

**§ 520.434**

**21 CFR Ch. I (4-1-13 Edition)**

pound of body weight two or three times daily.<sup>1</sup>

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

(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.<sup>1</sup>

(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.<sup>1</sup>

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

(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

<sup>1</sup>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.

drug to use by or on the order of a licensed veterinarian.<sup>1</sup>

[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—especially 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]

**§ 520.441 Chlortetracycline powder.**

(a) *Specifications.* Chlortetracycline powder contains not less than 15 milligrams per gram chlortetracycline hydrochloride, or chlortetracycline bisulfate equivalent to 25.6, 64 or 102.4 grams per pound (56.4, 141 or 225.6 milligrams per gram) chlortetracycline hydrochloride.

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

(1) No. 048164 for use as in paragraph (d) of this section.

(2) Nos. 046573 and 000010 for use as in paragraph (d) of this section.

(3) No. 000010 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) through (d)(4)(iv) of this section. (d)(4)(ii) through (iv) of this section.

(4) Nos. 012286 and 076475 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), (d)(4)(ii), and (d)(4)(iii) of this section.

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

(d) *Conditions of use.* (1) Use as chlortetracycline hydrochloride in drinking water as follows:

(i) *Swine*—(A) *Amount.* Ten milligrams per pound of body weight daily in divided doses.

(1) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(2) *Limitations.* Prepare a fresh solution twice daily; as sole source of chlortetracycline; administer for not more than 5 days.

(B) [Reserved]

(ii) [Reserved]

(2) Use as chlortetracycline hydrochloride in a drench or drinking water as follows:

(i) *Calves*—(A) *Amount.* Ten milligrams per pound of body weight daily in divided doses.

(1) Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia (shipping fever) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; administer for not more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal.

(B) [Reserved]

(ii) [Reserved]

(3) [Reserved]

(4) The following uses of chlortetracycline hydrochloride or chlortetracycline bisulfate in drinking water or drench were reviewed by the National Academy of Sciences/National Research Council (NAS/NRC) and found effective:

(i) *Chickens*—(A) *Amount.* 200 to 400 milligrams per gallon.

(1) *Indications for use.* Control of infectious synovitis caused by *Mycoplasma synoviae*.

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens.

(B) *Amount.* 400 to 800 milligrams per gallon.

(1) *Indications for use.* Control of chronic respiratory disease and air-sac infections caused by *M. gallisepticum* and *E. coli*.

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens.

(C) *Amount.* One thousand milligrams per gallon.

(1) *Indications for use.* Control of mortality due to fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.

(2) *Limitations.* See paragraph (d)(4)(i)(A)(2) of this section.

(ii) *Growing turkeys*—(A) *Amount.* 400 milligrams per gallon.

(1) *Indications for use.* Control of infectious synovitis caused by *M. synoviae*.

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment.

(B) *Amount.* 25 milligrams per pound of body weight daily.

(1) *Indications for use.* Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment.

(iii) *Swine*—(A) *Amount*. 10 milligrams per pound body weight daily in divided doses.

(B) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations*. Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 5 days. For Nos. 000010 and 021930, do not slaughter animals for food within 5 days of treatment. For No. 000010, do not slaughter animals for food within 24 hours of treatment.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount*. 10 milligrams per pound daily in divided doses.

(B) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations*. Prepare fresh solution daily; use as a drench; as sole source of chlortetracycline; do not use for more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not use in lactating cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in prurminating calves; do not use in calves to be processed for veal.

(5) Use in a drench or drinking water as follows:

(i) *Chickens*—(A) *Amount*. 200 to 400 mg/gal, for 7 to 14 days.

(1) *Indications for use*. Control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.

(2) *Limitations*. Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 14 consecutive days; do not use in laying chickens; do not administer to chickens within 24 hours of slaughter.

(B) *Amount*. 400 to 800 mg/gal, for 7 to 14 days.

(1) *Indications for use*. Control of chronic respiratory disease (CRD) and air-sac infections caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.

