

§ 520.2645

21 CFR Ch. I (4–1–16 Edition)

in chickens. For the control of CRD associated with *Mycoplasma synoviae* in broiler chickens. Treated chickens should consume enough medicated drinking water to provide 50 milligrams (mg) tylosin per pound of body weight per day.

(B) Administer 851 to 1,419 mg/gallon (225 to 375 ppm) for 5 days for the control of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.

(ii) *Limitations.* Do not use in layers producing eggs for human consumption. Do not administer within 24 hours of slaughter.

(2) *Turkeys*—(i) *Amount.* 2 grams per gallon for 2 to 5 days as the sole source of drinking water. Treated turkeys should consume enough medicated drinking water to provide 60 mg tylosin per pound of body weight per day.

(ii) *Indications for use.* For the reduction in severity of effects of infectious sinusitis associated with *Mycoplasma gallisepticum*.

(iii) *Limitations.* Do not use in layers producing eggs for human consumption. Do not administer within 5 days of slaughter.

(3) *Swine*—(i) *Amount.* 250 mg per gallon as the only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated.

(ii) *Indications for use.* (A) For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* when followed immediately by tylosin phosphate medicated feed; and for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* when followed immediately by tylosin phosphate medicated feed.

(B) For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae*.

(iii) *Limitations.* Do not administer within 48 hours of slaughter. As indicated in paragraph (d)(3)(ii)(A) of this section, follow with tylosin phosphate medicated feed as in § 558.625(f)(1)(vi)(c) of this chapter.

(4) *Honey bees*—(i) *Amount.* Mix 200 milligrams tylosin in 20 grams confectioners' powdered sugar. Use immediately. Apply (dust) this mixture over the top bars of the brood chamber once weekly for 3 weeks.

(ii) *Indications for use.* For the control of American foulbrood (*Paenibacillus larvae*).

(iii) *Limitations.* The drug should be fed early in the spring or fall and consumed by the bees before the main honey flow begins, to avoid contamination of production honey. Complete treatments at least 4 weeks before main honey flow.

[40 FR 13838, Mar. 27, 1975, as amended at 50 FR 49841, Dec. 5, 1985; 59 FR 14365, Mar. 28, 1994; 62 FR 39443, July 23, 1997; 68 FR 24879, May 9, 2003; 70 FR 69439, Nov. 16, 2005; 73 FR 76946, Dec. 18, 2008; 75 FR 76259, Dec. 8, 2010; 76 FR 59024, Sept. 23, 2011; 77 FR 29217, May 17, 2012; 79 FR 37620, July 2, 2014; 79 FR 53136, Sept. 8, 2014; 79 FR 64116, Oct. 28, 2014; 80 FR 34278, June 16, 2015]

§ 520.2645 Tylvalosin.

(a) *Specifications.* Granules containing 62.5 percent tylvalosin (w/w) as tylvalosin tartrate.

(b) *Sponsor.* See No. 066916 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.748 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer 50 parts per million tylvalosin in drinking water for 5 consecutive days.

(2) *Indications for use.* For the control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[77 FR 55415, Sept. 10, 2012]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

- Sec.
- 522.23 Acepromazine.
- 522.52 Alfaxalone.
- 522.56 Amikacin.
- 522.62 Aminopentamide.
- 522.82 Aminopropazine.
- 522.84 Beta-aminopropionitrile.
- 522.88 Amoxicillin.
- 522.90 Ampicillin injectable dosage forms.
- 522.90a Ampicillin trihydrate suspension.
- 522.90b Ampicillin trihydrate powder for injection.
- 522.90c Ampicillin sodium.

- 522.144 Arsenamide.
 522.147 Atipamezole.
 522.150 Azaperone.
 522.161 Betamethasone.
 522.163 Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension.
 522.167 Betamethasone sodium phosphate and betamethasone acetate.
 522.204 Boldenone.
 522.230 Buprenorphine.
 522.234 Butamisolol.
 522.246 Butorphanol.
 522.275 N-Butylscopolammonium.
 522.300 Carfentanil.
 522.304 Carprofen.
 522.311 Cefovecin.
 522.313 Ceftiofur injectable dosage forms.
 522.313a Ceftiofur crystalline free acid.
 522.313b Ceftiofur hydrochloride.
 522.313c Ceftiofur sodium.
 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate.
 522.390 Chloramphenicol.
 522.454 Clodronate.
 522.460 Cloprostenol.
 522.468 Colistimethate sodium powder for injection.
 522.480 Corticotropin.
 522.518 Cupric glycinate injection.
 522.522 Danofloxacin.
 522.533 Deslorelin.
 522.535 Desoxycorticosterone.
 522.536 Detomidine.
 522.540 Dexamethasone solution.
 522.542 Dexamethasone suspension.
 522.558 Dexmedetomidine.
 522.563 Diatrizoate.
 522.650 Dihydrostreptomycin sulfate injection.
 522.690 Dinoprost.
 522.723 Diprenorphine.
 522.770 Doramectin.
 522.775 Doxapram.
 522.784 Doxylamine.
 522.800 Droperidol and fentanyl.
 522.810 Embutramide, chloroquine, and lidocaine solution.
 522.812 Enrofloxacin.
 522.814 Eprinomectin.
 522.820 Erythromycin.
 522.840 Estradiol.
 522.842 Estradiol benzoate and testosterone propionate.
 522.850 Estradiol valerate and norgestomet in combination.
 522.863 Ethylisobutrazine.
 522.870 Etodolac.
 522.883 Etorphine.
 522.900 Euthanasia solution.
 522.914 Fenprostalene.
 522.930 Firocoxib.
 522.955 Florfenicol.
 522.956 Florfenicol and flunixin.
 522.960 Flumethasone injectable dosage forms.
 522.960a Flumethasone suspension.
 522.960b Flumethasone acetate solution.
 522.960c Flumethasone solution.
 522.970 Flunixin.
 522.995 Fluprostenol.
 522.1002 Follicle stimulating hormone.
 522.1010 Furosemide.
 522.1014 Gamithromycin.
 522.1020 Gelatin.
 522.1044 Gentamicin.
 522.1066 Glycopyrrolate.
 522.1077 Gonadorelin.
 522.1079 Serum gonadotropin and chorionic gonadotropin.
 522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.
 522.1083 Gonadotropin releasing factor analog-diphtheria toxoid conjugate.
 522.1085 Guaifenesin powder for injection.
 522.1086 Guaifenesin solution.
 522.1125 Hemoglobin glutamer-200 (bovine).
 522.1145 Hyaluronate.
 522.1150 Hydrochlorothiazide.
 522.1155 Imidocarb powder for injection.
 522.1156 Imidocarb solution.
 522.1160 Insulin.
 522.1182 Iron injection.
 522.1185 Isoflupredone.
 522.1192 Ivermectin.
 522.1193 Ivermectin and clorsulon.
 522.1204 Kanamycin.
 522.1222 Ketamine.
 522.1223 Ketamine, promazine, and aminopentamide.
 522.1225 Ketoprofen.
 522.1242 Levamisole.
 522.1260 Lincomycin.
 522.1289 Lufenuron.
 522.1290 Luprostiol.
 522.1315 Maropitant.
 522.1335 Medetomidine.
 522.1350 Melatonin implant.
 522.1362 Melarsomine powder for injection.
 522.1367 Meloxicam.
 522.1372 Mepivacaine.
 522.1380 Methocarbamol.
 522.1410 Methylprednisolone.
 522.1450 Moxidectin solution.
 522.1451 Moxidectin microspheres for injection.
 522.1452 Nalorphine.
 522.1465 Naltrexone.
 522.1468 Naproxen for injection.
 522.1484 Neomycin.
 522.1503 Neostigmine.
 522.1610 Oleate sodium.
 522.1620 Orgotein for injection.
 522.1660 Oxytetracycline injectable dosage forms.
 522.1660a Oxytetracycline solution, 200 milligrams/milliliter.
 522.1660b Oxytetracycline solution, 300 milligrams/milliliter.
 522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.
 522.1662a Oxytetracycline hydrochloride injection.

