

culturing and susceptibility tests on samples collected prior to treatment. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis. Not for animals that are raised for food production. Chloramphenicol products should not be administered in conjunction with or 2 hours prior to the induction of general anesthesia with pentobarbital because of prolonged recovery. Chloramphenicol should not be administered to dogs maintained for breeding purposes. Because of potential antagonism, chloramphenicol should not be administered simultaneously with penicillin or streptomycin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37323, Aug. 18, 1992, as amended at 62 FR 35076, June 30, 1997; 66 FR 14073, Mar. 9, 2001; 68 FR 4914, Jan. 31, 2003]

§ 520.390b Chloramphenicol capsules.

(a) *Specifications.* Each capsule contains 50, 100, 250, or 500 milligrams (mg) chloramphenicol.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) Nos. 000069 and 050057 for capsules containing 50, 100, 250, or 500 mg chloramphenicol.

(2) No. 058034 for capsules containing 100 or 250 mg chloramphenicol.

(c) *Special considerations.* Federal law prohibits the extralabel use of this product in food-producing animals.

(d) *Conditions of use in dogs—(1) Amount.* 25 mg per pound of body weight every 6 hours.

(2) *Indications for use.* For treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

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

[70 FR 75398, Dec. 20, 2005, as amended at 73 FR 18442, Apr. 4, 2008]

§ 520.390c Chloramphenicol palmitate oral suspension.

(a) *Specifications.* Each milliliter contains chloramphenicol palmitate equivalent to 30 milligrams of chloramphenicol.

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

(c) *Conditions of use. Dogs—(1) Amount.* 25 milligrams per pound of body weight every 6 hours. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.

(2) *Indications for use.* Treatment of bacterial pulmonary infections, infections of the urinary tract, enteritis, and infections associated with canine distemper that are caused by organisms susceptible to chloramphenicol.

(3) *Limitations.* Not for use in animals that are raised for food production. Must not be used in meat-, egg-, or milk-producing animals. The length of time that residues persist in milk or tissues has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37323, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 520.420 Chlorothiazide tablets and boluses.

(a)(1) *Specifications.* Each tablet contains 0.25 gram of chlorothiazide.

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

(3) *Conditions of use—(i) Amount.* Usual dosage is 5 to 10 milligrams per pound of body weight two or three times daily.¹

(ii) *Indications for use.* For use in dogs for treatment of congestive heart failure and renal edema.¹

(iii) *Limitations. (a) Dosage* must be adjusted to meet the changing needs of the individual animal. In mild and responsive cases, it is suggested that a dose of 5 milligrams per pound of body weight be administered two or three times daily. In moderately edematous and moderately responsive animals, a dose of 7.5 to 10 milligrams per pound of body weight may be administered three times daily. Severe conditions may require higher doses. Certain animals may respond adequately to intermittent therapy; in these cases, the

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.

§ 520.434

21 CFR Ch. I (4–1–10 Edition)

drug may be administered either every other day or for 3 to 5 days each week.

(b) Animals should be regularly and carefully observed for early signs of fluid and electrolyte imbalance. Take appropriate countermeasures if this should occur. In some dogs, hypochloremic alkalosis may occur (that is, excretion of chloride in relation to sodium is excessive; the plasma bicarbonate level increases and alkalosis results). Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

(b)(1) *Specifications.* Each bolus contains 2 grams of chlorothiazide.

(2) *Sponsor.* See No. 000006 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* 2 grams once or twice daily for 3 or 4 days.¹

(ii) *Indications for use.* For use in cattle as an aid in reduction of postparturient udder edema.¹

(iii) *Limitations.* Animals should be regularly and carefully observed for early signs of fluid and electrolyte imbalance. Take appropriate countermeasures if this should occur. Milk taken from dairy animals during treatment and for 72 hours (six milkings) after latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[43 FR 39085, Sept. 1, 1978, as amended at 62 FR 63270, Nov. 28, 1997]

§ 520.434 Chlorphenesin carbamate tablets.

(a) *Specifications.* Each tablet contains 400 milligrams of chlorphenesin carbamate.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 50 milligrams per pound of body weight on first day; 25 milligrams per pound of body weight each following day. Divide total daily dose into 2 or 3 equal doses—administer at 12- or 8-hour intervals.

(2) *Indications for use.* For use as an adjunct to therapy of acute inflammatory and traumatic conditions of skeletal muscles. The drug provides relief of the signs of discomfort associated with myositis, muscle sprains, traumatic injuries, stifle injuries—es-

pecially when administered before or after surgery—and vertebral disc syndrome (can be used concurrently with adrenal corticosteroids).

(3) *Limitations.* Not recommended for pregnant animals or those with a known hepatic dysfunction. Periodic liver function studies are recommended for animals on prolonged treatment. If no response is evident within 5 days of the beginning of treatment, the diagnosis should be redetermined and appropriate therapy instituted. Not recommended for use with general anesthetics other than the barbiturates. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 16009, Mar. 16, 1979]

§ 520.445 Chlortetracycline oral dosage forms.

§ 520.445a Chlortetracycline bisulfate/sulfamethazine bisulfate soluble powder.

(a) *Specifications.* Each pound contains chlortetracycline bisulfate equivalent to 102.4 grams of chlortetracycline hydrochloride with sulfamethazine bisulfate equivalent to 102.4 grams of sulfamethazine.

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

(c) *Related tolerances.* See §§ 556.150 and 556.670 of this chapter.

(d) *Conditions of use. Swine*—Used in drinking water as follows:

(1) *Amount.* 250 milligrams of chlortetracycline with 250 milligrams of sulfamethazine per gallon.

(2) *Indications for use.* Prevention and treatment of bacterial enteritis; aid in the reduction of the incidence of cervical abscesses; aid in the maintenance of weight gains in the presence of bacterial enteritis and atrophic rhinitis.

(3) *Limitations.* Not to be used for more than 28 consecutive days; withdraw 15 days before slaughter; as sole source of chlortetracycline and sulfonamide.

[57 FR 37323, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002]