3) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(e) * * *

(3) Cattle.

Amount fenbendazole	Indications for use	Limitations	Sponsor
(i) 5 mg/kg body weight (2.27 mg/lb)	Dairy and beef cattle: For the removal and control of: Lungworms (<i>Dictyocaulus viviparus</i>); Stomach worms: barberpole worms (<i>Haemonchus contortus</i>), brown stomach worms (<i>Ostertagia ostertagi</i>), small stomach worms (<i>Trichostrongylus axei</i>); Intestinal worms: 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 the sole ration or as a top dress for one day. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	057926
(ii) [Reserved]			

(iii) *Free-choice feeds*—(A) *Amount.* 5 mg/kg body weight (2.27 mg/lb),

including the following formulations:

Ingredient ¹	Percent	International Feed No.
(1) Free-choice, dry Type C feed:		
Salt (sodium chloride)	59.00	6-04-152
Monosodium phosphate	31.16	6-04-288
Dried cane molasses	3.12	4-04-695
Zinc sulfate	0.76	6-05-556
Copper sulfate	0.45	6-01-720
Fenbendazole 20% Type A article	5.51	n/a
(2) Free-choice, dry Type C feed:		
Salt (sodium chloride)	35.93	6-04-152
Dicalcium phosphate (18.5% P)	32.44	6-00-080
Calcium carbonate (38% Ca)	15.93	6-01-069
Magnesium oxide (56% Mg)	10.14	6-02-756
Zinc sulfate	1.47	6-05-556
Mineral oil	1.00	8-03-123
Dried cane molasses (46% sugars)	0.98	4-04-695
Potassium iodide	0.01	6-03-759
Fenbendazole 20% Type A article	2.10	n/a
(3) Free-choice, liquid Type C feed:		
Cane molasses ²	80.902	4-13-251
Water	9.36	n/a
Urea solution, 55%	7.05	5-05-707
Phosphoric acid 75% (feed grade)	2.00	6-03-707
Xantham gum	0.20	8-15-818

Ingredient ¹	Percent	International Feed No.
Trace minerals	0.20	n/a
Vitamin premix	0.01	n/a
Fenbendazole 20% Type A article	0.278	n/a

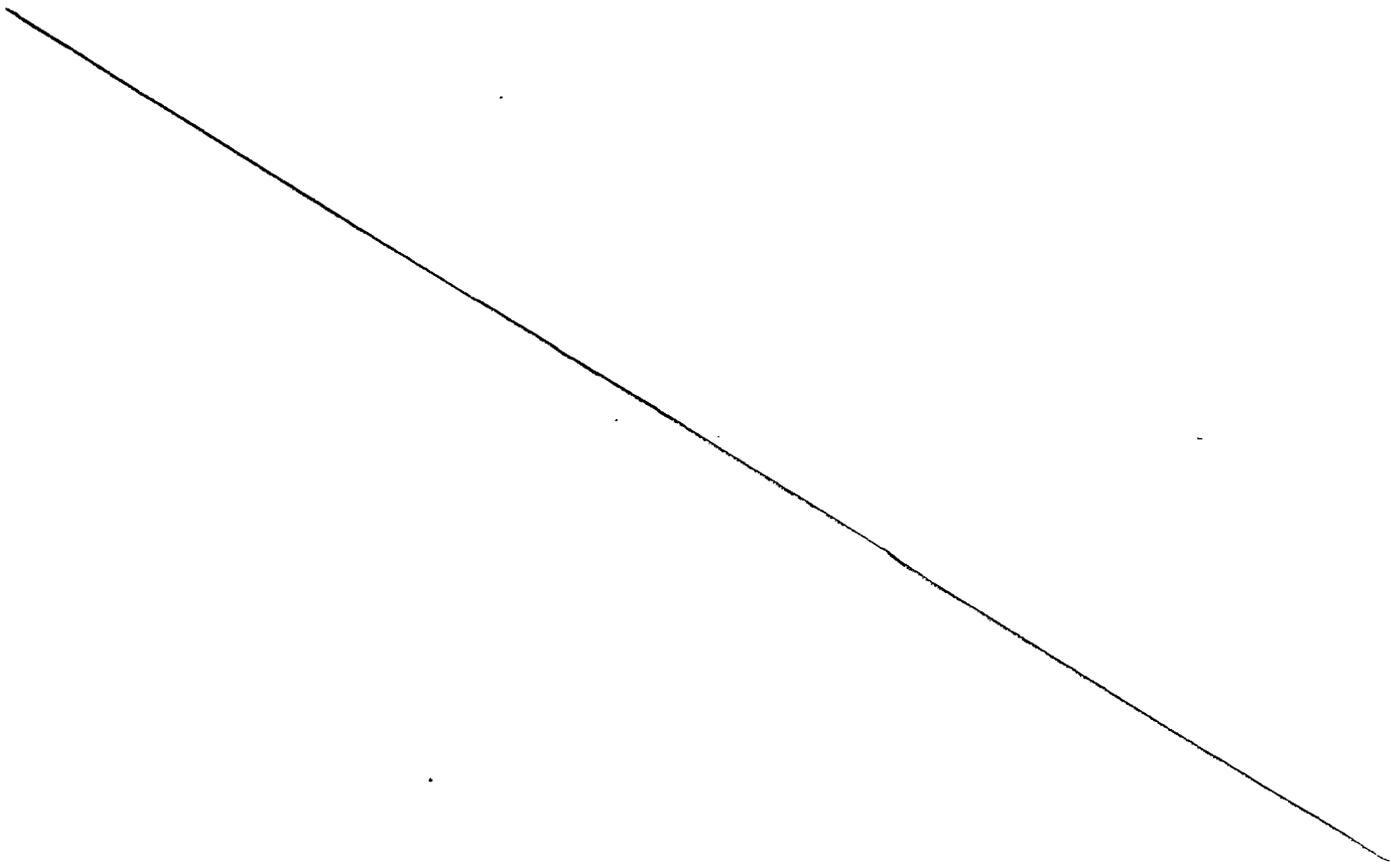
¹The content of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the manufacturer for other free-choice cattle feeds. Formulation modifications require FDA approval prior to marketing. Selenium is not approved for the free-choice formulations described in paragraph (e)(3)(iii) of this section. Free-choice cattle feeds containing selenium must comply with published regulations (see 21 CFR 573.920).

²The percentage of cane molasses and water in the formulation may be adjusted as needed in order to bring the brix value of the molasses to the industry standard of 79.5 brix.

(B) *Indications for use.* As in paragraph (e)(3)(i) of this section.

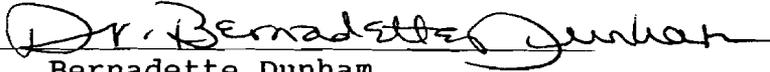
(C) *Limitations.* Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

* * * * *



Dated: 9/29/08

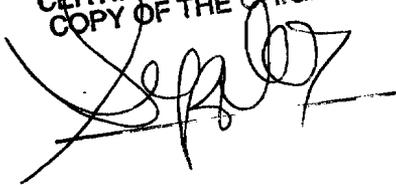
September 29, 2008.



Bernadette Dunham,
Director,
Center for Veterinary Medicine.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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