

(d) *Conditions of use*—(1) *Chickens*—(i) *Amounts and indications for use*—(A) As an aid in the control of coccidiosis caused by *Eimeria tenella* and *E. necatrix* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.4 percent solution) for 2 to 3 days, then plain water for 3 days, then medicated water (0.25 percent solution) for 2 days. If bloody droppings appear, repeat at 0.25 percent level for 2 more days. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.4 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

(ii) *Limitations*. Make fresh solution daily. Do not treat chickens within 14 days of slaughter for food. Do not medicate chickens producing eggs for human consumption.

(2) *Turkeys*—(i) *Amounts and indications for use*—(A) As an aid in the control of coccidiosis caused by *Eimeria meleagriditis* and *E. adenoides* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.25 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.25 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.25 percent solution) for 2 days. Repeat if necessary. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: provide medicated water (0.4 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

(ii) *Limitations*. Make fresh solution daily. Do not treat turkeys within 14 days of slaughter for food. Do not medicate turkeys producing eggs for human consumption.

[71 FR 13001, Mar. 14, 2006]

**§ 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, 054925, 057561, and 059130 in § 510.600(c).

(2) For soluble powder, each 107 grams contain the equivalent of 94.6 grams of sulfadimethoxine (as the sodium salt); see Nos. 000069, 054925, 057561, 058829, 059130, and 061623 in § 510.600(c) of this chapter.

(b) *Special considerations*. Federal law prohibits the extralabel use of this product in lactating dairy cattle.

(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. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[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; 70 FR 73137, Dec. 9, 2005; 71 FR 13542, Mar. 16, 2006; 74 FR 60156, Nov. 20, 2009]

#### § 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).

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

(c) [Reserved]

(d) It is used as follows:

(1) *Cattle*—(i) *Amount.* 1.25 to 2.5 grams per 100 pounds body weight.

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

(iii) *Limitations.* Administer 2.5 grams per 100 pounds body weight for 1 day followed by 1.25 grams per 100 pounds body weight per day; treat from 4 to 5 days; do not administer within 7 days of slaughter; milk that has been taken from animals during treatment and 60 hours (5 milkings) after the latest treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Dogs and cats.* (i) *Amount.* 12.5 to 25 milligrams per pound of body weight.

(ii) *Indications for use.* Treatment of sulfadimethoxine-susceptible bacterial infections.

(iii) *Limitations.* Administer 25 milligrams per pound of body weight on the first day followed by 12.5 milligrams per pound of body weight per day until the animal is free of symptoms for 48 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* 12.5-gram-sustained-release bolus.

(ii) *Indications for use.* Treatment of shipping fever complex and bacterial pneumonia associated with organisms such as *Pasteurella spp.* sensitive to sulfadimethoxine; calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.

(iii) *Limitations.* Administer one bolus for the nearest 200 pounds of body weight, i.e., 62.5 milligrams per pound of body weight. Do not repeat treatment for 7 days. Do not use in lactating dairy cattle. Do not administer within 12 days of slaughter. During treatment make certain that animals maintain adequate water intake. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 43488, Sept. 22, 1975; 49 FR 36830, Sept. 20, 1984; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997; 64 FR 15684, Apr. 1, 1999; 70 FR 16934, Apr. 4, 2005]

#### § 520.2220c Sulfadimethoxine oral suspension.

(a) *Chemical name.* *N*-(2,6-Dimethoxy-4-pyrimidinyl) sulfanilamide.

(b) *Specifications.* Each milliliter of the drug contains 50 milligrams of sulfadimethoxine.

(c) *Sponsor.* See Nos. 000061 and 000069 in § 510.600(c) of this chapter.

(1) It is intended for use in the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

(2) On the first day of treatment administer an oral dose of 25 milligrams per pound of body weight, then follow with a daily dosage of 12.5 milligrams per pound of body weight. Length of treatment will depend upon clinical response. Continue treatment until patient is asymptomatic for 48 hours.