

§ 520.2345e

21 CFR Ch. I (4–1–11 Edition)

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

(1) No. 000069: 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(2) No. 000010: 25, 102.4, and 324 grams per pound as in paragraph (d) of this section.

(3) No. 046573: 25, 102.4, and 324 grams per pound as in paragraph (d) of this section.

(4) Nos. 054925, 057561, 059130, and 061623: 324 grams per pound as in paragraph (d) of this section.

(c) *Related tolerances*. See § 556.720 of this chapter.

(d) *Conditions of use*. It is administered in drinking water as follows:

(1) *Calves*—(i) *Amount*. 10 milligrams per pound of body weight per day in divided doses.

(ii) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp., susceptible to tetracycline.

(iii) *Limitations*. Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for No. 000010 and within 5 days of treatment for Nos. 046573, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Swine*—(i) *Amount*. 10 milligrams per pound of body weight per day in divided doses.

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

(iii) *Limitations*. Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for No. 000010 and within 4 days of treatment for Nos. 046573, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline.

(3) *Chickens*—(i) *Amount*. Chronic respiratory disease: 400 to 800 milligrams per gallon. Infectious synovitis: 200 to 400 milligrams per gallon.

(ii) *Indications for use*. Control of chronic respiratory disease (CRD or air-sac disease) caused by *Mycoplasma gallisepticum* and *E. coli*; control of infectious synovitis caused by *M. synoviae* susceptible to tetracycline.

(iii) *Limitations*. Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in chickens producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline.

(4) *Turkeys*—(i) *Amount*. For infectious synovitis: 400 milligrams per gallon. For complicating bacterial organisms associated with bluecomb (transmissible enteritis or coronaviral enteritis): 25 milligrams per pound of body weight per day.

(ii) *Indications for use*. Control of infectious synovitis caused by *M. synoviae*; control of bluecomb complicated by organisms sensitive to tetracycline.

(iii) *Limitations*. Administer for 7 to 14 days; do not slaughter for food within 4 days of treatment; not for use in turkeys producing eggs for human consumption; prepare a fresh solution daily; use as the sole source of tetracycline.

[59 FR 17693, Apr. 14, 1994, as amended at 59 FR 19133, Apr. 22, 1994; 62 FR 5319, Feb. 5, 1997; 62 FR 35076, June 30, 1997; 62 FR 46668, Sept. 4, 1997; 62 FR 55160, Oct. 23, 1997; 64 FR 37673, July 13, 1999; 67 FR 78355, Dec. 24, 2002; 70 FR 16934, Apr. 4, 2005; 70 FR 67353, Nov. 7, 2005; 71 FR 13542, Mar. 16, 2006; 75 FR 10166, Mar. 5, 2010; 75 FR 12981, Mar. 18, 2010; 76 FR 17338, Mar. 29, 2011]

§ 520.2345e Tetracycline oral liquid.

(a) *Specifications*. Each milliliter contains the equivalent of either 25 or 100 milligrams of tetracycline hydrochloride.

(b) *Sponsor*. See No. 000069, in § 510.600(c) of this chapter for use of 25 or 100 milligrams per milliliter liquid in dogs as in paragraph (c)(1) of this section; see No. 000009 in § 510.600(c) of this chapter for use of 100 milligrams per milliliter liquid in dogs and cats as in paragraph (c)(2).

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(ii) *Indications for use*. Treatment of infections caused by organisms sensitive to tetracycline hydrochloride, such as bacterial gastroenteritis due to *Escherichia coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(iii) *Limitations*. Administer orally; continue treatment until symptoms have subsided and the temperature is normal for 48 hours; not for use in animals which are raised for food production; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) *National Academy of Sciences/National Research Council (NAS/NRC) status*. These conditions were NAS/NRC reviewed and found 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.

(2) *Dogs and cats*—(i) *Amount*. 25 milligrams per pound of body weight per day in divided doses every 6 hours.

(ii) *Indications for use*. Treatment of infections caused by organisms susceptible to tetracycline hydrochloride, such as bacterial gastroenteritis due to *E. coli* and urinary tract infections due to *Staphylococcus* spp. and *E. coli*.

(iii) *Limitations*. Administer orally; continue treatment until the temperature has been normal for 48 hours; not for use in food-producing animals; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 520.2345f Tetracycline phosphate complex and sodium novobiocin capsules.

(a) *Specifications*. Each capsule contains the equivalent of 60 milligrams of tetracycline hydrochloride and 60 milligrams of novobiocin.

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

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 10 milligrams of each antibiotic per pound of body weight (1 capsule for each 6 pounds) every 12 hours.

(2) *Indications for use*. Treatment of acute or chronic canine respiratory in-

fections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli*.

(3) *Limitations*. Continue treatment for at least 48 hours after the temperature has returned to normal and all evidence of infection has disappeared. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 520.2345g Tetracycline hydrochloride and sodium novobiocin tablets.

(a) *Specifications*. Each tablet contains the equivalent of 60 milligrams of tetracycline hydrochloride and 60 milligrams of novobiocin, or 180 milligrams of tetracycline hydrochloride and 180 milligrams of novobiocin.

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

(c) *Conditions of use*. *Dogs*—(1) *Amount*. 10 milligrams of each antibiotic per pound of body weight (one single-strength tablet for each 6 pounds or one triple-strength tablet for each 18 pounds).

(2) *Indications for use*. Treatment of acute or chronic canine respiratory infections such as tonsillitis, bronchitis, and tracheobronchitis when caused by pathogens susceptible to tetracycline and/or novobiocin, such as *Staphylococcus* spp. and *Escherichia coli*.

(3) *Limitations*. Continue treatment for at least 48 hours after the temperature has returned to normal and all evidence of infection has disappeared. As with all antibiotics, appropriate in vitro culturing and susceptibility tests of samples taken before treatment should be conducted. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37329, Aug. 18, 1992]

§ 520.2345h Tetracycline hydrochloride, sodium novobiocin, and prednisolone tablets.

(a) *Specifications*. Each tablet contains the equivalent of 60 milligrams of