cellulitis, and dermatitis caused by susceptible strains of *Pasteurella multocida*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, and *Streptococcus* spp.

(ii) *Amount*. 10 milligrams per pound of body weight, once daily.

(3) *Limitations*. Discard unused portion of reconstituted product after 14 days. Treatment should continue for 48 hours after animal is afebrile or asymptomatic. If no response after 3 days, discontinue treatment and reevaluate therapy. Not for use in animals raised for food production. Safe use in pregnant or breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[53 FR 27344, July 20, 1988]

§ 520.370 Cefpodoxime tablets.

(a) *Specifications*. Each tablet contains cefpodoxime proxetil equivalent to 100 or 200 milligrams (mg) cefpodoxime.

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

(c) *Conditions of use in dogs*—(1) *Amount*. 5 to 10 mg per kilogram (2.3 to 4.5 mg per pound) body weight daily for 5 to 7 days, or for 2 to 3 days beyond the cessation of clinical signs, up to a maximum of 28 days.

(2) *Indications for use*. For the treatment of skin infections (wounds and abscesses) caused by susceptible strains of *Staphylococcus intermedius*, *S. aureus*, *Streptococcus canis* (group G, -hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

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

[69 FR 52815, Aug. 30, 2004]

§ 520.390 Chloramphenicol oral dosage forms.

§ 520.390a Chloramphenicol tablets.

(a)(1) *Specifications*. Each tablet contains 100, 250, or 500 milligrams, 1 or 2.5 grams of chloramphenicol.

(2) *Sponsor*. In § 510.600(c) of this chapter: No. 000010 for 100-, 250-, and 500-milligram and 1-gram tablets; No. 000856 for 100-, 250-. and 500-milligram tablets; No. 017030 for 100-milligram tablets; No. 000010 for 100-, 250-, and 500-milligram and 1- and 2.5-gram tablets; No. 000069 for 250-milligram tablets.

(3) *Conditions of use*. *Dogs*—(i) *Amount*. 25 milligrams per pound of body weight every 6 hours.

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

(iii) *Limitations*. Laboratory tests should be conducted, including in vitro culturing and susceptibility tests on samples collected prior to treatment. If no response to chloramphenicol therapy is obtained in 3 to 5 days, discontinue its use and review diagnosis. Not for animals which are raised for food production. Chloramphenicol products 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. 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.

(b)(1) *Specifications*. Each tablet contains 50, 100, 250, or 500 milligrams, or 1 gram of chloramphenicol.

(2) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use*. *Dogs*—(i) *Amount*. 25 milligrams per pound of body weight every 6 hours.

(ii) *Indications for use*. Oral treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.

(iii) *Limitations*. Laboratory tests should be conducted, including in vitro 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, 000185, 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]

§ 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 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]

[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.