## Food and Drug Administration, HHS

- (C) Limitations. Do not slaughter within 44 days of treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (ii) 300 mg/mL florfenicol in n-meth-yl-2-pyrrolidone (inactive vehicle).
- (A)(1) Amount. 20 mg/kg of body weight as an intramuscular injection. A second dose should be administered 48 hours later. Alternatively, 40 mg/kg of body weight as a single subcutaneous injection may be used.
- (2) Indications for use. For treatment of BRD associated with Mannheimia (Pasteurella) haemolytica, P. multocida, and Haemophilus somnus. For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with Fusobacterium necrophorum and Bacteroides melaninogenicus.
- (B)(1) Amount. 40 mg/kg of body weight as a single subcutaneous injection.
- (2) Indications for use. For control of respiratory disease in cattle at high risk of developing BRD associated with Mannheimia (Pasteurella) haemolytica, P. multocida, and Haemophilus somnus.
- (C) Limitations. Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
  - (2) [Reserved]

[73 FR 21041, Apr. 18, 2008, as amended by 74 FR 66574, Dec. 16, 2009]

## §522.956 Florfenicol and flunixin.

- (a) Specifications. Each milliliter (mL) of solution contains 300 milligrams (mg) florfenicol and 16.5 mg flunixin (27.37 mg flunixin meglumine).
- (b) Sponsor. See No. 000061 in  $\S510.600$ (c) of this chapter for use as in paragraph (d) of this section.

- (c) Tolerances. See §§ 556.283 and 556.286 of this chapter.
- (d) Conditions for use in cattle—(1) Amount. 40 mg florfenicol/kg body weight (BW) and 2.2 mg flunixin/kg BW (equivalent to 2 mL/15 kg BW or 6 mL/100 lbs) once, by subcutaneous injection.
- (2) Indications for use. For treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni, and Mycoplasma bovis, and control of BRD-associated pyrexia in beef and non-lactating dairy cattle.
- (3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Animals intended for human consumption must not be slaughtered within 38 days of treatment. Do not use in female dairy cattle 20 months of age or older. Use of florfenicol in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

[75 FR 1275, Jan. 11, 2010, as amended at 75 FR 54018, Sept. 3, 2010]

## § 522.960 Flumethasone implantation or injectable dosage forms.

## §522.960a Flumethasone suspension.

- (a) Chemical name.  $6\alpha,9\alpha$ -Difluoro-11 $\beta,17,21$  - trihydroxy -  $16\alpha$  - methylpregna - 1,4 - diene - 3,20 - dione.
- (b) Specifications. Flumethasone suspension is sterile and each milliliter of the drug contains: 2 milligrams of flumethasone, 20 milligrams of propylene glycol, 9 milligrams of benzyl alcohol (as preservative), 8 milligrams of sodium chloride, 0.02 milligram of polysorbate-80, 0.1 milligram of citric acid, and water for injection q.s.
- (c) Sponsor. See No. 000856 in \$510.600(c) of this chapter.
- (d) Conditions of use. (1) It is recommended in the various disease states involving synovial structures (joints) of horses where excessive synovial fluid of inflammatory origin is present and where permanent structural changes do not exist. Such conditions include arthritis, carpitis, and osselets.
- (2) The drug is administered intraarticularly at a dosage level of 6