

§ 520.182

21 CFR Ch. I (4–1–10 Edition)

(d) *Conditions of use*—(1) *Broiler chickens*—(i) *Amount*. 100 milligrams per gallon in drinking water.

(A) *Indications for use*. Prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations*. Prepare a fresh solution daily.

(ii) *Amount*. 200 to 400 milligrams per gallon in drinking water.

(A) *Indications for use*. Control of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin zinc.

(B) *Limitations*. Prepare a fresh solution daily.

(2) *Growing quail*—(i) *Amount*. 500 milligrams per gallon in drinking water for 5 days followed by 165 milligrams per gallon in drinking water for 10 days.

(ii) *Indications for use*. Control of ulcerative enteritis caused by *Clostridium* spp. susceptible to bacitracin zinc.

(iii) *Limitations*. Prepare a fresh solution daily.

[57 FR 37322, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002]

§ 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

¹These 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.

(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 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. 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

¹These 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.