adjunctive therapy in septicemia accompanying mastitis and metritis.

(ii) *Limitations.* Administer 25 milligrams per pound of animal weight per day for 4 days; do not treat within 16 days of slaughter; as sole source of sulfonamide; milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food; for use only by or on the order of a licensed veterinarian.

(2) *Amount.* 15-gram controlled release tablets.

(i) *Indications for use.* Treatment of foot rot and respiratory infections (shipping fever and pneumonia) caused by sulfonamide-susceptible pathogens (*E. coli*, streptococci, staphylococci, *Sphaerophorus necrophorus* and Gram-negative rods including *Pasteurella*); for use prophylactically in cattle during periods of stress for reducing losses due to sulfonamide sensitive disease conditions.

(ii) *Limitations.* Administer 100 milligrams per pound of body weight; do not treat within 16 days of slaughter; as sole source of sulfonamide; not for use in lactating dairy cows; 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 67 FR 78355, Dec. 24, 2002]

§ 520.2260 Sulfamethazine oral dosage forms.

§ 520.2260a Sulfamethazine oblet, tablet, and bolus.

(a)(1) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter for use of 2.5-, 5-, and 15-gram sulfamethazine oblet in beef cattle, nonlactating dairy cattle, and horses. See No. 061690 in § 510.600(c) of this chapter for use of 5-, 15-, and 25-gram tablet in beef and nonlactating dairy cattle.

(2) *Related tolerance in edible products.* See § 556.670 of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer as a single dose 100 milligrams of sulfamethazine per pound of body weight the first day and 50 milligrams per pound of body weight on each following day.

(ii) *Indications for use.* For treatment of diseases caused by organisms susceptible to sulfamethazine.

(A) *Beef cattle and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), acute metritis (*Streptococcus* spp.), coccidiosis (*Eimeria bovis* and *Eimeria zurnii*).

(B) *Horses.* Treatment of bacterial pneumonia (secondary infections associated with *Pasteurella* spp.), strangles (*Streptococcus equi*), and bacterial enteritis (*Escherichia coli*).

(iii) *Limitations.* Administer daily until animal's temperature and appearance are normal. If symptoms persist after using for 2 or 3 days consult a veterinarian. Fluid intake must be adequate. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed 5 consecutive days. Follow dosages carefully. Not for use in lactating dairy animals. Do not treat cattle within 10 days of slaughter. Not to be used in horses intended for food.

(b)(1) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter for use of 5-gram sulfamethazine bolus.

(2) *Related tolerances in edible products.* See § 556.670 of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer 10 grams (2 boluses) of sulfamethazine per 100 pounds of body weight the first day, then 5 grams (1 bolus) of sulfamethazine per 100 pounds of body weight daily for up to 4 additional consecutive days.

(ii) *Indications for use.* Ruminating beef and dairy calves. For treatment of the following diseases caused by organisms susceptible to sulfamethazine: bacterial scours (colibacilloosis) caused by *E. coli*; necrotic pododermatitis (foot rot) and calf diphtheria caused by *F. necrophorum*; bacterial pneumonia associated with *Pasteurella* spp.; and coccidiosis caused by *E. bovis* and *E. zurnii*.

(iii) *Limitations.* Do not administer for more than 5 consecutive days. Do not treat calves within 11 days of slaughter. Do not use in calves to be slaughtered under 1 month of age or in calves being fed an all milk diet. Do

not use in female dairy cattle 20 months of age or older; such use may cause drug residues in milk. Administer with adequate supervision. Follows recomended dosages carefully. Fluid intake must be adequate. If symptoms persist after 2 or 3 days, consult a veterinarian.

[54 FR 15751, Apr. 19, 1989; 54 FR 19283, May 4, 1989, as amended at 56 FR 50653, Oct. 8, 1991; 59 FR 22754, May 3, 1994; 61 FR 4875, Feb. 9, 1996; 64 FR 66383, Nov. 26, 1999; 67 FR 78355, Dec. 24, 2002; 75 FR 10166, Mar. 5, 2010]

§ 520.2260b Sulfamethazine sustained-release boluses.

(a)(1) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter for use of a 22.5-gram sulfamethazine prolonged-release bolus.

(2) *Conditions of use*—(i) *Amount*. Depending on the duration of therapeutic levels desired, administer boluses as a single dose as follows: 3½ days—1 bolus (22.5 grams) per 200 pounds of body weight; 5 days—1 bolus per 100 pounds of body weight.

(ii) *Indications for use*. Beef and nonlactating cattle for sustained treatment of shipping fever pneumonia caused or complicated by *Pasteurella multocida;* as an aid in the treatment of foot rot, mastitis, pneumonia, metritis, bacterial enteritis, calf diphtheria, and septicemia when caused or complicated by bacteria susceptible to sulfamethazine.

(iii) *Limitations*. Cattle that are acutely ill should be treated parenterally with a suitable antibacterial product to obtain immediate therapeutic blood levels; do not slaughter animals for food within 16 days of treatment; do not use in lactating dairy cattle; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Sponsor*. See No. 053501 in § 510.600(c) of this chapter for use of a 27-gram sulfamethazine sustained-release bolus.

(2) *Conditions of use*—(i) *Amount*. 27 grams (1 bolus) for each 150 pounds of body weight as a single dose.

(ii) *Indications for use*. For nonlactating cattle for the treatment of infections caused by organisms sensitive to sulfamethazine such as hemorrhagic septicemia (shipping fever complex), bacterial pneumonia, foot rot, and calf diphtheria and as an aid in the control of bacterial diseases usually associated with shipping and handling of cattle.

(iii) *Limitations*. If no response within 2 to 3 days, reevaluate therapy; do not crush tablets; treated animals must not be slaughtered for food within 28 days after the latest treatment; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter for use of a 32.1-gram sustained-release bolus.

(2) *Conditions of use*—(i) *Amount*. 32.1 grams (1 bolus) per 200 pounds of body weight.[1]

(ii) *Indications for use*. For beef and nonlactating dairy cattle for the treatment of diseases caused by sulfamethazine-sensitive organisms as follows: bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) caused by *Pasteurella* spp., colibacillosis (bacterial scours) caused by *E. coli*, necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum*, and acute mastitis and acute metritis caused by *Streptococcus* spp.)[1]

(iii) *Limitations*. After 72 hours, all animals should be reexamined for persistence of observable disease signs. If signs are present, consult a veterinarian. It is strongly recommended that a second dose be given to provide for an additional 72 hours of therapy, particularly in more severe cases. The dosage schedule should be used at each 72-hour interval. Animals should not receive more than 2 doses because of the possibility of incurring residue violations. This drug, like all sulfonamides, may cause toxic reactions and irreparable injury unless administered with adequate and continuous supervision; *follow dosages carefully*. Fluid intake must be adequate at all times throughout the 3-day therapy, Do not use in lactating dairy cattle. Do not treat animals within 12 days of slaughter.

[1] These conditions are NAS/NRC reviewed and found effective. Applications for these uses need not inlcude effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.