

§ 520.2043

21 CFR Ch. I (4–1–01 Edition)

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)(1) *Specifications.* Pyrantel pamoate suspension contains pyrantel pamoate equivalent to 50 milligrams of pyrantel base per milliliter.

(2) *Sponsors.* See Nos. 000069 and 059130 in § 510.600(c) of this chapter.

(3) *Conditions of use.* It is used in horses and ponies as follows:

(i) *Amount.* Equivalent of 3 milligrams pyrantel base per pound of body weight.

(ii) *Indications for use.* For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris*, *Strongylus edentatus*, *Strongylus equinus*), small strongyles, pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(iii) *Limitations.* Administered as a single dose mixed with the usual grain ration, or by stomach tube, or by dose syringe. 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." When the drug is not for administration by stomach tube, it shall be labeled: "Consult your veterinarian for assistance in the diagnosis, control, and treatment of parasitism."

(b)(1) *Specifications.* Pyrantel pamoate suspension contains pyrantel pamoate equivalent to 2.27 or 4.54 milligrams of pyrantel base per milliliter.

(2) *Sponsors.* See Nos. 000069, 011615, and 059130 for use of 2.27 and 4.54 milligrams per milliliter product. See No. 023851 for use of 4.54 milligrams per milliliter product.

(3) *Conditions of use.* It is used in puppies and dogs as follows:

(i) *Amount.* Equivalent of 2.27 milligrams of pyrantel base per pound of body weight.

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

(iii) *Limitations.* Administer in the animal's feed bowl as a single dose by itself or mixed in a small quantity of food. Additional treatment may be required and should be confirmed by fecal examination within 2 to 4 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

(4) *Conditions of use.* It is used in puppies and adult dogs and in lactating bitches after whelping as follows:

(i) *Amount.* Equivalent to 2.27 milligrams of pyrantel base per pound of body weight.

(ii) *Indications for use.* To prevent reinfections of *Toxocara canis*.

(iii) *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. Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism.

[42 FR 28534, June 3, 1977, as amended at 44 FR 36381, June 22 1979; 45 FR 10760, Feb. 19, 1980; 47 FR 16776, Apr. 20, 1982; 51 FR 11440, Apr. 3, 1986; 61 FR 29477, June 11, 1996; 61 FR 63712, Dec. 2, 1996; 62 FR 37712, July 15, 1997; 63 FR 39727, July 24, 1998; 63 FR 45945, Aug. 28, 1998]

§ 520.2044 Pyrantel pamoate paste.

(a) *Specifications.* Each milliliter of paste contains 180 milligrams of pyrantel base (as pyrantel pamoate).

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used in horses and ponies as follows:

(1) *Amount.* Equivalent of 3 milligrams pyrantel base per pound of body weight.

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

(3) *Limitations.* Administer as single dose by depositing paste on dorsum of

the tongue using the dose syringe. Not for use in horses intended for food. It is recommended that severely debilitated animals not be treated with this preparation. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[47 FR 47377, Oct. 26, 1982; 48 FR 3367, Jan. 25, 1983]

§ 520.2045 Pyrantel tartrate powder; pyrantel tartrate pellets.

(a) *Specifications.* (1) Pyrantel tartrate powder horse wormer contains 11.3 percent and swine wormer 10.6 percent pyrantel tartrate.

(2) Pyrantel tartrate pellets colt and horse wormer contains 1.25 percent pyrantel tartrate.

(b) *Sponsor.* (1) See No. 000069 in § 510.600(c) of this chapter for conditions of use provided for in paragraphs (d) (1) and (2) of this section.

(2) See No. 060594 in § 510.600(c) of this chapter, for conditions of use provided for in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.560 of this chapter.

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

(i) For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris*, *Strongylus edentatus*, *Strongylus equinus*), small strongyles (*Trichonema spp.*, *Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted ration. The ration is ad-

ministered as a single treatment as the sole ration at the rate of 1 pound per 40 pounds of animal weight for animals up to 200 pounds. Animals 200 pounds and over are administered 5 pounds of ration per animal.

(iii) Fast pigs over night for optimum results. Water should be made available to animals during fasting and treatment periods. Consult veterinarian before using in severely debilitated animals. The drug should be used immediately after the package is opened.

(iv) Warning: Do not treat within 24 hours of slaughter.

(3) Horses and colts:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris*, *Strongylus edentatus*, *Strongylus equinus*), small strongyles (*Trichonema spp.*, *Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(ii) It is administered as a single dose at 12.5 milligrams of pyrantel tartrate per 2.2 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug.

(iv) Warning: Do not use in horses or colts intended for food.

[40 FR 13838, Mar. 27, 1975, as amended at 59 FR 28769, June 3, 1994]

§ 520.2087 Roxarsone soluble powder.

(a) *Specifications.* Each ounce (avoirdupois) of soluble powder contains 21.7 grams of roxarsone (monosodium 3-nitro-4-hydroxyphenylarsonate).

(b) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.60 of this chapter.

(d) *NAS/NRC status.* These conditions of use are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(e) *Conditions of use—(1) Growing chickens and growing turkeys—(i) Amount.* 0.002 percent roxarsone in drinking water (one packet per each 250 gallons of drinking water).