§ 520.182 Bicyclohexylammonium fumagillin.

(a) *Specifications.* The drug is a soluble powder containing bicyclohexylammonium fumagillin and appropriate phosphate buffers.

(b) *Sponsor.* See No. 059620 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the prevention of nosema in honey bees.[1]

(2) It is administered usually in a 2:1 sugar sirup containing a concentration of from 75 to 100 milligrams of fumagillin activity per gallon of sugar sirup.[1]

(3) Colonies used for package production should be fed medicated sirup as a principal food supply for a month prior to stocking nuclei or shaking packages for market.[1]

(4) The medicated sirup should not be fed immediately before or during the honey flow.

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 65151, Dec. 30, 1977; 56 FR 43699, Sept. 4, 1991; 58 FR 5608, Jan. 22, 1993]

§ 520.222 Bunamidine hydrochloride.

(a) *Chemical name.* *N*,*N*-Dibutyl-4-(hexyloxy)-1-naphthamidine hydrochloride.

(b) *Specifications.* The drug is an oral tablet containing 100, 200, or 400 milligrams of bunamidine hydrochloride.

(c) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) The drug is intended for oral administration to dogs for the treatment of the tapeworms *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*, and to cats for the treatment of the tapeworms *Dipylidium caninum* and *Taenia taeniaeformis*.

(2) It is administered to cats and dogs at the rate of 25 to 50 milligrams per kilogram of body weight. The drug should be given on an empty stomach and food should not be given for 3 hours following treatment.

(3) Tablets should not be crushed, mixed with food, or dissolved in liquid. Repeat treatments should not be given within 14 days. The drug should not be given to male dogs within 28 days prior to their use for breeding. Do not administer to dogs or cats having known heart conditions.

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

[40 FR 13838, Mar. 27, 1975, as amended at 42 FR 13018, Mar. 8, 1977; 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61624, Nov. 19, 1997]

§ 520.246 Butorphanol tartrate tablets.

(a) *Specifications.* Each tablet contains 1, 5, or 10 milligrams of butorphanol base activity as butorphanol tartrate.

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

(c) *Conditions of use.* The drug is used for the treatment of dogs as follows:

(1) *Amount.* 0.25 milligram of butorphanol base activity per pound of body weight.

(2) *Indications for use.* For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

(3) *Limitations.* For oral use in dogs only. Repeat at intervals of 6 to 12 hours as required. If necessary, increase dose to a maximum of 0.5 milligram per pound of body weight. Treatment should not normally be required for longer than 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 14702, Apr. 6, 1982, as amended at 53 FR 27851, July 25, 1988]

§ 520.260 *n*-Butyl chloride capsules.

(a)(1) *Specifications.* *n*-Butyl chloride capsules, veterinary contain 272 milligrams or 816 milligrams of *n*-butyl chloride in each capsule.

(2) *Sponsor.* See No. 021091 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) from dogs and of the ascarid (*Toxocara*

[1] 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.

cati) and hookworm (*Ancylostoma tubaeforme*) from cats.

(ii)(*a*) Animals should not be fed for 18 to 24 hours before being given the drug. Puppies and kittens should be wormed at 6 weeks of age. However, if heavily infested, they may be wormed at 4 or 5 weeks of age. Administration of the drug should be followed in ½ to 1 hour with a teaspoonful to a tablespoonful of milk of magnesia or 1 or 2 milk of magnesia tablets. Normal rations may be resumed 4 to 8 hours after treatment. Puppies and kittens should be given a repeat treatment in a week or 10 days. After that they should be treated every 2 months (or as symptoms reappear) until a year old. When the puppy or kitten is a year old, one treatment every 3 to 6 months is sufficient.

(*b*) For dogs or cats that have been wormed regularly, treatment every 3 to 6 months will be sufficient. If a dog or cat has not been wormed previously and has the symptoms of large roundworms a dose should be given and repeated in 10 days. Removal of hookworms may require 3 or 4 doses at 10-day intervals.

(*c*) Puppies, dogs, cats, or kittens weighing 1 to 3 pounds should be given 2 capsules per dose which contain 272 milligrams of *n*-butyl chloride each. Such animals weighing 4 to 5 pounds should be given 3 such capsules. Animals weighing 6 to 7 pounds should be given 4 such capsules and animals weighing 8 to 9 pounds should be given 5 such capsules. Animals weighing 10 to 20 pounds should be given 3 capsules which contain 816 milligrams of *n*-butyl chloride each, animals weighing 20 to 40 pounds should be given 4 such capsules and animals weighing over 40 pounds should be given 5 such capsules with the maximum dosage being 5 capsules, each of which contains 816 milligrams of *n*-butyl chloride.

