

(2) *Sponsor*. Nos. 000061 and 059079 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Indications for use*. For the humane, painless, and rapid euthanasia of dogs.

(ii) *Amount*. One milliliter (390 milligrams of pentobarbital sodium and 50 milligrams of phenytoin sodium) for each 10 pounds of body weight.

(iii) *Limitations*. For intravenous injection or intracardiac injection when intravenous use is impractical. Do not use for therapeutic purposes. Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications*. Each milliliter of nonsterile, aqueous solution contains 400 milligrams of secobarbital sodium and 25 milligrams of dibucaine hydrochloride.

(2) *Sponsor*. See 000033 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Indications for use*. To induce rapid, humane, painless euthanasia of dogs.

(ii) *Amount*. For dogs, 1 milliliter for each 10 pounds of body weight.

(iii) *Limitations*. For intravenous injection. Do not use for therapeutic purposes. Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 23232, Apr. 24, 1981, as amended at 47 FR 15327, Apr. 9, 1982; 48 FR 16241, Apr. 15, 1983; 52 FR 7832, Mar. 13, 1987; 56 FR 9623, Mar. 7, 1991; 59 FR 14367, Mar. 28, 1994]

§ 522.914 Fenprostalene solution.

(a) *Specifications*—(1) *Cattle*. Each milliliter of sterile solution contains 0.5 milligram of fenprostalene.

(2) *Swine*. Each milliliter of sterile solution contains 0.25 milligram of fenprostalene.

(b) *Sponsor*. See 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.277 of this chapter.

(d) *Special considerations*. Labeling shall bear the following statements: Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. It is readily absorbed through the skin and may cause abortion and/or bronchospasms. Acci-

dental spillage on the skin should be washed off immediately with soap and water.

(e) *Conditions of use*—(1) *Cattle*—(i) *Amount*. 1 milligram (2 milliliters) subcutaneously per animal.

(ii) *Indications for use*. For feedlot heifers to induce abortion when pregnant 150 days or less. For beef or non-lactating dairy cattle for estrus synchronization.

(iii) *Limitations*. Subcutaneous use in cattle only. Feedlot heifers to induce abortion, single dose. Beef or nonlactating dairy cattle for estrus synchronization, a single dose or two doses 11 to 13 days apart. Do not use in pregnant animals unless abortion is desired. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount*. 0.25 milligram (1 milliliter) subcutaneously once per animal.

(ii) *Indications for use*. For sows and gilts pregnant at least 112 days for the induction of parturition.

(iii) *Limitations*. Subcutaneous use in swine only. Federal law restricts this 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]

§ 522.940 Colloidal ferric oxide injection.

(a) *Specifications*. Each milliliter of the drug contains colloidal ferric oxide equivalent to 100 milligrams of iron stabilized with a low-viscosity dextrin and contains 0.5 percent phenol as a preservative.

(b) *NAS/NRC status*. Use of this drug has been NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(c)(1) *Sponsor*. See Nos. 017800 and 053501 in § 510.600(c) of this chapter.

(2) *Conditions of use*. It is used in baby pigs as follows:

(i) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 1 milliliter of the drug to each animal at any

§ 522.955

time between 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of from 1 to 2 milliliters of the drug to each animal at any time between 5 to 28 days of age.

[40 FR 13858, Mar. 27, 1975, as amended at 49 FR 38938, Oct. 2, 1984; 50 FR 23298, June 3, 1985; 50 FR 25216, June 18, 1985; 51 FR 14989, Apr. 22, 1986; 51 FR 18314, May 19, 1986; 67 FR 78355, Dec. 24, 2002]

§ 522.955 Florfenicol.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) of florfenicol.

(b) *Sponsor.* See 000061 in § 510.600(c) of this chapter.

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

(d) *Conditions of use—(1) Cattle—(i) Amount.* 20 mg per kilogram (/kg) of body weight as an intramuscular injection. A second dose should be administered 48 hours later.

(A) *Indications for use.* For treatment of bovine respiratory disease (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) [Reserved]

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

(A) *Indications for use.* As in paragraph (d)(1)(i)(A) of this section; for control of respiratory disease in cattle at high risk of developing BRD associated with *M. (Pasteurella) haemolytica*, *P. multocida*, and *H. somnus*.

(B) [Reserved]

(iii) *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.

21 CFR Ch. I (4–1–03 Edition)

(2) [Reserved]

[61 FR 42383, Aug. 15, 1996, as amended at 63 FR 26981, May 15, 1998; 63 FR 41191, Aug. 3, 1998; 64 FR 5596, Feb. 4, 1999; 64 FR 9435, Feb. 26, 1999; 67 FR 6866, Feb. 14, 2002]

§ 522.960 Flumethasone implantation or injectable dosage forms.

§ 522.960a Flumethasone suspension.

(a) *Chemical name.* 6 α ,9 α -Difluoro-11 β ,17,21 - trihydroxy - 16 α - 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, carpalis, 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]