§ 522.23

21 CFR Ch. I (4-1-16 Edition)

- 522.1662b Oxytetracycline hydrochloride with lidocaine injection.
- 522.1662 Oxytetracycline and flunixin.
- 522.1680 Oxytocin.
- 522.1696 Penicillin G procaine injectable dosage forms.
- 522.1696a Penicillin G benzathine and penicillin G procaine suspension.
- 522.1696b Penicillin G procaine aqueous suspension.
- 522.1696c Penicillin G procaine in oil.
- 522.1698 Pentazocine.
- 522.1704 Pentobarbital.
- 522.1720 Phenylbutazone.
- 522.1820 Pituitary luteinizing hormone powder for injection.
- 522.1850 Polysulfated glycosaminoglycan.
- 522.1862 Pralidoxime powder for injection.
- 522.1870 Praziquantel.
- 522.1881 Prednisolone acetate.
- 522.1883 Prednisolone sodium phosphate.
- 522.1884 Prednisolone sodium succinate.
- 522.1885 Prednisolone tertiary butylacetate.
- 522.1890 Sterile prednisone suspension.
- 522.1920 Prochlorperazine and isopropamide.
- 522.1940 Progesterone and estradiol benzoate.
- 522.1962 Promazine.
- 522.2002 Propiopromazine.
- 522.2005 Propofol.
- 522.2012 Prostalene.
- 522.2063 Pyrilamine.
- 522.2075 Robenacoxib.
- 522.2076 Romifidine.
- 522.2100 Selenium and vitamin E.
- 522.2112 Sometribove zinc suspension.
- 522.2120 Spectinomycin dihydrochloride injection.
- 522.2121 Spectinomycin sulfate.
- 522.2150 Stanozolol.
- 522.2200 Sulfachlorpyridazine.
- 522.2220 Sulfadimethoxine.
- 522.2240 Sulfaethoxyypyridazine.
- 522.2260 Sulfamethazine.
- 522.2340 Sulfomyxin.
- 522.2404 Thialbarbitone sodium for injection.
- 522.2424 Thiamylal.
- 522.2444 Thiopental injectable dosage forms.
- 522.2444a Thiopental powder for injection.
- 522.2444b Thiopental and pentobarbital powder for injection.
- 522.2460 Tildipirosin.
- 522.2470 Tiletamine and zolazepam for injection.
- 522.2471 Tilmicosin.
- 522.2473 Tiludronate.
- 522.2474 Tolazoline.
- 522.2476 Trenbolone acetate.
- 522.2477 Trenbolone acetate and estradiol.
- 522.2478 Trenbolone acetate and estradiol benzoate.
- 522.2483 Triamcinolone.
- 522.2582 Triflupromazine.
- 522.2610 Trimethoprim and sulfadiazine.
- 522.2615 Tripelennamine.
- 522.2630 Tulathromycin.

- 522.2640 Tylosin.
- 522.2662 Xylazine.
- 522.2670 Yohimbine.
- 522.2680 Zeranol.
- 522.2690 Zinc gluconate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13858, Mar. 27, 1975, unless otherwise noted.

§ 522.23 Acepromazine.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) acepromazine maleate.

(b) *Sponsors.* See Nos. 000010 and 000859 in § 510.600(c) of this chapter:

(c) *Conditions of use in dogs, cats, and horses*—(1) *Amount.* Dogs: 0.25 to 0.5 mg per pound (lb) of body weight; Cats: 0.5 to 1.0 mg/lb of body weight; Horses: 2.0 to 4.0 mg per 100 lbs of body weight.

(2) *Indications for use.* For use as a tranquilizer and as a preanesthetic agent.

(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 10167, Mar. 5, 2010; 78 FR 17597, Mar. 22, 2013; 79 FR 16182, Mar. 25, 2014]

§ 522.52 Alfaxalone.

(a) *Specifications.* Each milliliter contains 10 milligrams (mg) alfaxalone.

(b) *Sponsor.* See No. 049480 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats and dogs*—(1) *Amount*—(i) *Cats*—(A) *Induction of general anesthesia.* Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 2.2 to 9.7 mg/kilogram (kg) for cats that did not receive a preanesthetic or 1.0 to 10.8 mg/kg for cats that received a preanesthetic.

(B) *Maintenance of general anesthesia following induction.* Administer an intravenous bolus containing 1.1 to 1.3 mg/kg to provide an additional 7 to 8 minutes of anesthesia in preanesthetized cats; a dose containing 1.4 to 1.5 mg/kg provides an additional 3 to 5 minutes anesthesia in unpreanesthetized cats.

(ii) *Dogs*—(A) *Induction of general anesthesia.* Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 1.5 to 4.5 mg/kg for dogs that did not receive a preanesthetic or

0.2 to 3.5 mg/kg for dogs that received a preanesthetic.

(B) *Maintenance of general anesthesia following induction.* Administer an intravenous bolus containing 1.2 to 1.4 mg/kg to provide an additional 6 to 8 minutes of anesthesia in preanesthetized dogs; a dose of 1.5 to 2.2 mg/kg provides an additional 6 to 8 minutes of anesthesia in unpreanesthetized dogs.

(2) *Indications for use.* For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic, in dogs and cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Alfaxalone is a Class IV controlled substance.

[77 FR 64717, Oct. 23, 2012, as amended at 79 FR 64116, Oct. 28, 2014]

§ 522.56 Amikacin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of amikacin as amikacin sulfate.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—*(1) *Amount.* 5 mg/pound (lb) of body weight twice daily by intramuscular or subcutaneous injection.

(2) *Indications for use.* For treatment of genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli*.

(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; 81 FR 17608, Mar. 30, 2016]

§ 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 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 in § 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, 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 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.

§ 522.88

(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.

