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.* For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* (*Sphaerophorus necrophorus*) sensitive to sulfadimethoxine.

(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; 76 FR 17337, Mar. 29, 2011]

§ 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) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 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 for 4 to 5 days.

(ii) *Indications for use.* For the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(iii) *Limitations.* 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.* 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.

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

(iii) *Limitations*. 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*. Administer one 12.5-gram-sustained-release 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.

(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 *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(iii) *Limitations*. Do not use in female dairy cattle 20 months of age or older. Do not administer within 12 days of slaughter. 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; 76 FR 17337, Mar. 29, 2011]

§ 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.

Maintain adequate water intake during the treatment period.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2220d Sulfadimethoxine-ormetoprim tablets.

(a) *Specifications*. Each tablet contains 120 milligrams (100 milligrams of sulfadimethoxine and 20 milligrams of ormetoprim), 240 milligrams (200 milligrams of sulfadimethoxine and 40 milligrams of ormetoprim), 600 milligrams (500 milligrams of sulfadimethoxine and 100 milligrams of ormetoprim), or 1200 milligrams (1,000 milligrams of sulfadimethoxine and 200 milligrams of ormetoprim).

(b) *Sponsor*. See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. On the first day of treatment, administer 25 milligrams per pound (55 milligrams per kilogram) of body weight. Then follow with a daily dosage of 12.5 milligrams per pound (27.5 milligrams per kilogram) of body weight.

(2) *Indications of use*. Treatment of skin and soft tissue infections (wounds and abscesses) in dogs caused by strains of *Staphylococcus aureus* and *Escherichia coli* and urinary tract infections caused by *Escherichia coli*, *Staphlococcus* spp., and *Proteus mirabilus* susceptible to ormetoprim-potentiated sulfadimethoxine.

(3) *Limitations*. Continue treatment until patient is asymptomatic for 48 hours, but do not exceed a total of 21 consecutive days. Maintain adequate water intake during the treatment period. Safety in breeding animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[54 FR 48593, Nov. 24, 1989, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 61 FR 46719, Sept. 5, 1996]

§ 520.2240 Sulfaethoxypyridazine.

§ 520.2240a Sulfaethoxypyridazine drinking water.

(a) *Chemical name*. *N′*-(6-Ethoxy-3-pyridazinyl) sulfanilamide.