produce nephrotoxicity as manifested by albuminuria, presence of granular casts and depressed urinary output. If it is desirable to administer a vasoconstrictor, norepinephrine is the drug of choice. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 14103, Apr. 10, 1984, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1962 Promazine hydrochloride.

(a)(1) *Chemical name.* 10-[3-(Dimethylamino)propyl]phenothiazine monohydrochloride.

(2) *Specifications.* Conforms to N.F. XII.

(3) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(4) [Reserved]

(5) *Conditions of use.* (i) The drug is used for quieting excitable, unruly, or intractable horses. It is administered at a dosage level of 0.45 to 0.9 milligrams of promazine hydrochloride per pound of body weight mixed with an amount of feed that will be readily consumed.

(ii) Do not use in horses intended for food.

(iii) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) [Reserved]

[40 FR 13838, Mar. 27, 1975, as amended at 43 FR 55386, Nov. 28, 1978; 59 FR 5705, Feb. 8, 1994]

§ 520.2002 Propiopromazine hydrochloride.

(a) *Chemical name.* 1-Propanone, 1-[10-[3-(dimethylamino) propyl] phenothiazine-2-yl]-, monohydrochloride.

(b) *Specifications.* The drug is administered in a chewable tablet containing 10 to 20 milligrams of propiopromazine hydrochloride.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is intended for oral administration to dogs as a tranquilizer. It is used as an aid in handling difficult, excited, and unruly dogs, and in controlling excessive kennel barking, car sickness, and severe dermatitis. It is also indicated for use in minor surgery and prior to routine examinations, laboratory procedures, and diagnostic procedures.

(2) It is administered at the rate of 0.5 to 2 milligrams of propiopromazine hydrochloride per pound of body weight once or twice daily depending upon the degree of tranquilization desired.

NOTE: Not for use with organophosphates and/or procaine hydrochloride, as phenothiazine may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride. Overdosage may produce significant depression.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 46 FR 60570, Dec. 11, 1981; 61 FR 5506, Feb. 13, 1996]

§ 520.2041 Pyrantel pamoate chewable tablets.

(a) *Specifications.* Each tablet contains pyrantel pamoate equivalent to 22.7 or 113.5 milligrams pyrantel base.

(b) *Sponsor.* See Nos. 017135 and 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Provides at least 2.27 milligrams pyrantel base per pound body weight for dogs weighing more than 5 pounds, and at least 4.54 milligrams of pyrantel base per pound body weight for dogs weighing 5 pounds or less.

(2) *Indications for use*—(i) *In dogs and puppies.* For removal of ascarids (*Toxocara canis; Toxascaris leonina*) and hookworms (*Ancylostoma caninum; Uncinaria stenocephala*).

(ii) In puppies and adult dogs and in lactating bitches after whelping. To prevent reinfection of *Toxocara canis.*

(3) *Limitations.* Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Retreatment of adult dogs may be necessary at monthly intervals as determined by laboratory fecal examinations. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[52 FR 37937, Oct. 13, 1987, as amended at 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993; 66 FR 9650, Feb. 9, 2001; 67 FR 21996, May 2, 2002]

§ 520.2042 Pyrantel pamoate tablets.

(a) *Specifications.* Each tablet contains pyrantel pamoate equivalent to

22.7, 45.4, or 113.5 milligrams of pyrantel base.

(b) *Sponsor*. See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*. It is used for dogs as follows:

(1) *Amount*. For dogs weighing over 5 pounds, use at least 2.27 milligrams of pyrantel base per pound of body weight; for dogs weighing 5 pounds or less, use at least 4.54 milligrams of pyrantel base per pound of body weight.

(2) *Indications for use*. For removal and control of large roundworms (ascarids) (*Toxocara canis* and *Toxascaris leonina*), and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(3) *Limitations*. Administer orally directly or in a small amount of food. To prevent reinfection of *T. canis* in puppies, lactating bitches after whelping, and adult dogs; treat puppies 2, 3, 4, 6, 8, and 10 weeks of age; treat lactating bitches 2 to 3 weeks after whelping; routinely treat adult dogs monthly. Do not withhold food prior to or after treatment. The presence of these parasites should be confirmed by laboratory fecal examination. A followup fecal examination should be conducted 2 to 4 weeks after first treatment regimen to determine the need for re-treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[43 FR 52700, Nov. 14, 1978, as amended at 49 FR 22073, May 25, 1984; 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993]

§ 520.2043 Pyrantel pamoate suspension.

(a) *Specifications*. (1) Each milliliter (mL) contains pyrantel pamoate equivalent to 50 milligrams (mg) pyrantel base.

(2) Each mL contains pyrantel pamoate equivalent to 2.27 or 4.54 mg pyrantel base.

(3) Each mL contains pyrantel pamoate equivalent to 4.54 mg pyrantel base.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) Nos. 000069, 058829, and 059130 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(2) Nos. 000069, 010237, 058829, and 059130 for use of the products described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(3) No. 023851 for use of the product described in paragraph (a)(3) as in paragraph (d)(2) of this section.

(c) *Special considerations*. See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Horses and ponies*. It is used as follows:

(i) *Amount*. 3 mg per pound (/lb) body weight as a single dose mixed with the usual grain ration, or by stomach tube or dose syringe.

(ii) *Indications for use*. For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles.

(iii) *Limitations*. Not for use in horses and ponies to be slaughtered for food purposes. When the drug is for administration by stomach tube, it shall be labeled: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(2) *Dogs*. It is used as follows:

(i) *Dogs and puppies*—(A) *Amount*. 2.27 mg/lb body weight as a single dose in the animal's feed bowl by itself or mixed in a small quantity of food.

(B) *Indications for use*. For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(C) *Limitations*. Additional treatment may be required and should be confirmed by fecal examination within 2 to 4 weeks.

(ii) *Dogs, puppies, and lactating bitches after whelping*—(A) *Amount*. 2.27 mg/lb body weight.

(B) *Indications for use*. To prevent reinfections of *T. canis*.

(C) *Limitations*. Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals.

[67 FR 43248, June 27, 2002, as amended at 68 FR 54803, Sept. 19, 2003; 68 FR 55199, Sept. 23, 2003; 68 FR 55825, Sept. 29, 2003]