(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 in-

21 CFR Ch. I (4–1–16 Edition)

fections due to *S. aureus*, *Staphylococcus* spp., *Streptococcus* spp., *Haemophilus* spp., *E. coli*, *Pasteurella* spp., and *P. mirabilis*; genitourinary infections (cystitis) due to *S. aureus*, *Streptococcus* spp., *E. coli*, *P. mirabilis*, and *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.

(iii) *Limitations.* Treated animals must not be slaughtered for food use during treatment or for 15 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Dogs*—(i) *Amount*—(A) 3 to 6 mg per pound of body weight by intramuscular injection, once or twice daily. Usual treatment is 3 to 5 days.

(B) 3 to 5 mg of ampicillin per pound of body weight, once a day for up to 4 days.

(ii) *Indications for use*—(A) Treatment of respiratory tract infections due to *E. coli*, *Pseudomonas* spp., *Proteus* spp., *Staphylococcus* spp., and *Streptococcus* spp.; tonsillitis due to *E. coli*, *Pseudomonas* spp., *Streptococcus* spp., and *Staphylococcus* spp.; generalized infections (septicemia) associated with

abscesses, lacerations, and wounds due to *Staphylococcus* spp. and *Streptococcus* spp.

(B) Treatment of bacterial infections of the upper respiratory tract (tonsillitis) due to *Streptococcus* spp., *Staphylococcus* spp., *E. coli*, *Proteus* spp., and *Pasteurella* spp., and soft tissue infections (abscesses, lacerations, and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., and *E. coli*, when caused by susceptible organisms.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Cats*—(i) *Amount.* 5 to 10 mg per pound of body weight by intramuscular or subcutaneous injection, once or twice daily. Usual treatment is 3 to 5 days.

(ii) *Indications for use.* Treatment of generalized infections (septicemia) associated with abscesses, lacerations, and wounds due to *Staphylococcus* spp., *Streptococcus* spp., and *Pasteurella* spp.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16183, Mar. 25, 2014]

§ 522.90b Ampicillin trihydrate powder for injection.

(a) *Specifications.* Each milliliter of aqueous suspension constituted from ampicillin trihydrate powder contains 50, 100, or 250 milligrams (mg) ampicillin equivalents.

(b) *Sponsors.* See Nos. 000010 and 010515 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.40 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* 3 mg/pound (lb) of body weight twice daily by subcutaneous or intramuscular injection.

(ii) *Indications for use.* For treatment of strains of organisms susceptible to ampicillin and associated with respiratory tract infections, urinary tract infections, gastrointestinal infections, skin infections, soft tissue infections, and postsurgical infections.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* 2 to 5 mg/lb of body weight once daily by intramuscular injection.

§ 522.90c

21 CFR Ch. I (4–1–16 Edition)

(ii) *Indications for use.* For treatment of respiratory tract infections caused by organisms susceptible to ampicillin, bacterial pneumonia (shipping fever, calf pneumonia, and bovine pneumonia) caused by *Aerobacter* spp., *Klebsiella* spp., *Staphylococcus* spp., *Streptococcus* spp., *Pasteurella multocida*, and *Escherichia coli*.

(iii) *Limitations.* Do not treat cattle for more than 7 days. Milk from treated cows must not be used for food during treatment and for 48 hours (4 milkings) after the last treatment. Cattle must not be slaughtered for food during treatment and for 144 hours (6 days) after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 18304, Apr. 8, 1993; 63 FR 41420, Aug. 4, 1998; 75 FR 10167, Mar. 5, 2010; 76 FR 17338, Mar. 29, 2011; 76 FR 53051, Aug. 25, 2011]

§ 522.90c Ampicillin sodium.

(a) *Specifications.* Each milliliter of aqueous solution constituted from ampicillin sodium powder contains 300 milligrams (mg) ampicillin equivalents.

(b) *Sponsors.* See Nos. 010515 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount:* 3 mg per pound of body weight twice daily by intravenous or intramuscular injection.

(2) *Indications for use.* For the treatment of respiratory tract infections (pneumonia and strangles) due to *Staphylococcus* spp., *Streptococcus* spp. (including *S. equi*), *Escherichia coli*, and *Proteus mirabilis*, and skin and soft tissue infections (abscesses and wounds) due to *Staphylococcus* spp., *Streptococcus* spp., *E. coli*, and *P. mirabilis*, when caused by susceptible organisms.

(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.

[72 FR 45158, Aug. 13, 2007, as amended at 79 FR 16184, Mar. 25, 2014]

§ 522.144 Arsenamide.

(a) *Specifications.* Each milliliter of solution contains 10.0 milligrams arsenamide sodium.

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

(c) *Conditions of use in dogs—(1) Amount.* Administer 0.1 milliliter (mL) per pound of body weight (1.0 mL for every 10 pounds) by intravenous injection twice a day for 2 days.

(2) *Indications for use.* For the treatment and prevention of canine heartworm disease caused by *Dirofilaria immitis*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16184, Mar. 25, 2014]

§ 522.147 Atipamezole.

(a) *Specifications.* Each milliliter of solution contains 5.0 milligrams atipamezole hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Inject intramuscularly the same volume as that of dexmedetomidine or medetomidine used.

(2) *Indications for use.* For reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride or medetomidine hydrochloride.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 48830, Sept. 17, 1996, as amended at 64 FR 71640, Dec. 22, 1999; 72 FR 264, Jan. 4, 2007]

§ 522.150 Azaperone.

(a) *Specifications.* Each milliliter of solution contains 40 milligrams (mg) azaperone.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Indications for use.* For control of aggressiveness when mixing or regrouping weanling or feeder pigs weighing up to 80 pounds.

(2) *Dosage.* 2.2 mg per kilogram (1 mg per pound) by deep intramuscular injection.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[74 FR 65689, Dec. 11, 2009, as amended at 77 FR 46613, Aug. 6, 2012]

§ 522.161 Betamethasone.

(a) *Specifications.* Each milliliter of suspension contains:

(1) Betamethasone acetate equivalent to 10.8 milligrams (mg) betamethasone and betamethasone disodium phosphate equivalent to 3 mg of betamethasone.

(2) Betamethasone dipropionate equivalent to 5 mg betamethasone and betamethasone sodium phosphate equivalent to 2 mg of betamethasone.

(b) *Sponsor*. See sponsor numbers in § 510.600(c) of this chapter:

(1) No. 000061 for product described in paragraph (a)(1) of this section for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii)(A), and (c)(2)(iii) of this section.

(2) No. 000061 for product described in paragraph (a)(2) of this section for use as in paragraphs (c)(1), (c)(2)(i), (c)(2)(ii)(B), and (c)(2)(iii) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer by intramuscular injection 0.25 to 0.5 milliliter (mL) per 20 pounds of body weight, depending on the severity of the condition. Frequency of dosage depends on recurrence of pruritic symptoms. Dosage may be repeated every 3 weeks or when symptoms recur, not to exceed a total of four injections.

