# Food and Drug Administration, HHS

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17338, Mar. 29, 2011, as amended at 78 FR 17597, Mar. 22, 2013; 79 FR 16183, Mar. 25, 2014]

### § 522.62 Aminopentamide.

- (a) Specifications. Each milliliter of solution contains 0.5 milligram (mg) aminopentamide hydrogen sulfate.
- (b) *Sponsor*. See No. 054771 in §510.600(c) of this chapter.
- (c) Conditions of use in dogs and cats—(1) Amount. Administer by subcutaneous or intramuscular injection every 8 to 12 hours as follows: For animals weighing up to 10 pounds (lbs): 0.1 mg; For animals weighing 11 to 20 lbs: 0.2 mg; For animals weighing 21 to 50 lbs: 0.3 mg; For animals weighing 21 to 50 lbs: 0.4 mg; For animals weighing 51 to 100 lbs: 0.4 mg; For animals weighing over 100 lbs: 0.5 mg. Dosage may be gradually increased up to a maximum of five times the suggested dosage. Following parenteral use, dosage may be continued by oral administration of tablets.
- (2) Indications for use. For the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.
- (3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

#### §522.82 Aminopropazine.

- (a) Specifications. Each milliliter of solution contains aminopropazine fumarate equivalent to 25 milligrams (mg) aminopropazine base.
- (b) *Sponsor*. See No. 000061 ir §510.600(c) of this chapter.
- (c) Conditions of use—(1) Dogs and cats—(i) Amount. 1 to 2 mg per pound of body weight, repeated every 12 hours as indicated, by intramuscular or intravenous injection.
- (ii) *Indications for use.* For reducing excessive smooth muscle contractions, such as occur in urethral spasms associated with urolithiasis.
- (iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (2) Horses—(i) Amount. Administer 0.25 mg per pound of body weight, re-

peated every 12 hours as indicated, by intramuscular or intravenous injection.

- (ii) *Indications for use*. For reducing excessive smooth muscle contractions, such as occur in colic spasms.
- (iii) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

#### §522.84 Beta-aminopropionitrile.

- (a) Specifications. The drug is a sterile powder. Each milliliter of constituted solution contains 0.7 milligrams (mg) beta-aminopropionitrile fumarate.
- (b) *Sponsor*. See No. 064146 in §510.600(c) of this chapter.
- (c) Conditions of use in horses—(1) Amount. Administer 7 mg by intralesional injection every other day for five treatments beginning about 30 days after initial injury.
- (2) Indications for use in horses. For treatment of tendinitis of the superficial digital flexor tendon (SDFT) in horses where there is sonographic evidence of fiber tearing.
- (3) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

## §522.88 Amoxicillin.

- (a) Specifications—(1) Each vial contains 3 grams (g) of amoxicillin trihydrate. Each milliliter of constituted suspension contains 100 or 250 milligrams (mg) amoxicillin trihydrate for use as in paragraph (d)(1) of this section.
- (2) Each vial contains 25 g of amoxicillin trihydrate. Each milliliter of constituted suspension contains 250 mg amoxicillin trihydrate for use as in paragraph (d)(2) of this section.
- (b) *Sponsor*. See No. 054771 in §510.600(c) of this chapter.
- (c) Related tolerance. See §556.38 of this chapter.
- (d) Conditions of use—(1) Dogs and cats—(i) Amount. Administer 5 mg per pound of body weight daily for up to 5 days by intramuscular or subcutaneous injection.

#### § 522.90

- (ii) Indications for use—(A) Dogs. For treatment of infections caused by susceptible strains of organisms as follows: Respiratory infections (tonsillitis, tracheobronchitis) due to Staphylococcus aureus, Streptococcus spp., Escherichia coli, and Proteus mirabilis; genitourinary infections (cystitis) due to S. aureus, Streptococcus spp., E. coli, and P. mirabilis; gastrointestinal infections (bacterial gastroenteritis) due to S. aureus, Streptococcus spp., E. coli, and P. mirabilis; bacterial dermatitis due to S. aureus, Streptococcus spp., and P. mirabilis; soft tissue infections (abscesses, lacerations, and wounds), due to S. aureus, Streptococcus spp., E. coli, and P. mirabilis.
- (B) Cats. For treatment of infections caused by susceptible strains of organisms as follows: Upper respiratory infections due to S. aureus. Staphylococcus spp., Streptococcus Haemophilus spp., E. coli, Pasteurella spp., and P. mirabilis; genitourinary infections (cystitis) due to S. aureus, Streptococcus spp., E. coli, P. mirabilis, Corynebacterium spp.; gastrointestinal infections due to E. coli. Proteus spp., Staphylococcus spp., and Streptococcus spp.; skin and soft tissue infections (abscesses, lacerations, and wounds) due to S. aureus, Staphylococcus spp., Streptococcus spp., E. coli, and Pasteurella multocida.
- (iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (2) Cattle—(i) Amount. Administer 3 to 5 mg per pound of body weight daily for up to 5 days by intramuscular or subcutaneous injection.
- (ii) Indications for use. For treatment of diseases due to amoxicillin-susceptible organisms as follows: Respiratory tract infections (shipping fever, pneumonia) due to P. multocida, P. hemolytica, Haemophilus spp., Staphylococcus spp., and Streptococcus spp. and acute necrotic pododermatitis (foot rot) due to Fusobacterium necrophorum.
- (iii) Limitations. Treated animals must not be slaughtered for food during treatment and for 25 days after the last treatment. Milk from treated cows must not be used for human consumption during treatment or for 96 hours (8 milkings) after last treatment. Federal

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

[79 FR 16183, Mar. 25, 2014]

# § 522.90 Ampicillin injectable dosage forms.

[79 FR 16183, Mar. 25, 2014]

# § 522.90a Ampicillin trihydrate suspension.

- (a) Specifications. (1) Each milliliter contains ampicillin trihydrate equivalent to 200 milligrams (mg) of ampicillin.
- (2) Each milliliter contains ampicillin trihydrate equivalent to 150 mg of ampicillin.
- (b) *Sponsors*. See sponsor numbers in §510.600(c) of this chapter.
- (1) No. 054771 for use of product described in paragraph (a)(1) as in paragraphs (d)(1), (d)(2), (d)(3)(i)(A), (d)(3)(ii)(A), (d)(3)(iii), and (d)(4) of this section.
- (2) No. 054771 for use of product described in paragraph (a)(2) as in paragraphs (d)(3)(i)(B), (d)(3)(ii)(B), and (d)(3)(iii) of this section.
- (c) Related tolerances. See §556.40 of this chapter.
- (d) Conditions of use—(1) Cattle—(i) Amount. For enteritis: 3 mg per pound of body weight, intramuscularly, once or twice daily, for up to 3 days. For pneumonia: 3 mg per pound of body weight, intramuscularly, twice daily, for up to 3 days.
- (ii) *Indications for use*. For treatment of bacterial enteritis in calves caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella* spp. susceptible to ampicillin.
- (iii) *Limitations*. Treated animals must not be slaughtered for food use during treatment or for 9 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (2) Swine—(i) Amount. 3 mg per pound of body weight by intramuscular injection, once or twice daily, for up to 3 days.
- (ii) *Indications for use*. Treatment of bacterial enteritis (colibacillosis) caused by *E. coli* and bacterial pneumonia caused by *Pasteurella* spp. susceptible to ampicillin.