

due to susceptible strains of *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum*, and *Clostridium perfringens*; dental infections due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*; and osteomyelitis due to susceptible strains of *S. aureus*, *B. fragilis*, *P. melaninogenicus*, *F. necrophorum*, and *C. perfringens*.

(2) Cats—(i) *Amount*. 5.0 to 15.0 mg/lb body weight every 24 hours for a maximum of 14 days.

(ii) *Indications for use*. For the treatment of skin infections (wounds and abscesses) due to susceptible strains of *Staphylococcus aureus*, *S. intermedius*, *Streptococcus spp.*; deep wounds and abscesses due to susceptible strains of *Clostridium perfringens* and *Bacteroides fragilis*; and dental infections due to susceptible strains of *S. aureus*, *S. intermedius*, *Streptococcus spp.*, *C. perfringens*, and *B. fragilis*.

[67 FR 54954, Aug. 27, 2002, as amended at 67 FR 78684, Dec. 26, 2002; 68 FR 55824, Sept. 29, 2003; 69 FR 31734, June 7, 2004; 71 FR 39543, July 13, 2006; 72 FR 19796, Apr. 20, 2007]

§ 520.452 Clenbuterol syrup.

(a) *Specifications*. Each milliliter contains 72.5 micrograms of clenbuterol hydrochloride.

(b) *Sponsor*. See 000010 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. Administer orally twice a day (b.i.d.). Initial dose is 0.5 milliliter per 100 pounds body weight (0.8 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1 milliliter per 100 pounds (1.6 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 1.5 milliliters per 100 pounds (2.4 micrograms per kilogram) for 3 days (6 treatments). If no improvement, administer 2.0 milliliters per 100 pounds (3.2 micrograms per kilogram) for 3 days (6 treatments). If no improvement, horse is non-responder to clenbuterol and treatment should be discontinued.

(ii) *Indications for use*. Indicated for the management of horses affected with airway obstruction, such as occurs in chronic obstructive pulmonary disease (COPD).

(iii) *Limitations*. Treat at effective dose for 30 days. At the end of the 30-day treatment period, drug should be withdrawn. If signs return, the 30-day treatment period may be repeated. If repeating treatment, the step-wise dosage schedule should be repeated. The effect of this drug on breeding stallions and brood mares has not been determined. Treatment starting with dosages higher than the initial dose is not recommended. Federal law prohibits the extralabel use of this drug in food animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 41419, Aug. 4, 1998]

§ 520.455 Clomipramine tablets.

(a) *Specifications*. Each tablet contains 5, 20, 40, or 80 milligrams (mg) clomipramine hydrochloride.

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. 2 to 4 milligrams of clomipramine hydrochloride per kilogram (0.9 to 1.8 milligrams per pound) of body weight per day, administered as a single daily dose or divided twice daily.

(2) *Indications for use*. For use as part of a comprehensive behavioral management program to treat separation anxiety in dogs greater than 6 months of age.

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

[64 FR 1762, Jan. 12, 1999, as amended at 72 FR 262, Jan. 4, 2007]

§ 520.462 Clorsulon drench.

(a) *Specifications*. The drug is a suspension containing 8.5 percent clorsulon (85 milligrams per milliliter).

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

(c) *Conditions of use*. *Cattle*—(1) *Amount*. One-quarter fluid ounce per 200 pounds of body weight (7 milligrams per kilogram or 3.2 milligrams per pound of body weight).

(2) *Indications for use*. For the treatment of immature and adult liver fluke (*Fasciola hepatica*) infestations in cattle.

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(3) *Limitations.* Using dose syringe, deposit drench over back of tongue. Do not treat cattle within 8 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[50 FR 10221, Mar. 14, 1985, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.522 Cyclosporine.

(a) *Specifications*—(1) Each cyclosporine capsule, USP (MODIFIED) contains 10, 25, 50, or 100 milligrams (mg) cyclosporine.

(2) Each milliliter of cyclosporine oral solution, USP (MODIFIED) contains 100 mg cyclosporine.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs.* Use capsules described in paragraph (a)(1) of this section as follows:

(i) *Amount.* Administer 5 mg per kilogram (mg/kg) of body weight given orally as a single daily dose for 30 days. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or two times a week, until a minimum frequency is reached which will maintain the desired therapeutic effect.

(ii) *Indications for use.* For the control of atopic dermatitis in dogs weighing at least 4 pounds.

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

(2) *Cats.* Use the solution described in paragraph (a)(2) of this section as follows:

(i) *Amount.* Administer 7 mg/kg of body weight orally as a single daily dose for a minimum of 4 to 6 weeks or until resolution of clinical signs. Following this initial daily treatment period, the dosage may be tapered by decreasing the frequency of administration to every other day or twice weekly to maintain the desired therapeutic effect.

(ii) *Indications for use.* For the control of feline allergic dermatitis in cats at least 6 months of age and weighing at least 3 pounds.

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

[68 FR 54804, Sept. 19, 2003, as amended at 76 FR 78815, Dec. 20, 2011]

§ 520.530 Cythioate oral liquid.

(a) *Specifications.* Each milliliter contains 15 milligrams of cythioate.

(b) *Sponsor.* See Nos. 000859 and 053501 in § 510.600 of this chapter.

(c) *Special considerations.* Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use*—(1) *Amount.* 15 milligrams cythioate per 10 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

(3) *Limitations.* For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under stress, or recovering from surgery. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[49 FR 5614, Feb. 14, 1984, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.531 Cythioate tablets.

(a) [Reserved]

(b) *Sponsors.* See No. 000859 in § 510.600(c) of this chapter for use of 30- and 90-milligram (mg) tablets and see No. 053501 in § 510.600(c) of this chapter for use of 30-mg tablet.

(c) *Special considerations.* Cythioate is a cholinesterase inhibitor. Do not use this product in animals simultaneously with or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, insecticides, pesticides, or chemicals.

(d) *Conditions of use*—(1) *Amount.* 30 milligrams cythioate per 20 pounds of body weight every third day or twice a week.

(2) *Indications for use.* Dogs, for control of fleas.

(3) *Limitations.* For oral use in dogs only. Do not use in greyhounds or in animals that are pregnant, sick, under