Food and Drug Administration, HHS

- (b) *Sponsor*. See sponsors in §510.600(c) of this chapter for use as in paragraph (c) of this section:
- (1) No. 000009: 250 mg per capsule.
- (2) No. 000069: 125, 250, or 500 mg per capsule.
- (c) Conditions of use in dogs—(1) Amount. 25 mg per pound of body weight per day in divided doses every 6 hours
- (2) Indications for use. For 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*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 50182, Aug. 26, 2005, as amended at 73 FR 18442, Apr. 4, 2008]

§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).
- (b) Sponsors. See No. 053501 in $\S510.600$ (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 powder.

- (a) *Specifications*. Each pound of powder contains 25, 102.4, or 324 grams tetracycline hydrochloride.
- (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. 054628: 25, 102.4, and 324 grams per pound as in paragraph (d) of this section.