(iii) A veterinarian should be consulted before using in severely debilitated dogs or cats and also prior to repeated use in cases which present signs of persistent parasitism.

(b)(1) *Specifications.* *n*-Butyl chloride capsules contain 221, 442, 884, or 1,768 milligrams or 4.42 grams of *n*-butyl chloride in each capsule.[1]

(2) *Sponsors.* See No. 023851 in § 510.600(c) of this chapter for 221, 442, 884, or 1,768 milligram or 4.42 gram capsules; No. 000115 or 038782 for 884 or 1,768 milligram or 4.42 gram capsules; and No. 000069 for 221 milligram capsules.

(3) *Conditions of use.* (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) from dogs.[1]

(ii)(*a*) Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal feeding may be resumed 4 to 8 hours after treatment. Animals subject to reinfection may be retreated in 2 weeks.[1]

(*b*) The drug is administered orally to dogs. Capsules containing 221 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 1¼ pound of body weight. Capsules containing 442 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 2½ pounds body weight. Capsules containing 884 milligrams of *n*-butyl chloride are administered to dogs as follows: Weighing under 5 pounds, 1 capsule; weighing 5 to 10 pounds, 2 capsules; weighing 10 to 20 pounds, 3 capsules; weighing 20 to 40 pounds, 4 capsules; over 40 pounds, 5 capsules. Capsules containing 1,768 milligrams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 5 to 10 pounds. Capsules containing 4.42 grams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 40 pounds or over.[1]

(iii) A veterinarian should be consulted before using in severely debilitated dogs.[1]

(c)(1) *Specifications.* *n*-Butyl chloride capsules, veterinary contain 884 or 1,768 milligrams or 4.42 grams of *n*-butyl chloride in each capsule.

[1] 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.

(2) *Sponsor*. See No. 000115 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) It is used for the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancyclostoma caninum*, *Ancyclostoma braziliense*, and *Uncinaria stenocephala*) from dogs.

(ii)(*a*) Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal rations may be resumed 4 to 8 hours after treatment.

(*b*) The drug is administered orally to dogs. Capsules containing 884 milligrams of *n*-butyl chloride are administered to dogs as follows: weighing under 5 pounds, 1 capsule; weighing 5–10 pounds, 2 capsules; weighing 10–20 pounds, 3 capsules; weighing 20–40 pounds, 4 capsules; over 40 pounds, 5 capsules. Capsules containing 1,768 milligrams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dogs to dogs weighing 5–10 pounds and 2 capsules per dog to dogs weighing 20–40 pounds. Capsules containing 4.42 grams of *n*-butyl chloride are administered at dosage level of 1 capsule per dog to dogs weighing 40 pounds or over.

(iii) A veterinarian should be consulted before using in severely debilitated dogs.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39858, Aug. 29, 1975; 44 FR 10059, Feb. 16, 1979; 54 FR 38515, Sept. 19, 1989; 55 FR 24556, June 18, 1990; 64 FR 15684, Apr. 1, 1999]

§ 520.300 Cambendazole oral dosage forms.

§ 520.300a Cambendazole suspension.

(a) *Specifications*. Each fluid ounce contains 0.9 gram of cambendazole.

(b) *Sponsor*. No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is used in horses for the control of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); small strongyles (*Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus*); roundworms (*Parascaris*); pinworms. (*Oxyuris*); and threadworms (*Strongyloides*).

(2) It is administered by stomach tube or as a drench at a dose of 0.9 gram of cambendazole per 100 pounds of body weight (20 milligrams per kilogram).

(3) For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

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

[40 FR 13838, Mar. 27, 1975. Redesignated at 41 FR 1276, Jan. 7, 1976, and amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997]

§ 520.300b Cambendazole pellets.

(a) *Specifications*. The drug is in feed pellets containing 5.3 percent cambendazole.

(b) *Sponsor*. No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) It is used in horses for the control of large strongyles (*Strongylus vulgaris, S. edentatus, S. equinus*); small strongyles (*Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(2) Administer 20 milligrams cambendazole per kilogram body weight (6 ounces per 1,000 pounds) by mixing with normal grain ration given at one feeding. Doses for individual horses should be mixed and fed separately to assure that each horse will consume the correct amount.

(3) For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

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

[41 FR 1276, Jan. 7, 1976, as amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997]