Food and Drug Administration, HHS

restricts this drug to use by or on the order of a licensed veterinarian.

[56 FR 50655, Oct. 8, 1991]

§ 520.905 Fenbendazole oral dosage forms.

§520.905a Fenbendazole suspension.

- (a) *Specifications*. Each milliliter of suspension contains 100 milligrams (mg) fenbendazole.
- (b) *Sponsor*. See No. 000061 in §510.600(c) of this chapter.
- (c) Related tolerances. See §556.275 of this chapter.
- (d) Special considerations. (1) See $\S 500.25$ of this chapter.
- (2) Fenbendazole suspension 10 percent and approved forms of trichlorfon, when used concomitantly for treating the indications provided in paragraph (e) of this section and for treating infections of stomach bot as provided in §520.2520, have been shown to be compatible and not to interfere with one another.
- (e) Conditions of use—(1) Horses—(i) Amount. Administer orally 5 mg per kilogram (/kg) (2.3 mg per pound (/lb)) for the control of large strongyles, small strongyles, and pinworms; 10 mg/kg for the control of ascarids.
- (ii) Indications for use. For the control of large strongyles (Strongylus edentatus, S. equinus, S. vulgaris), small strongyles (Cyanthostomum spp., Cylicocyclus spp., Cylicostephanus spp., Triodontophorus spp.), pinworms (Oxyuris equi), and ascarids (Parascaris equorum) in horses.
- (iii) *Limitations*. Administer by dose syringe or suitable plastic syringe. Do not use in horses intended for human consumption.
- (2) Cattle including dairy cows of breeding age—(i) Amount. Administer orally 5 mg/kg of body weight (2.3 mg/lb).
- (ii) Indications for use. For the removal and control of lungworm (Dictyocaulus viviparus); stomach worm (adults)—brown worm stomach (Ostertagia ostertagi); stomach worms and 4th-stage larvae) barberpole worm (Haemonchus contortus and H. placei) and small stomach worm (Trichostongylus axei); intestinal worms (adults and 4th-stage larvae) hookworm (Bunostonmum phlebotomum), threadnecked intestinal worm

(Nematodirus helvetianus), small intestinal worm (Cooperia punctata and C. oncophora), bankrupt worm (Trichostrongylus colubriformis), and nodular worm (Oesophagostomum radiatum).

- (iii) *Limitations*. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 8 days following last treatment.
- (3) Beef cattle—(i) Amount. Administer orally 10 mg/kg of body weight.
- (ii) Indications for use. For the removal and control of stomach worm (4th stage inhibited larvae/type II ostertagiasis), Ostertagia ostertagi, and tapeworm, Moniezia benedeni.
- (iii) *Limitations*. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 8 days following last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (4) Goats—(i) Amount. Administer orally 5 mg/kg of body weight (2.3 mg/lb).
- (ii) Indications for use. For the removal and control of stomach worms (adults) Haemonchus contortus and Teladorsagia circumcincta.
- (iii) Limitations. Retreatment may be needed after 4 to 6 weeks. Goats must not be slaughtered for food within 6 days following last treatment. Do not use in lactating goats.
- [42 FR 59069, Nov. 15, 1977; 43 FR 12311, Mar. 24, 1978. Redesignated at 44 FR 1375, Jan. 5, 1979, and amended at 46 FR 29464, June 2, 1981; 47 FR 15327, Apr. 9, 1982; 48 FR 42809, Sept. 20, 1983; 49 FR 1983, Jan. 17, 1984; 53 FR 40058, Oct. 13, 1988; 59 FR 26943, May 25, 1994; 61 FR 29478, June 11, 1996; 63 FR 63983, Nov. 18, 1998; 66 FR 47960, Sept. 17, 2001; 68 FR 26205, May 15, 2003; 74 FR 17770, Apr. 17, 2009; 74 FR 61516, Nov. 25, 2009]

§ 520.905b Fenbendazole granules.

- (a) Specifications. Each gram of granules contains 222 milligrams (mg) fenbendazole.
- (b) *Sponsor*. See No. 000061 in §510.600(c) of this chapter.
- (c) Special considerations. See §500.25 of this chapter.
- (d) Conditions of use—(1) Horses—(i) Amount. 5 mg/kilogram (kg) for large strongyles, small strongyles, and pinworms; 10 mg/kg for ascarids.
- (ii) *Indications for use*. For the control of infections of large strongyles

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(Strongylus edentatus, S. equinus, S. vulgaris), small strongyles, pinworms (Oxyuris equi), and ascarids (Parascaris equorum).

