

## § 520.870

(c) *Conditions of use.* (1) It is administered orally to dogs as a tranquilizer.<sup>1</sup>

(2) It is administered once daily at a dosage level of 2 to 5 milligrams of ethylisobutrazine hydrochloride per pound of body weight.<sup>1</sup>

(3) It is not to be used in conjunction with organophosphates and/or procaine hydrochloride because phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.<sup>1</sup>

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

## § 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-(phenylthio)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 milli-

<sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

## 21 CFR Ch. I (4-1-03 Edition)

grams 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.

(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) *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.