(ii) *Indications for use*. As an aid in the control of pruritus associated with dermatoses.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount*. Administer 2.5 to 5 mL by intra-articular injection.

(ii) *Indications for use*—(A) For the treatment of various inflammatory joint conditions; for example, acute and traumatic lameness involving the carpal and fetlock joints.

(B) As an aid in the control of inflammation associated with various arthropathies.

(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 16184, Mar. 25, 2014]

§ 522.163 Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension.

(a) *Specifications*. Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension is

a sterile aqueous suspension. Each milliliter of the suspension contains the equivalent of 5 milligrams of betamethasone as betamethasone dipropionate and 2 milligrams of betamethasone as betamethasone sodium phosphate.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*. (i) It is used as an aid in the control of pruritus associated with dermatoses.

(ii) It is administered by intramuscular injection at a dosage of 0.25 to 0.5 milliliter per 20 pounds of body weight, depending on the severity of the condition. Frequency of dosage depends on recurrence of pruritic symptoms. Dosage may be repeated every 3 weeks or when symptoms recur, not to exceed a total of 4 injections.

(2) *Horses*. (i) It is used as an aid in the control of inflammation associated with various arthropathies.

(ii) It is administered aseptically by intraarticular injection at a dosage of 2.5 to 5 milliliters per joint, depending on the severity of the condition and the joint size. Dosage may be repeated upon recurrence of clinical signs. Injection into the joint cavity should be preceded by withdrawal of synovial fluid.

(iii) Not for use in horses intended for food.

(3) *Clinical and experimental data*. It has been demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(4) *Restrictions*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 27316, July 2, 1976; 52 FR 7832, Mar. 13, 1987]

§ 522.167 Betamethasone sodium phosphate and betamethasone acetate.

(a) *Specifications*. Each milliliter (mL) of suspension contains 6 milligrams (mg) betamethasone (3.15 mg betamethasone sodium phosphate and 2.85 mg betamethasone acetate).

§ 522.204

(b) *Sponsor*. See No. 010797 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 1.5 mL (9 mg total betamethasone) per joint by intra-articular injection. May be administered concurrently in up to two joints per horse.

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

(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.

[80 FR 18776, Apr. 8, 2015]

§ 522.204 Boldenone.

(a) *Specifications*. Each milliliter of solution contains 25 or 50 milligrams (mg) boldenone undecylenate.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 0.5 mg per pound body weight by intramuscular injection. Treatment may be repeated at 3-week intervals.

(2) *Indications for use*. As an aid for treating debilitated horses when an improvement in weight, hair coat, or general physical condition is desired.

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

[70 FR 70998, Nov. 25, 2005, as amended at 79 FR 16184, Mar. 25, 2014]

§ 522.230 Buprenorphine.

(a) *Specifications*. Each milliliter of solution contains 1.8 milligrams (mg) buprenorphine.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount*. Administer 0.24 mg per kilogram (0.11 mg per pound) by subcutaneous injection once daily, for up to 3 days. Administer the first dose approximately 1 hour prior to surgery.

(2) *Indications for use*. For the control of postoperative pain associated with surgical procedures in cats.

21 CFR Ch. I (4–1–16 Edition)

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 53136, Sept. 8, 2014, as amended at 80 FR 18776, Apr. 8, 2015]

§ 522.234 Butamisol.

(a) *Specifications*. Each milliliter of solution contains 11 milligrams (mg) butamisol hydrochloride.

(b) *Sponsors*. See Nos. 000859 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer 0.1 mg per pound of body weight by subcutaneous injection. In problem cases, retreatment for whipworms may be necessary in approximately 3 months. For hookworms, a second injection should be given 21 days after the initial treatment.

(2) *Indications for use*. For the treatment of infections with whipworms (*Trichuris vulpis*), and the hookworm (*Ancylostoma caninum*).

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16184, Mar. 25, 2014]

§ 522.246 Butorphanol.

(a) *Specifications*. Each milliliter of solution contains butorphanol (as butorphanol tartrate) in the following amounts:

- (1) 0.5 milligrams (mg);
- (2) 2 mg; or
- (3) 10 mg

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter as follows:

(1) No. 054771 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section; for use of the product described in paragraph (a)(2) as in paragraph (d)(2) of this section; and for use of the product described in paragraph (a)(3) as in paragraph (d)(3) of this section.

(2) No. 000859 for use of the product described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(3) Nos. 000061, 000859, and 059399 for use of the product described in paragraph (a)(3) as in paragraph (d)(3) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer 0.025 mg per pound of body weight by subcutaneous injection at intervals of 6 to 12 hours, as required. If necessary, increase dose to a maximum of 0.05 mg per pound of body weight. Treatment should not normally be required for longer than 7 days.

(ii) *Indications for use*. For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

(2) *Cats*—(i) *Amount*. Administer 0.2 mg per pound of body weight by subcutaneous injection. Dose may be repeated up to 4 times per day. Do not treat for more than 2 days.

(ii) *Indications for use*. For the relief of pain in cats caused by major or minor trauma, or pain associated with surgical procedures.

(3) *Horses*—(i) *Amount*. Administer 0.05 mg per pound of body weight by intravenous injection. Dose may be repeated within 3 to 4 hours. Treatment should not exceed 48 hours.

(ii) *Indications for use*. For the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

(iii) *Limitations*. Do not use in horses intended for human consumption.

[72 FR 27957, May 18, 2007, as amended at 73 FR 31358, June 2, 2008; 74 FR 61516, Nov. 25, 2009; 75 FR 22524, Apr. 29, 2010; 77 FR 60302, Oct. 3, 2012; 78 FR 17597, Mar. 22, 2013; 79 FR 16184, Mar. 25, 2014; 79 FR 74020, Dec. 15, 2014; 80 FR 13229, Mar. 13, 2015]

§ 522.275 N-Butylscopolammonium.

(a) *Specifications*. Each milliliter of solution contains 20 milligrams (mg) N-butylscopolammonium bromide.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 0.3 mg per kilogram of body weight (0.14 mg per pound) slowly intravenously.

(2) *Indications for use*. For the control of abdominal pain (colic) associated with spasmodic colic, flatulent colic, and simple impactions.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 35512, June 25, 2004]

§ 522.300 Carfentanil.

(a) *Specifications*. Each milliliter of solution contains 3 milligrams (mg) carfentanil citrate.

(b) *Sponsor*. See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer 5 to 20 micrograms per kilogram (0.005 to 0.020 mg per kilogram) of body weight into large muscle of the neck, shoulder, back, or hindquarter.

(2) *Indications for use*. For immobilizing free ranging and confined members of the family Cervidae (deer, elk, and moose).

(3) *Limitations*. Do not use in domestic animals intended for food. Do not use 30 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian. The licensed veterinarian shall be a veterinarian engaged in zoo and exotic animal practice, wildlife management programs, or research.

