

§ 520.622b

21 CFR Ch. I (4–1–02 Edition)

(ii) Three milligrams per pound of body weight daily as an aid in the control of ascarid infections (*Toxocara canis*) in dogs.

(iii) Twenty-five to 50 milligrams per pound of body weight as an aid in the treatment of ascarid infections in dogs (*Toxocara canis*) and cats (*Toxocara canis* and *Toxascaris leonina*).

(2) *Limitations.* Administer orally either pulverized and given in feed or water or directly by mouth. For the treatment of ascarid infections, repeat in 10 to 20 days to remove immature worms that may enter the intestine from the lungs after the first dose. Do not treat dogs with established heartworm infections until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions because of pulmonary occlusion. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should start at the beginning of mosquito activity and be continued daily throughout the mosquito season and for approximately a month thereafter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 23230, Apr. 24, 1981, as amended at 46 FR 41038, Aug. 14, 1981; 46 FR 46315, Sept. 18, 1981; 46 FR 61653, Dec. 18, 1981; 47 FR 10805, Mar. 12, 1982; 47 FR 14150, Apr. 2, 1982; 50 FR 41489, Oct. 11, 1985; 50 FR 49372, Dec. 2, 1985; 53 FR 40056, Oct. 13, 1988; 53 FR 40727, Oct. 18, 1988; 55 FR 8461, Mar. 8, 1990; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001]

§ 520.622b Diethylcarbamazine citrate syrup.

(a)(1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is indicated for use in dogs for the prevention of infection with *Dirofilaria immitis* and *T. canis* and *T. leonina*. It is also indicated for treatment of ascarid infections of *T. canis* and *T. leonina* in dogs and *T. cati* in cats.

(ii) For prevention of heartworm and ascarid infections in dogs, the drug may be added to the daily diet at a dos-

age rate of 3.0 milligrams per pound of body weight per day or given directly by mouth at the same dosage rate. For treatment of ascarid infections in dogs and cats, the drug is administered at a dosage level of 25 to 50 milligrams per pound of body weight preferably administered immediately after feeding.

(iii) Older dogs should be proven negative for the presence of *Dirofilaria immitis* infection before administration of the drug. Those with proven infection of *Dirofilaria immitis* should be rendered negative using adulticidal and microfilaricidal drugs before administration of this drug.

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

(b)(1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsors.* (i) See No. 017030 for use as in paragraphs (b)(3)(ii)(a) and (b)(3)(ii)(c) of this section.

(ii) See No. 017030 for use as in paragraphs (b)(3)(ii) (a) and (c) of this section.

(3) *Conditions of use*—(i) *Amount.* 3 milligrams per pound of body weight per day for prevention of heartworm disease and as an aid in control of large roundworms; 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.

(ii) *Indications for use.* (a) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(b) As an aid in control of large roundworms (*T. canis*) in dogs.

(c) As an aid in treatment of ascarid infections in dogs (*T. canis*) and cats (*T. canis* and *T. leonina*).

(iii) *Limitations.* The drug may be placed on the daily ration or given directly by mouth. For treatment of ascarid infections, a repeat dose should be given in 10 to 20 days to remove immature worms which may enter the intestine from the lungs after the first dose. Older dogs should be proven negative for presence of *Dirofilaria immitis* infections before administering the drug. Dogs with established heartworm infections should not receive the drug until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs.

Inadvertent administration to heartworm-infected dogs may cause adverse reactions due to pulmonary occlusion. Overdosage may cause emesis. For prevention of heartworm disease in heartworm-endemic areas, administration of the drug should start 1 month before the mosquito season and be continued daily throughout the mosquito season and for 2 months thereafter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter of syrup contains 60 milligrams of diethylcarbamazine citrate.

(2) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is used in dogs between 4 weeks and 8 months of age for the removal of ascarids (*Toxocara canis*) and in animals over 4 weeks of age for the prevention of heartworm disease (*Dirofilaria immitis*).

(ii) The drug is administered (a) for removal of ascarids at a dosage of 50 milligrams per pound of body weight divided into two equal doses and administered 8 to 12 hours apart (morning and night), orally or mixed with either dry or wet food, and (b) for prevention of heartworm disease at a dosage of 3 milligrams per pound of body weight daily, orally or in food, in heartworm endemic areas, from the beginning of mosquito activity, during the mosquito season, and for 2 months following the end thereof.

(iii) Dogs older than 8 months of age may be infected with *Dirofilaria immitis*. Use of the drug is contraindicated in dogs with active *D. immitis* infections.

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

[40 FR 13838, Mar. 27, 1975, as amended at 41 FR 28265, July 9, 1976; 44 FR 3967, Jan. 19, 1979; 47 FR 14150, Apr. 2, 1982; 47 FR 35186, Aug. 13, 1982; 49 FR 33997, Aug. 28, 1984; 50 FR 41489, Oct. 11, 1985; 53 FR 47027, Oct. 18, 1988; 61 FR 34728, July 3, 1996; 62 FR 35076, June 30, 1997; 62 FR 38906, July 21, 1997]

§ 520.622c Diethylcarbamazine citrate chewable tablets.

(a) *Specifications.* Each chewable tablet contains 30, 45, 60, 120, 150, or 180 milligrams of diethylcarbamazine citrate.

(b) *Sponsors.* See drug listing nos. in § 510.600(c) of this chapter for identification of sponsors as follows:

(1) For 015579, use of 30 or 120 milligram tablets as in paragraph (c)(2)(i) of this section.

(2) For 000069, use of 60, 120, or 180 milligram tablets as in paragraph (c)(2)(ii) of this section.

(3) For 061690, use of 45 or 150 milligram tablets as in paragraph (c)(2)(iii) of this section.

(4) For 061133, use of 60-, 120-, or 180-milligram tablets as in paragraph (c)(2)(i) of this section.

(5) For 000061, use of 60-milligram tablets as in paragraph (c)(2)(i) of this section.

(6) For 000010, use of 30, 60, 120, or 180 milligram tablets as in paragraph (c)(2)(i) of this section.

(7) [Reserved]

(c) *Conditions of use*—(1) *Amount.* 3 milligrams per pound of body weight per day for prevention of heartworm disease and control of ascarids; 25 to 50 milligrams per pound of body weight as an aid in treatment of ascarid infections.

(2) *Indications for use.* (i) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs; as an aid in control of ascarids (*Toxocara canis*) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs and cats.

(ii) For prevention of infection with *Dirofilaria immitis* (heartworm disease) in dogs; as an aid in treatment of ascarid (*Toxocara canis* and *Toxascaris leonina*) infections in dogs.

(iii) For prevention of heartworm disease (*Dirofilaria immitis*) in dogs.

(3) *Limitations.* Tablets are administered orally or pulverized and given in the feed. For treatment of ascarid infections, a repeat dose should be given in 10 to 20 days to remove immature worms which may enter the intestine from the lungs after the first dose. Dogs with established heartworm infections should not receive the drug until they have been converted to a negative status by the use of adulticidal and microfilaricidal drugs. Inadvertent administration to heartworm-infected dogs may cause adverse reactions due to pulmonary occlusion. Overdosage may cause emesis. For prevention of