

§ 520.2220

21 CFR Ch. I (4-1-02 Edition)

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in dogs as a broad spectrum antibacterial agent to aid in the treatment of infectious tracheobronchitis and infections caused by *E. coli*. It can also be used in the treatment of infections caused by other gram-positive and gram-negative organisms that are susceptible to sulfonamide therapy.

(2) It is administered orally at a dosage level of 500 milligrams per 10 to 15 pounds of body weight daily, in two or three divided doses.

(3) The administration of the drug should be discontinued if a response is not noted within 7 to 10 days.

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

[43 FR 36622, Aug. 18, 1978, as amended at 50 FR 41489, Oct. 11, 1985]

§ 520.2220 Sulfadimethoxine oral dosage forms.

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

(a) *Approvals.* (1) For oral solution containing 12.5 percent (3.75 grams per ounce) sulfadimethoxine, see Nos. 000010, 000069, 051259, 057561, and 059130 in § 510.600(c).

(2) For soluble powder, each package containing the equivalent of 94.6 grams of sulfadimethoxine (as the sodium salt), see Nos. 000069, 051259, 057561, and 059130 in § 510.600(c).

(b) *Special considerations.* Chickens and turkeys that have survived fowl cholera outbreaks should not be kept for replacements or breeders.

(c) *Related tolerances.* See § 556.640 of this chapter.

(d) *Conditions of use.* The oral solution is administered as a cattle drench or diluted as directed to prepare drinking water. The powder is used to prepare a drench or drinking water. The concentrations and uses of the various solutions are as follows:

(1) *Broiler and replacement chickens only.* (i) *Amount.* 1.875 (0.05 percent) grams per gallon.

(ii) *Indications for use.* Treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

(iii) *Limitations.* Administer for 6 consecutive days; do not administer to chickens over 16 weeks of age; as sole source of drinking water and sulfonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.

(2) *Meat-producing turkeys only*—(i) *Amount.* 0.938 (0.025 percent) grams per gallon.

(ii) *Indications for use.* Treatment of disease outbreaks of coccidiosis and fowl cholera.

(iii) *Limitations.* Administer for 6 consecutive days; do not administer to turkeys over 24 weeks of age; as sole source of drinking water and sulfonamide medication; as sulfadimethoxine solution or sulfadimethoxine soluble sodium salt; withdraw 5 days before slaughter.

(3) *Dairy calves, dairy heifers, and beef cattle only*—(i) *Amount.* 1.18 to 2.36 (0.031 to 0.062 percent) grams per gallon.

(ii) *Indications for use.* Treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

(iii) Administer 2.5 grams per 100 pounds of body weight for first day, then 1.25 grams per 100 pounds of body weight per day for the next 4 consecutive days; in drinking water or drench; available as a sulfadimethoxine soluble powder or a 12.5 percent sulfadimethoxine sodium solution (3.75 grams sulfadimethoxine per fluid ounce); if no improvement within 2 to 3 days, reevaluate diagnosis; do not treat beyond 5 days; withdraw 7 days before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 58 FR 6092, Jan. 26, 1993; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 8371, Feb. 25, 1997; 62 FR 23357, Apr. 30, 1997; 62 FR 35076, June 30, 1997; 62 FR 40932, July 31, 1997; 63 FR 59714, Nov. 5, 1998; 64 FR 18572, Apr. 15, 1999]

§ 520.2220b Sulfadimethoxine tablets and boluses.

(a) *Sponsors.* Approval to firms identified in § 510.600(c) of this chapter as follows:

(1) To 000069, approval for use as in paragraphs (d)(1), (d)(2), and (d)(3) of this section.

(2) To 000061, approval for use as in paragraph (d)(2).