(2) *Limitations*. As in paragraph (d)(5)(i)(A)(2) of this section.

(C) *Amount*. One thousand mg/gal, for 7 to 14 days.

(1) *Indications for use*. Control of mortality due to fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.

(2) *Limitations*. As in paragraph (d)(5)(i)(A)(2) of this section.

(ii) *Growing Turkeys*—(A) *Amount*. 400 mg/gal, for 7 to 14 days.

(1) *Indications for use*. Control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.

(2) *Limitations*. Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 14 consecutive days; do not administer to growing turkeys within 24 hours of slaughter.

(B) *Amount*. 25 mg/lb body weight daily, for 7 to 14 days.

(1) *Indications for use*. Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) susceptible to chlortetracycline.

(2) *Limitations*. As in paragraph (d)(5)(ii)(A)(2) of this section.

(iii) *Swine*—(A) *Amount*. 10 mg/lb body weight daily, for 3 to 5 days.

(B) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *A. pleuropneumoniae*, and *Klebsiella* spp. susceptible to chlortetracycline.

(C) *Limitations*. Prepare fresh solution daily; use as the sole source of chlortetracycline; do not use for more than 5 days; do not administer to swine within 24 hours of slaughter.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount*. 10 mg/lb body weight daily in divided doses, for 3 to 5 days.

(B) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp.,

*Histophilus* spp., and *Klebsiella* spp. susceptible to chlortetracycline.

(C) *Limitations.* Prepare fresh solution daily; use as a drench; use as the sole source of chlortetracycline; do not use for more than 5 days; do not administer to cattle within 24 hours of slaughter; do not use in lactating dairy cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating calves; do not use in calves to be processed for veal.

[57 FR 37324, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 61015, Nov. 19, 1993; 59 FR 39439, Aug. 3, 1994; 60 FR 26827, May 19, 1995; 60 FR 47052, Sept. 11, 1995; 62 FR 27691, May 21, 1997; 62 FR 35076, June 30, 1997; 62 FR 60656, Nov. 12, 1997; 64 FR 37673, July 13, 1999; 65 FR 10706, Feb. 29, 2000; 66 FR 35898, July 10, 2001; 67 FR 78355, Dec. 24, 2002; 69 FR 62406, Oct. 26, 2004; 72 FR 1174, Jan. 10, 2007; 72 FR 63987, Nov. 14, 2007; 73 FR 35340, June 23, 2008; 74 FR 62491, Nov. 30, 2009. Redesignated and amended at 76 FR 49649, Aug. 11, 2011; 77 FR 5700, Feb. 6, 2012]

#### § 520.443 Chlortetracycline tablets and boluses.

(a) *Specifications.* Each tablet/bolus contains 25, 250, or 500 milligrams (mg) chlortetracycline hydrochloride.

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

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

(d) *Conditions of use in calves*—(1) *Amount.* One 250 milligram bolus per 50 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Klebsiella* spp., and *Hemophilus* spp.

(ii) *Limitations.* Administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

(2) *Amount.* One 25 milligram tablet for each 5 pounds of body weight every 12 hours daily for 3 to 5 days.

(i) *Indications for use.* Control and treatment of bacterial enteritis

(scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations.* Administer tablet directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; when feeding milk or milk replacer, administration 1 hour before or 2 hours after feeding; do not administer within 24 hours of slaughter.

(3) *Amount.* One 500 milligram bolus per 100 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp., and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.

(ii) *Limitations.* Administer directly by mouth or crush and dissolve in water for drenching; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

[57 FR 37325, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002. Redesignated and amended at 76 FR 49649, Aug. 11, 2011]

#### § 520.445 Chlortetracycline and sulfamethazine powder.

(a) *Specifications.* Each pound of soluble powder contains chlortetracycline bisulfate equivalent to 102.4 grams (g) of chlortetracycline hydrochloride and sulfamethazine bisulfate equivalent to 102.4 g of sulfamethazine.

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

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

(d) *Conditions of use in swine.* Administer in drinking water as follows:

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

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