

Food and Drug Administration, HHS

§ 520.2345c

initiated as soon as the diagnosis is determined. Consult a veterinarian for diagnosis. Do not give to cattle within 10 days of slaughter for food. Not for use in lactating dairy cattle.

[48 FR 3964, Jan. 28, 1983, as amended at 55 FR 29843, July 23, 1990; 59 FR 33197, June 28, 1994]

§ 520.2330 Sulfisoxazole tablets.

(a) *Specifications.* Each tablet contains 260 milligrams (4 grains) of sulfisoxazole.

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

(c) *Conditions of use*—(1) *Amount.* Administer one tablet orally per 4 pounds of body weight.¹

(2) *Indications for use.* Use in dogs and cats as an aid in treatment of bacterial pneumonia and bacterial enteritis when caused by organisms sensitive to sulfisoxazole.¹

(3) *Limitations.* Repeat dosage at 24-hour intervals until 2 to 3 days after disappearance of clinical symptoms. (Administration of one-half daily dosage at 12-hour intervals or one-third daily dosage at 8-hour intervals will provide a more constant blood level.) Provide adequate supply of drinking water. If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian.¹

[43 FR 60895, Dec. 29, 1978]

§ 520.2345 Tetracycline oral dosage forms.

§ 520.2345a Tetracycline hydrochloride capsules.

(a) *Specifications.* Each capsule contains 50, 100, 125, 250, or 500 milligrams of tetracycline hydrochloride.

(b) *Sponsor.* See § 510.600(c) of this chapter for identification of the sponsors:

(1) To No. 000009: 250 milligrams per capsule.

(2) To No. 000069: 125, 250, and 500 milligrams per capsule.

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.

(3) To No. 000115: 50, 100, 250, and 500 milligrams per capsule.

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

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

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

[57 FR 37327, Aug. 18, 1992, as amended at 59 FR 59365, Nov. 17, 1994; 63 FR 5255, Feb. 2, 1998]

§ 520.2345b Tetracycline tablets.

(a) *Specifications.* Each tablet contains 100, 250, or 500 milligrams of tetracycline (as the hydrochloride).

(b) *Sponsor.* For 100, 250, or 500 milligrams per tablet, see No. 000069 in § 510.600(c) of this chapter. For 250 milligrams per tablet, see No. 000009 in § 510.600(c) of this chapter.

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

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

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

[57 FR 37327, Aug. 18, 1992]

§ 520.2345c Tetracycline boluses.

(a) *Specifications.* Each bolus contains 500 milligrams of tetracycline (as the hydrochloride).

§ 520.2345d

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(b) *Sponsors*. See No. 053501 in § 510.600(c) of this chapter for use as in paragraph (d)(1) of this section. See No. 000009 in § 510.600(c) of this chapter for use as in paragraph (d)(2) of this section.

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

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

(i) *Indications for use*. Control and treatment of bacterial enteritis (scours) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp.

(ii) *Limitations*. Administer orally for 3 to 5 days; do not slaughter animals for food within 14 days of treatment; use as sole source of tetracycline.

(iii) *National Academy of Sciences/National Research Council (NAS/NRC) status*. The conditions of use specified in paragraph (d)(1)(i) of this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

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

(i) *Indications for use*. Treatment of bacterial pneumonia caused by organisms susceptible to tetracycline, bacterial enteritis caused by *E. coli*, and salmonella organisms susceptible to tetracycline.

(ii) *Limitations*. Administer orally for not more than 5 days; do not slaughter animals for food within 12 days of treatment; use as sole source of tetracycline.

[57 FR 37328, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002]

§ 520.2345d Tetracycline hydrochloride soluble powder.

(a) *Sponsors*. The following sponsors listed in § 510.600(c) of this chapter hold approvals for the drug concentrations (i.e., grams of tetracycline hydrochloride per pound) and conditions of use indicated:

(1) 000010, 046573, 051259, 057561, and 059130 102.4 and 324 grams per pound as in paragraph (d) of this section.

(2) 000069, 25 grams per pound as in paragraphs (d)(3) and (d)(4) of this section.

(3) 053501, 102.4 and 324 grams per pound as in paragraphs (d)(1) and (d)(2) of this section.

(4) 046573, 102.4 and 324 grams per pound as in paragraph (d)(3) of this section.

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

(c) [Reserved]

(d) *Conditions of use in drinking water*—(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 sponsor 053501 and within 5 days of treatment for sponsors 046573 and 000010; prepare a fresh solution daily; use as the sole source of tetracycline.

(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 sponsor 053501 and within 4 days of treatment for sponsors 046573 and 000010; 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.