[79 FR 16185, Mar. 25, 2014]

§ 522.304 Carprofen.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) carprofen.

(b) *Sponsors*. See Nos. 026637, 054771, and 055529 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount*. 2 mg/lb (4.4 mg/kg) body weight once daily or 1 mg/lb (2.2 mg/kg) twice daily, by subcutaneous injection. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Conditions of use*. For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 26205, May 15, 2003, as amended at 68 FR 34796, June 11, 2003; 68 FR 49351, Aug. 18, 2003. Redesignated at 73 FR 29685, May 22, 2008, as amended at 79 FR 74020, Dec. 15, 2014]

§ 522.311 Cefovecin.

(a) *Specifications.* Each milliliter of constituted solution contains 80 milligrams (mg) cefovecin as the sodium salt.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use—(1) Dogs—(i) Amount.* Administer 3.6 mg/pound (1b) (8 mg/kilograms (kg)) body weight as a single subcutaneous injection. A second subcutaneous injection of 3.6 mg/lb (8 mg/kg) may be administered if response to therapy is not complete.

(ii) *Indications for use.* For the treatment of skin infections (secondary superficial pyoderma, abscesses, and wounds) in dogs caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G).

(2) *Cats—(i) Amount.* Administer 3.6 mg/lb (8 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use.* For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida*.

[73 FR 29685, May 22, 2008, as amended at 79 FR 16185, Mar. 25, 2014]

§ 522.313 Ceftiofur injectable dosage forms.**§ 522.313a Ceftiofur crystalline free acid.**

(a) *Specifications.* The product is a suspension of ceftiofur crystalline free acid.

(1) Each milliliter (mL) contains 100 milligrams (mg) ceftiofur equivalents.

(2) Each mL contains 200 mg ceftiofur equivalents.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use—(1) Swine.* The formulation described in paragraph (a)(1) of this section is used as follows:

(i) *Amount.* 5.0 mg CE per kilogram (kg) of body weight by intramuscular injection in the postauricular region of the neck.

(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus*

pleuropneumoniae, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*. For the control of SRD associated with *A. pleuropneumoniae*, *P. multocida*, *H. parasuis*, and *S. suis* in groups of pigs where SRD has been diagnosed.

(iii) *Limitations.* Following label use as a single treatment, a 14-day pre-slaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in swine for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved, major food-producing species/production classes.

(2) *Cattle.* The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount.* For subcutaneous (SC) injection in the posterior aspect of the ear where it attaches to the head (base of the ear) in lactating dairy cattle. For SC injection in the middle third of the posterior aspect of the ear or in the base of the ear in beef and non-lactating dairy cattle.

(A) Single-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight as a single injection.

(B) Two-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight given as two injections in the base of the ear approximately 72 hours apart.

(ii) *Indications for use—(A) Single-dose regimen:* For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef, non-lactating dairy, and lactating dairy cattle. For the control of respiratory disease in beef and non-lactating dairy cattle which are at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii* in beef, non-lactating dairy, and lactating dairy cattle.

(B) Two-dose regimen: For the treatment of acute metritis (0-to 10-days postpartum) associated with bacterial

organisms susceptible to ceftiofur in lactating dairy cattle.

(iii) *Limitations*. Following label use as either a single-dose or 2-dose regimen, a 13-day pre-slaughter withdrawal period is required after the last treatment. 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. Federal law prohibits extra-label use of this drug in cattle for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved, major food-producing species/production classes.

(3) *Horses*. The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount*. Two intramuscular injections, 4 days apart, at a dose of 3.0 mg/lb (6.6 mg/kg) body weight.

(ii) *Indications for use*. For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* ssp. *zooeidemicus*.

(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.

[68 FR 60296, Oct. 22, 2003, as amended at 69 FR 43892, July 23, 2004. Redesignated and amended at 71 FR 39546, July 13, 2006; 73 FR 58872, Oct. 8, 2008; 75 FR 4692, Jan. 29, 2010; 75 FR 62468, Oct. 12, 2010; 77 FR 26162, May 3, 2012; 79 FR 16185, Mar. 25, 2014; 79 FR 37620, July 2, 2014]

§ 522.313b Ceftiofur hydrochloride.

(a) *Specifications*. Each milliliter of ceftiofur hydrochloride suspension contains 50 milligrams (mg) ceftiofur equivalents.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.113 of this chapter.

(d) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle and swine for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unap-

proved major food-producing species/production classes.

(e) *Conditions of use*—(1) *Swine*—(i) *Amount*. 3 to 5 mg per kilogram (/kg) of body weight by intramuscular injection. Treatment should be repeated at 24-hour intervals for a total of 3 consecutive days.

(ii) *Indications for use*. For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella Choleraesuis*, and *Streptococcus suis*.

(iii) *Limitations*. Treated swine must not be slaughtered for 4 days following the last treatment.

(2) *Cattle*—(i) *Amount*. Administer by subcutaneous or intramuscular injection as follows:

(A) For bovine respiratory disease and acute bovine interdigital necrobacillosis: 1.1 to 2.2 mg/kg of body weight at 24-hour intervals for 3 to 5 consecutive days.

(B) For bovine respiratory disease: 2.2 mg/kg of body weight administered twice at a 48 hour interval.

(C) For acute metritis: 2.2 mg/kg of body weight at 24-hour intervals for 5 consecutive days.

(ii) *Indications for use*. For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *P. multocida*, and *Histophilus somni*; acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*; and acute metritis (0 to 14 days post-partum) associated with bacteria susceptible to ceftiofur.

(iii) *Limitations*. Treated cattle must not be slaughtered for 4 days following the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

[61 FR 29479, June 11, 1996, as amended at 63 FR 53578, Oct. 6, 1998; 67 FR 45901, July 11, 2002; 69 FR 47362, Aug. 5, 2004. Redesignated and amended at 71 FR 39544, July 13, 2006; 73 FR 45612, Aug. 6, 2008; 76 FR 17338, Mar. 29, 2011; 78 FR 66264, Nov. 5, 2013]

§522.313c Ceftiofur sodium.

(a) *Specifications.* Each milliliter of aqueous solution constituted from ceftiofur sodium powder contains 50 milligrams (mg) ceftiofur equivalents.

(b) *Sponsors.* See Nos. 000409, 054771, and 068330 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.113 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle, swine, chickens, and turkeys for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

(e) *Conditions of use*—(1) *Swine*—(i) *Amount.* 3 to 5 mg per kilogram (/kg) body weight by intramuscular injection for 3 consecutive days.

(ii) *Indications for use.* For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis*, and *Streptococcus suis*.

(iii) *Limitations.* Treated pigs must not be slaughtered for 4 days following the last treatment.

(2) *Cattle*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular or subcutaneous injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.

(ii) *Indications for use.* For treatment of bovine respiratory disease (shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*. Also, for the treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(iii) *Limitations.* Treated cattle must not be slaughtered for 4 days following the last treatment.

