**§ 522.2630 Tulathromycin.**

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use*. For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*. For the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.

* * * * *

Dated: September 29, 2008.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. E8–23832 Filed 10–7–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 558

**[Docket No. FDA–2008–N–0039]**

## 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 October 8, 2008.

**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.

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 (*Dictyocaulus viviparus*); Stomach worms: barberpole worms (*Haemonchus contortus*), brown stomach worms (*Ostertagia ostertagi*), small stomach worms (*Trichostrongylus axei*); Intestinal worms: hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia oncophora* and *C. punctata*); Bankrupt worms (*Trichostrongylus colubriformis*); and Nodular worms (*Oesophagostomum radiatum*). | 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 |
| Trace minerals | 0.20 | n/a |
| Vitamin premix | 0.01 | n/a |
| Fenbendazole 20% Type A article | 0.278 | n/a |

[1]The 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).

[2]The 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.

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Dated: September 29, 2008.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. E8–23845 Filed 10–7–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 801

**[Docket No. FDA–2008–N–0148]**

## Medical Devices; Hearing Aids; Technical Data Amendments; Confirmation of Effective Date

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

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is confirming the effective date of October 15, 2008, for the final rule that appeared in the **Federal Register** of June 2, 2008 (73 FR 31358). The direct final rule amends the hearing aid labeling to reference the most recent version of the consensus standard used to determine the technical data to be included in labeling for hearing aids. This document confirms the effective date of the direct final rule.

**DATES:** Effective date confirmed: October 15, 2008.

**FOR FURTHER INFORMATION CONTACT:** Eric A. Mann, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration,9200 Corporate Blvd., Rockville, MD 20850, 240–276–4242.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 2, 2008 (73 FR 31358), FDA solicited comments concerning the direct final rule for a 75-day period ending August 18, 2008. FDA stated that the effective date of the direct final rule would be on October 15, 2008, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA received one letter of comment on the direct final rule. However, this comment does not constitute a significant adverse comment. Therefore, FDA is confirming the effective date of the direct final rule. The comment received and FDA's response to the comment are discussed as follows:

The only comment on the direct final rule requested clarification regarding the applicability of the proposed change in the standard of the American National Standards Institute to hearing aid models that were tested and characterized prior to the effective date