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

[48 FR 7164, Feb. 18, 1983, as amended at 49 FR 26715, June 29, 1984; 54 FR 400, Jan. 6, 1989; 61 FR 5506, Feb. 13, 1996]

§ 522.930 Firocoxib.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) firocoxib.

(b) *Sponsors.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.04 mg/pound (lb) (0.09 mg/kilogram (kg)) of body weight (BW) intravenously, once daily, for up to 5 days. If further treatment is needed, firocoxib oral paste can be administered at a dosage of 0.045 mg/lb (0.1 mg/kg) of BW for up to an additional 9 days of treatment.

(2) *Indications for use.* For the control of pain and inflammation associated with osteoarthritis.

(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.

[75 FR 59611, Sept. 28, 2010]

§ 522.955 Florfenicol.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 300 milligrams (mg) florfenicol in the inactive vehicles 2-pyrrolidone and triacetin.

(2) 300 mg florfenicol in the inactive vehicle n-methyl-2-pyrrolidone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use of product described in paragraph (a)(1) as in paragraph (d)(1)(i) and for use of product described in paragraph (a)(2) as in paragraph (d)(1)(ii).

(c) *Related tolerance.* See § 556.283 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) 300 mg/mL florfenicol in 2-pyrrolidone and triacetin (inactive vehicles).

(A) *Amount.* 40 mg/kilogram (kg) body weight as a single subcutaneous injection.

(B) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and nonlactating dairy cattle.

(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-methyl-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 § 510.600(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.* 6α,9α-Difluoro-11β,17,21 - trihydroxy - 16α - 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 to 10 milligrams per injection. The dosage level is dependent upon the size of the involved synovial structure and the degree of severity of the condition under treatment. The dosage is limited to a single injection per week in any one synovial structure.

(3) Clinical and experimental data have demonstrated that corticosteroids administered orally and parenterally to animals during the last trimester of pregnancy may induce the first stage of parturition and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis. The drug is not to be used in horses intended for slaughter for food purposes.

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

[40 FR 13858, Mar. 27, 1975. Redesignated at 44 FR 16011, Mar. 16, 1979, as amended at 61 FR 5506, Feb. 13, 1996]

§ 522.960b Flumethasone acetate injection.

(a) *Chemical name.* 6-alpha,9-alpha-difluoro - 16 - alpha - methylprednisolone 21-acetate.

(b) *Specifications.* Flumethasone injection is sterile and contains per cubic centimeter: 2 milligrams of flumethasone acetate; 20 milligrams of propylene glycol; 9 milligrams of benzyl alcohol (as preservative); 8 milligrams of sodium chloride; 1 milligram of polysorbate 80; 0.1 milligram of citric acid; 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 certain acute and chronic canine dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(2) The drug is administered intramuscularly at the following recommended daily dosage:

Weight of animal in pounds	Dosage in milligrams
Up to 10	1.0
10 to 25	2.0
25 and over	4.0

Dosage should be adjusted according to the weight of the animal, the severity of the symptoms, and the response noted. Dosage by injection should not exceed 3 days of therapy. With chronic