(3) *Sheep*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.

(ii) *Indications for use.* For treatment of sheep respiratory disease (sheep pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

(4) *Goats*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.

(ii) *Indications for use.* For treatment of caprine respiratory disease (goat pneumonia) associated with *Mannheimia haemolytica* and *Pasteurella multocida*.

(5) *Chickens*—(i) *Amount.* 0.08 to 0.20 mg as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For control of early mortality associated with *Escherichia coli* organisms susceptible to ceftiofur in day-old chicks.

(6) *Turkeys*—(i) *Amount.* 0.17 to 0.5 mg as a single subcutaneous injection in the neck.

(ii) *Indications for use.* For control of early mortality associated with *E. coli* organisms susceptible to ceftiofur in day-old poults.

(7) *Horses*—(i) *Amount.* 2.2 to 4.4 mg/kg (1.0 to 2.0 mg/lb) body weight by intramuscular injection. Treatment should be repeated every 24 hours, continued for 48 hours after clinical signs have disappeared, and should not exceed 10 days. A maximum of 10 mL should be administered per injection site.

(ii) *Indications for use.* For treatment of respiratory infections in horses associated with *Streptococcus zooepidemicus*.

(iii) *Limitations.* Do not use in horses intended for human consumption.

(8) *Dogs*—(i) *Amount.* 1.0 mg/lb (2.2 mg/kg) body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 5 to 14 days.

(ii) *Indications for use.* For treatment of canine urinary tract infections associated with *E. coli* and *Proteus mirabilis*.

[53 FR 5369, Feb. 24, 1988, as amended at 55 FR 13768, Apr. 12, 1990; 56 FR 12119, Mar. 22, 1991; 57 FR 41862, Sept. 14, 1992; 59 FR 41666, Aug. 15, 1994; 59 FR 54518, Nov. 1, 1994; 60 FR 51719, Oct. 3, 1995; 61 FR 35130, July 5, 1996; 61 FR 66583, Dec. 18, 1996; 66 FR 21283, Apr. 30, 2001; 66 FR 32540, June 15, 2001; 69 FR 47362, Aug. 5, 2004. Redesignated and amended at 71 FR 39544, July 13, 2006; 74 FR 34236, July 15, 2009; 77 FR 29218, May 17, 2012; 79 FR 16185, Mar. 25, 2014; 79 FR 21127, Apr. 15, 2014]

§ 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate.

(a) *Specifications.* Each milliliter of solution contains 42.5 milligrams (mg) of chloral hydrate, 8.86 mg of pentobarbital, and 21.2 mg of magnesium sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* For general anesthesia: Administer 20 to 50 milliliters per 100 pounds of body weight by intravenous injection until the desired effect is produced. Cattle usually require a lower dosage on the basis of body weight. As a sedative-relaxant: Administer at a level of one-fourth to one-half of the anesthetic dosage level.

(2) *Indications for use.* For general anesthesia and as a sedative-relaxant in cattle and horses.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16185, Mar. 25, 2014]

§ 522.390 Chloramphenicol.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams of chloramphenicol.

(b) *Sponsor.* See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs—(1) Amount.* 5 to 15 milligrams per pound of body weight, intramuscularly or intravenously, every 6 hours. In severe infections, use 4 to 6 hour treatment intervals the first day. If no response is obtained in 3 to 5 days, discontinue use and reevaluate diagnosis.

(2) *Indications for use.* Treatment of infections of the respiratory tract, the urinary tract, and enteritis and tonsil-

litis caused by organisms susceptible to chloramphenicol.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

[57 FR 37331, Aug. 18, 1992, as amended at 65 FR 45877, July 26, 2000; 78 FR 17597, Mar. 22, 2013; 79 FR 16185, Mar. 25, 2014; 81 FR 17608, Mar. 30, 2016]

§ 522.454 Clodronate.

(a) *Specifications.* Each milliliter of solution contains 60 milligrams (mg) clodronate disodium.

(b) *Sponsor.* See No. 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 1.8 mg per kilogram of body weight by intramuscular injection up to a maximum dose of 900 mg per horse.

(2) *Indications for use.* For the control of clinical signs associated with navicular syndrome.

(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 37620, July 2, 2014]

§ 522.460 Cloprostenol.

(a) *Specifications.* Each milliliter of solution contains cloprostenol sodium equivalent to:

(1) 125 micrograms (μg) of cloprostenol; or

(2) 250 μg of cloprostenol.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 000061 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1)(i) and (c)(2) of this section.

(2) Nos. 000061 and 068504 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(ii), (c)(1)(iii), and (c)(2) of this section.

(c) *Conditions of use in cattle—(1) Amount and indications for use—(i)* Administer 375 μg by intramuscular injection to induce abortion in pregnant feedlot heifers from 1 week after mating until 4 1/2 months of gestation.

(ii) Administer 500 μg by intramuscular injection for terminating unwanted pregnancies from mismatings from 1 week after mating

§ 522.468

21 CFR Ch. I (4–1–16 Edition)

until 5 months after conception; for treating unobserved (nondetected) estrus, mummified fetus, and luteal cysts; and for the treatment of pyometra.

(iii) Administer 500 µg by intramuscular injection as a single injection regimen or double injection regimen with a second injection 11 days after the first, for scheduling estrus and ovulation to control the time at which cycling cows or heifers can be bred.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16185, Mar. 25, 2014]

§ 522.468 Colistimethate sodium powder for injection.

(a) *Specifications.* Each vial contains colistimethate sodium equivalent to 10 grams colistin activity and mannitol to be reconstituted with 62.5 milliliters sterile saline or sterile water for injection. The resulting solution contains colistimethate sodium equivalent to 133 milligrams per milliliter colistin activity.

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use.* (1) 1- to 3-day-old chickens.

(i) *Dosage.* 0.2 milligram colistin activity per chicken.

(ii) *Indications for use.* Control of early mortality associated with *Escherichia coli* organisms susceptible to colistin.

(iii) *Limitations.* For subcutaneous injection in the neck of 1- to 3-day-old chickens. Not for use in laying hens producing eggs for human consumption. Do not use in turkeys. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13123, Mar. 18, 1998, as amended at 79 FR 16185, Mar. 25, 2014]

§ 522.480 Corticotropin.

(a) *Specifications.* Each milliliter of aqueous solution contains 40 or 80 U.S.P. (I.U.) units of repository corticotropin.

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

(1) No. 061623 for use as in paragraphs (c)(1) and (2) of this section.

(2) No. 026637 for use as in paragraph (c)(2) and (3) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer one unit per pound of body weight by intramuscular injection.

(ii) *Indications for use.* As a diagnostic aid to test for adrenal dysfunction.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs and cats*—(i) *Amount.* Administer one unit per pound of body weight by intramuscular or subcutaneous injection, to be repeated as indicated.

(ii) *Indications for use.* For stimulation of the adrenal cortex where there is a general deficiency of corticotropin (ACTH).

