

§ 520.903c

21 CFR Ch. I (4–1–98 Edition)

milliliters per 100 pounds of body weight.

[45 FR 8587, Feb. 8, 1980]

§ 520.903c [Reserved]

§ 520.903d Febantel-praziquantel paste.

(a) *Specifications.* Each gram of paste contains 34 milligrams of febantel and 3.4 milligrams of praziquantel.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount—(i) Dogs and cats (over 6 months of age):* 10 milligrams of febantel and 1 milligram of praziquantel per kilogram of body weight (1 gram of paste per 7.5 pounds body weight) administered by mouth or in the food once daily for 3 days.

(ii) *Puppies and kittens (less than 6 months of age):* 15 milligrams of febantel and 1.5 milligrams of praziquantel per kilogram of body weight (1 gram of paste per 5 pounds body weight) administered by mouth on a full stomach once daily for 3 days.

(2) *Indications for use.* (i) *Dogs and puppies:* For removal of hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), ascarids (*Toxocara canis* and *Toxascaris leonina*), and tapeworms (*Dipylidium caninum* and *Taenia pisiformis*).

(ii) *Cats and kittens:* For removal of hookworms (*Ancylostoma tubaeforme*), ascarids (*Toxocara cati*) and tapeworms (*Dipylidium caninum* and *Taenia taeniaeformis*).

(3) *Limitations.* Do not use in pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Special considerations.* Consider alternative therapy or use with caution in animals with pre-existing liver or kidney dysfunction.

[50 FR 19167, May 7, 1985, as amended at 53 FR 48533, Dec. 1, 1988; 56 FR 50813, Oct. 9, 1991]

§ 520.903e Febantel tablets.

(a) *Specifications.* Each scored tablet contains 27.2 milligrams of febantel for use in dogs, puppies, cats, and kittens or 163.3 milligrams of febantel for use in dogs, puppies, and cats.

(b) *Sponsor.* See 000859 in § 510.600(c)(2) of this chapter.

(c) *Conditions of use—(1) Amount—(i) Dogs and cats.* Ten milligrams per kilogram body weight. Administer once daily for 3 consecutive days.

(ii) *Puppies and kittens fewer than 6 months of age.* Fifteen milligrams per kilogram body weight. Administer once daily for 3 consecutive days.

(2) *Indications for use.* (i) For removal of hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), ascarids (*Toxocara canis* and *Toxascaris leonina*) and whipworms (*Trichuris vulpis*) in dogs and puppies.

(ii) For removal of hookworms (*Ancylostoma tubaeforme*) and ascarids (*Toxocara cati*) in cats and kittens.

(3) *Limitations.* Do not use in pregnant animals. Consider alternative therapy or use with caution in animals with preexisting liver or kidney dysfunction. Administer to puppies and kittens on a full stomach. Federal law 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) *Chemical name.* Carbamic acid, [5-(phenylthio)-1*H*-benzimidazol-2-yl]-methyl ester.

(b) *Specifications.* The drug is a suspension containing 10 percent (100 milligrams per milliliter) fenbendazole.

(c) *Sponsor.* See No. 012799 in § 510.600(c) of this chapter.

(d) *Conditions of use—(1) Horses—(i) Amount.* 5 milligrams per kilogram (2.3 milligrams per pound) for the control of large strongyles, small strongyles, and pinworms; 10 milligrams per kilogram for the control of ascarids.

(ii) *Indications for use.* For the control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Triodontophorus* spp.), pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*) in horses.

(iii) *Limitations.* Administer orally by dose syringe or suitable plastic syringe. Do not use in horses intended for

food. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Beef and dairy cattle*—(i) *Amount*. Administer orally 5 milligrams per kilogram of body weight (2.3 milligrams per pound).

(A) *Indications for use*. For the removal and control of lungworm (*Dictyocaulus viviparus*); stomach worm (adults)—brown stomach worm (*Ostertagia ostertagi*); stomach worms (adults and 4th-stage larvae)—barberpole worm (*Haemonchus contortus* and *H. placei*) and small stomach worm (*Trichostrongylus axei*); intestinal worms (adults and 4th-stage larvae)—hookworm (*Bunostomum phlebotomum*), threadnecked intestinal worm (*Nematodirus helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), and nodular worm (*Oesophagostomum radiatum*).

(B) *Limitations*. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 8 days following last treatment. Consult a veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(ii) *Amount*. Administer orally 10 milligrams per kilogram of body weight.

(A) For the removal and control of stomach worm (4th-stage inhibited larvae/type II ostertagiasis), *Ostertagia ostertagi*, and tapeworm, *Moniezia benedeni*.

(B) *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.

(3) *Goats*—(i) *Amount*. Administer orally 5 milligrams per kilogram of body weight (2.3 milligrams per pound).

(ii) *Indications for use*. For the removal and control of stomach and intestinal worms *Haemonchus contortus* and *Ostertagia 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Special considerations*. Fenbendazole suspension 10 percent and approved forms of trichlorfon, when used concomitantly for treating the indications provided in paragraph (d) 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.

[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]

§ 520.905b Fenbendazole granules.

(a) *Specifications*. The drug is in granular form containing 22 percent (222 milligrams per gram) fenbendazole.

(b) *Sponsor*. See No. 012799 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount*. 5 milligrams per kilogram (2.3 milligrams per pound) for the control of large strongyles, small strongyles, and pinworms; 10 milligrams per kilogram for the control of ascarids.

(ii) *Indications for use*. For the control of infections of large strongyles (*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. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(2) *Dogs*—(i) *Amount*. 50 milligrams per kilogram (22.7 milligrams per pound) daily for 3 consecutive days.

(ii) *Indications for use*. For the removal 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