Food and Drug Administration, HHS

§ 520.2260a Sulfamethazine oral dosage forms.

§ 520.2260a Sulfamethazine oblet, tablet, and bolus.

(a)(1) Sponsor. See No. 053501 in §510.600(c) of this chapter for use of 2.5-5-15 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—(1) 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 scour) (Escherichia coli), necrotic pododermatitis (foot rot)
§ 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 non-lactating 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 symptoms persist after 2 or 3 days, consult a veterinarian.