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle*—(i) *Amount.* Administer 200 to 600 units by intramuscular or subcutaneous injection as an initial dose, followed by a dose daily or every other day of 200 to 300 units.

(ii) *Indications for use.* As a therapeutic agent for primary bovine ketosis; and for stimulation of the adrenal cortex where there is a general deficiency of ACTH.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16185, Mar. 25, 2014]

§ 522.518 Cupric glycinate injection.

(a) *Specifications.* Each milliliter (mL) of sterile aqueous suspension contains 200 milligrams of cupric glycinate (equivalent to 60 milligrams of copper).

(b) *Sponsor.* See No. 049185 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 200 milligrams (1 mL) for calves 300 pounds and under; 400 milligrams (2 mL) for calves over 300 pounds and adult cattle.

(2) *Indications for use.* For beef calves and beef cattle for the prevention of copper deficiency, or when labeled for veterinary prescription use, for the prevention and/or treatment of copper deficiency alone or in association with molybdenum toxicity.

(3) *Limitations.* For subcutaneous use only; repeat dose in 3 months in young

calves, in 6 months in cattle; discontinue use 30 days before treated animals are slaughtered for food use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 20159, Apr. 3, 1981, as amended at 52 FR 7832, Mar. 13, 1987; 62 FR 28630, May 27, 1997]

§ 522.522 Danofloxacin.

(a) *Specifications.* Each milliliter of solution contains 180 milligrams (mg) danofloxacin as the mesylate salt.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.169 of this chapter.

(d) *Conditions of use in cattle—(1) Amount and indications for use.* Administer by subcutaneous injection either:

(i) 6 mg per kilogram (/kg) of body weight, repeated in 48 hours, for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica* and *Pasteurella multocida*; or

(ii) 8 mg/kg of body weight as a single dose for the treatment of BRD associated with *M. haemolytica* and *P. multocida* and for the control of BRD in beef cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida*.

(2) *Limitations.* Animals intended for human consumption should not be slaughtered within 4 days from the last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in pre-ruminating 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. Federal law prohibits the extra-label use of this drug in food-producing animals.

[67 FR 78972, Dec. 27, 2002, as amended at 77 FR 4227, Jan. 27, 2012; 79 FR 16185, Mar. 25, 2014; 79 FR 53136, Sept. 8, 2014]

§ 522.533 Deslorelin.

(a) *Specifications—(1)* Each implant contains 2.1 milligrams (mg) deslorelin acetate.

(2) Each milliliter (mL) of suspension contains 1.8 mg deslorelin acetate.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) No. 051311 for use of product described in paragraph (a)(1) as in paragraph (c)(1) of this section.

(2) No. 051330 for use of product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) *Conditions of use—(1) Horses and ponies—(i) Amount.* One implant per mare subcutaneously in the neck.

(ii) *Indications for use.* For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 mL in diameter.

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

(2) *Horses—(i) Amount.* Administer 1.8 mg (1 mL) by intramuscular injection in the neck.

(ii) *Indications for use.* For inducing ovulation within 48 hours in cyclic estrous mares with an ovarian follicle between 30 and 40 mL in diameter.

(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.

[75 FR 81456, Dec. 28, 2010, as amended at 79 FR 18158, Apr. 1, 2014]

§ 522.535 Desoxycorticosterone.

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams of desoxycorticosterone pivalate.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs—(i) Amount.* Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(ii) *Indications for use.* For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13122, Mar. 18, 1998, as amended at 79 FR 16185, Mar. 25, 2014]

§ 522.536 Detomidine.

(a) *Specification.* Each milliliter of solution contains 10 milligrams of detomidine hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* For sedation, analgesia, or sedation and analgesia: 20 or 40 micrograms per kilogram (0.2 or 0.4 milliliter per 100 kilogram or 220 pounds) by body weight, depending on depth and duration required. For sedation, administer by intravenous (IV) or intramuscular (IM) injection; for analgesia, administer by IV injection; for both sedation and analgesia, administer by IV injection.

(2) *Indication for use.* As a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

(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 16186, Mar. 25, 2014]

§ 522.540 Dexamethasone solution.

(a)(1) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) dexamethasone.

(2) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(i) Nos. 000061, 000859, and 061623 for use as in paragraph (a)(3) of this section.

(ii) *Sponsors.* See Nos. 054925 and 058005 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) *Conditions of use*—(i) *Amount.* The drug is administered intravenously or intramuscularly and dosage may be repeated if necessary, as follows:

(A) *Dogs.* 0.25 to 1 mg.

(B) *Cats.* 0.125 to 0.5 mg.

(C) *Horses.* 2.5 to 5 mg.

(D) *Cattle.* 5 to 20 mg, depending on the severity of the condition.

(ii) *Indications for use.* The drug is indicated:

(A) For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses;

(B) As an anti-inflammatory agent in dogs and cats.

(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.

(b)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg dexamethasone).

(2) *Sponsor.* See number in § 510.600(c) of this chapter as follows:

(i) No. 061623 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(ii) No. 000402 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(3) *Conditions of use*—(i) *Amount.* Administer 0.25 to 1 mg by intravenous injection, repeated for 3 to 5 days or until a response is noted.

(ii) *Indications for use.* For use in dogs for the treatment of inflammatory conditions, as supportive therapy in canine posterior paresis, as supportive therapy before or after surgery to enhance recovery of poor surgical risks, and as supportive therapy in nonspecific dermatosis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg of dexamethasone).

(2) *Sponsor.* See Nos. 000402 and 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer 2.5 to 5.0 mg by intravenous injection.

(ii) *Indications for use.* For use in horses as a rapid adrenal glucocorticoid and/or anti-inflammatory agent.

(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.

(d)(1) *Specifications.* Each milliliter of solution contains 2.0 mg of dexamethasone or 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg of dexamethasone).

(2) *Sponsors.* See the following numbers in § 510.600(c) of this chapter:

(i) Nos. 000859 and 054771 for intravenous or intramuscular use of 2.0 milligrams dexamethasone injection.

(ii) No. 054771 for intravenous use of 2.0 milligrams dexamethasone injection.

(3) *Conditions of use*—(i) *Amount*. Administer by intravenous or intramuscular injection as follows:

(A) *Dogs*: 0.25 to 1 mg.

(B) *Cats*: 0.125 to 0.5 mg.

(C) *Horses*: 2.5 to 5 mg.

(ii) *Indications for use*. For use in dogs, cats, and horses as an anti-inflammatory agent.

(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.

(e)(1) *Specifications*. Each milliliter of solution contains 4.0 mg of dexamethasone sodium phosphate (equivalent to 3.0 mg dexamethasone).

(2) *Sponsor*. See No. 069043 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. Administer by intravenous injection as follows:

(A) *Dogs*: 0.25 to 1 mg; may be repeated for 3 to 5 days.

(B) *Horses*: 2.5 to 5 mg.