- (iii) Limitations. Sprinkle the appropriate amount of drug on a small amount of the usual grain ration. Prepare for each horse individually. Withholding feed or water is not necessary. Retreat in 6 to 8 weeks if required. Do not use in horses intended for food.
- (2) Dogs—(i) Amount. 50 mg/kg daily for 3 consecutive days.
- (ii) Indications for use. For the treatment and control of ascarids (Toxocara canis, Toxascaris leonina), hookworms (Ancylostoma caninum, Uncinaria stenocephala), whipworms (Trichuris vulpis), and tapeworms (Taenia pisiformis).
- (iii) *Limitations*. Mix the appropriate amount of drug with a small amount of the usual food; dry dog food may require slight moistening to facilitate mixing. Medicated food must be fully consumed.
- (3) Zoo and wildlife animals—(1) Amount. 10 mg/kg per day for 3 days.
- (ii) Indications for use. For control of internal parasites of Felidae and Ursidae as follows:
- (A) Lion (Panthera leo) and Tiger (Panthera tigris): Ascarid (Toxocara cati, Toxascaris leonina), Hookworm (Ancylostoma spp.).
- (B) Cheetah (Acinonyx jubatus): Ascarid (Toxocara cati, Toxascaris leonina).
- (C) Puma (Felis concolor), Panther (Panthera spp.), Leopard (Panthera pardus), Jaguar (Panthera onca): Ascarid (Toxocara cati, Toxascaris leonina), Hookworm (Ancylostoma spp.), Tapeworm (Taenia hydatigena, T. krabbei, T. taeniaeformis).
- (D) Black Bear (Ursus americanus):
 Ascarid (Baylisascaris transfuga,
 Toxascaris leonina), Hookworm
 (Ancylostoma caninum), Tapeworm
 (Taenia hydatigena, T. krabbei).
- (E) Polar Bear (*Ursus maritimus*) and Grizzly Bear (*Ursus horribilis*): Ascarid (*Baylisascaris transfuga*, *Toxascaris leonina*).
- (iii) *Limitations*. Top dress or mix with a small portion of food. Must be fully consumed prior to feeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Do not use 14 days before or during the hunting season.

[44 FR 1375, Jan. 5, 1979, as amended at 47 FR 15327, Apr. 9, 1982; 48 FR 50528, Nov. 2, 1983; 59 FR 35252, July 11, 1994; 66 FR 47960, Sept. 17, 2001; 67 FR 47450, July 19, 2002; 71 FR 19429, Apr. 14, 2006; 74 FR 61516, Nov. 25, 2009]

§520.905c Fenbendazole paste.

- (a) Specifications. Each gram of paste contains 100 milligrams (mg) fenbendazole (10 percent).
- (b) *Sponsor*. See No. 000061 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) Horses—(1) Indications for use and amounts—(A) For control of large strongyles (Strongylus edentatus, S. equinus, S. vulgaris), small strongyles, pinworms (Oxyuris equi), and ascarids (Parascaris equorum): 2.3 mg per pound (/lb) of body weight, or for foals and weanlings (less than 18 months of age), 4.6 mg/lb of body weight. Retreatment at intervals of 6 to 8 weeks may be required.
- (B) For control of arteritis caused by the fourth-stage larvae of S. vulgaris: 4.6 mg/lb of body weight daily for 5 days. Treatment should be initiated in the spring and repeated in 6 months.
- (C) For treatment of encysted mucosal cyathostome (small strongyle) larvae including early third-stage (hypobiotic), late third-stage, and fourth-stage larvae: 4.6 mg/lb of body weight daily for 5 consecutive days.
- (D) Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in paragraph (e)(1)(i)(A) of this section and for treating infections of stomach bots as provided in §520.2520.
- (ii) *Limitations*. Do not use in horses intended for human consumption.
- (2) Cattle—(i) Amount. 2.3 mg/lb of body weight. Retreatment may be needed after 4 to 6 weeks.
- (ii) Indications for use. For the removal and control of lungworms (Dictyocaulus viviparus), stomach (Haemonchus worms contortus. Ostertagia ostertagi, Trichostrongylus and intestinal axei), worms (Bunostomum phlebotomum, Nematodirus