Food and Drug Administration, HHS

§ 520.870 Etodolac.

- (a) Specifications. Each tablet contains 150 or 300 milligrams (mg) of etodolac
- (b) Sponsor. See 053501 in 510.600(c) of this chapter.
- (c) [Reserved]
- (d) Conditions of use—(1) Dogs—(i) Amount. 10 to 15 mg per kilogram (4.5 to 6.8 mg/pound) of body weight per day.
- (ii) *Indications for use*. For the management of pain and inflammation associated with osteoarthritis in dogs.
- (iii) *Limitations*. Use once-a-day. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 - (2) [Reserved]

[63 FR 51300, Sept. 25, 1998]

§520.903 Febantel oral dosage forms.

§520.903a Febantel paste.

- (a) Chemical name. Dimethyl [[2-[(methoxyacetyl)amino]-4-(phenyl-thio)phenyl] carbonimidoyl]bis [carbamate]
- (b) *Specifications*. The drug is a paste containing 45.5 percent febantel.
- (c) *Sponsor*. See No. 000859 in §510.600(c) of this chapter.
- (d) Conditions of use—(1) Amount. Six milligrams per kilogram (2.73 milligrams per pound) of body weight in horses.
- (2) Indications for use. For removal of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); ascarids (Parascaris equorum— sexually mature and immature); pinworms (Oxyuris equi— adult and 4th stage larva); and the various small strongyles in horses, foals, and ponies.
- (3) *Limitations*. (i) The paste may be administered on the base of the tongue or well mixed into a portion of the normal grain ration.
 - (ii) [Reserved]
- (iii) For animals maintained on premises where reinfection is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks.
- (iv) Not for use in horses intended for food.

- (v) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.
- [43 FR 8797, Mar. 3, 1978; 43 FR 12311, Mar. 24, 1978, as amended at 43 FR 60882, Dec. 29, 1978. Redesignated at 45 FR 8587, Feb. 8, 1980]

§ 520.903b Febantel suspension.

- (a) *Specifications*. The suspension contains 9.3 percent (2.75 grams per ounce) febantel.
- (b) Sponsor. See 000859 in 510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. 3 milliliters per 100 pounds body weight or 1 fluid ounce per 1000 pounds (6 milligrams per kilogram body weight).
- (2) Indications for use. For removal of ascarids (Parascaris equorum—adult and sexually immature), pinworms (Oxyuris equi—adult and 4th stage larvae), large strongyles (Strongylus vulgaris, S. edentatus, S. equinus), and the various small strongyles in horses, breeding stallions and mares, pregnant mares, foals, and ponies.
- (3) Limitations. Administer by stomach tube or drench, or by mixing well into a portion of the normal grain ration. For animals maintained on premises where reinfection is likely to occur, retreatment may be necessary. For most effective results, retreat in 6 to 8 weeks. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (d) Special considerations. Febantel suspension may be used in combination with trichlorfon oral liquid in accordance with the provisions of §520.2520c, this section, and the following conditions:
- (1) Combine 1 part febantel suspension with 5 parts trichlorfon liquid.
- (2) Allow animal to consume a portion of daily grain ration; administer mixture by stomach tube at rate of 18 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.

§520.903e

- (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.

 $[50~{\rm FR}~19167,~{\rm May}~7,~1985,~{\rm as~amended}~{\rm at}~53~{\rm FR}~48533,~{\rm Dec.}~1,~1988;~56~{\rm FR}~50813,~{\rm Oct.}~9,~19911$

§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) Specifications. The drug is a suspension containing 10 percent (100 milligrams per milliliter) fenbendazole.
- (b) *Sponsor*. See No. 057926 in §510.600(c) of this chapter.
- (c) $Related\ tolerances.$ See §556.275 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 (Cyanthostomum 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) Cattle including dairy cows of breeding age—(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 lungworm (Dictyocaulus viviparus); stomach worm (adults)—brown stomach worm (Ostertagia ostertagi); stomach worms (adults and 4th-stage larvae)—barberpole worm (Haemonchus contortus