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