(ii) *Indications for use*. For use in dogs and horses for glucocorticoid and anti-inflammatory effect.

(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.

[41 FR 28265, July 9, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.540, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 522.542 Dexamethasone suspension.

(a) *Specifications*. Each milliliter of suspension contains 1 milligram (mg) of dexamethasone-21-isonicotinate.

(b) *Sponsor*. No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Administer by intramuscular injection as follows: Dogs: 0.25 to 1 mg; cats: 0.125 to 0.5 mg; horses: 5 to 20 mg. Dosage may be repeated.

(2) *Indications for use*. For the treatment of various inflammatory conditions associated with the musculo-

skeletal system in dogs, cats, and horses.

(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 16186, Mar. 25, 2014]

§ 522.558 Dexmedetomidine.

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

(1) 0.1 milligrams (mg) dexmedetomidine hydrochloride; or

(2) 0.5 mg dexmedetomidine hydrochloride.

(b) *Sponsors*. See sponsors in in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 026637 for use of product described in paragraph (a)(2) of this section;

(2) No. 052483 for use of products described in paragraph (a) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Indications for use and amount*. (A) For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures, administer 375 micrograms (μg) per square meter (m^2) of body surface area by intravenous injection or 500 $\mu\text{g}/\text{m}^2$ of body surface area by intramuscular injection.

(B) For use as a preanesthetic to general anesthesia, administer 125 $\mu\text{g}/\text{m}^2$ of body surface area or 375 $\mu\text{g}/\text{m}^2$ of body surface area by intramuscular injection.

(ii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. 40 $\mu\text{g}/\text{kilogram}$ by intramuscular injection.

(ii) *Indications for use*. For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures; and as a preanesthetic to general anesthesia.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 263, Jan. 4, 2007, as amended at 72 FR 19797, Apr. 20, 2007; 72 FR 51365, Sept. 7, 2007; 75 FR 60308, Sept. 30, 2010; 78 FR 25183, Apr. 30, 2013; 78 FR 33699, June 5, 2013; 80 FR 13229, Mar. 13, 2015]

§ 522.563

21 CFR Ch. I (4–1–16 Edition)

§ 522.563 Diatrizoate.

(a) *Specifications.* Each milliliter of solution contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—*

(1) *Amount.* For excretion urography, administer 0.5 to 1.0 milliliter (mL) per pound of body weight to a maximum of 30 mL intravenously. For cystography, remove urine, administer 5 to 25 mL directly into the bladder via catheter. For urethrography, administer 1.0 to 5 mL via catheter into the urethra to provide desired contrasts delineation. For angiocardiology (including aortography) rapidly inject 5 to 10 mL directly into the heart via catheter or intraventricular puncture. For cerebral angiography, rapid injection of 3 to 10 mL via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography, rapidly inject 3 to 10 mL intravascularly into the vascular bed to be delineated. For lymphography, slowly inject 1.0 to 10 mL directly into the lymph vessel to be delineated. For arthrography, slowly inject 1.0 to 5 mL directly into the joint to be delineated. For discography, slowly inject 0.5 to 1.0 mL directly into the disc to be delineated. For sialography, slowly inject 0.5 to 1.0 mL into the duct to be delineated. For delineation of fistulous tracts, slowly inject quantity necessary to fill the tract. For delineation of peritoneal hernias, inject 0.5 to 1.0 mL per pound of body weight directly into the peritoneal cavity.

(2) *Indications for use.* For visualization in excretion urography, including renal angiography, uretography, cystography, and urethrography; aortography; angiocardiology, peripheral arteriography, and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography; and as an aid in delineating peritoneal hernias and fistulous tracts.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16186, Mar. 25, 2014]

§ 522.650 Dihydrostreptomycin sulfate injection.

(a) *Specifications.* Each milliliter contains dihydrostreptomycin sulfate equivalent to 500 milligrams of dihydrostreptomycin.

(b) *Sponsors.* See Nos. 054771 and 055529 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.200 of this chapter.

(d) *Conditions of use—* (1) *Amount.* Administer 5 milligrams per pound of body weight by deep intramuscular injection every 12 hours, for 3 to 5 days or until the urine is free of leptospira for at least 72 hours as measured by darkfield microscopic examination.

(2) *Indications for use.* Treatment of leptospirosis in dogs and horses due to *Leptospira canicola*, *L. icterohemorrhagiae*, and *L. pomona*; in cattle due to *L. pomona*; and in swine due to *L. pomona*; and *L. grippotyphosa*.

(3) *Limitations.* Discontinue use 30 days before slaughter for food. Not for use in animals producing milk because use of the drug will contaminate the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 79 FR 16187, Mar. 25, 2014]

§ 522.690 Dinoprost.

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to 5 milligrams (mg) or 12.5 mg dinoprost.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 054771 for use of the 12.5 mg/mL product as in paragraph (d)(1) of this section.

(2) No. 054771 for use of the 5 mg/mL product as in paragraphs (d)(1), (2), and (3) of this section.

(3) No. 000859 for use of the 5 mg/mL product as in paragraphs (d)(2), (3), and (4) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Cattle*. Administer product described in paragraph (b)(1) of this section as follows:

(i) *Amount*. 25 mg as a single intramuscular or subcutaneous injection.

(ii) *Indications for use*. As a luteolytic agent; effective only in those cattle having a corpus luteum, *i.e.*, those which ovulated at least 5 days prior to treatment.

(A) For estrus synchronization in beef cows, beef heifers and replacement dairy heifers.

(B) For unobserved (silent) estrus in lactating dairy cows with a corpus luteum.

(C) For treatment of pyometra (chronic endometritis) in cattle.

(D) For abortion in beef cows, beef heifers and replacement dairy heifers.

(E) For use with gonadorelin injection as in § 522.1077 of this chapter to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows.

(F) For use with progesterone intravaginal inserts as in § 529.1940 of this chapter for synchronization of estrus in lactating dairy cows.

(G) For use with progesterone intravaginal inserts as in § 529.1940 of this chapter for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, advancement of first postpartum estrus in suckled beef cows, and advancement of first pubertal estrus in beef heifers.

(2) *Horses*—(i) *Amount*. 1 mg per 100 pounds of body weight as a single intramuscular injection.

(ii) *Indications for use*. For its luteolytic effect to control timing of estrus in estrous cycling mares and in clinically anestrous mares that have a corpus luteum.

(iii) *Limitations*. Do not use in horses intended for human consumption.

(3) *Swine*—(i) *Amount*. 10 mg as a single intramuscular injection.

(ii) *Indications for use*. For parturition induction in swine when injected within 3 days of normal predicted farrowing.

(4) *Cattle*. Administer product described in paragraph (b)(2) of this section as follows:

(i) *Beef cattle and nonlactating dairy heifers*—(A) *Amount*. 25 mg as an

intramuscular injection either once or twice at a 10- to 12-day interval.

(B) *Indications*. For its luteolytic effect to control timing of estrus and ovulation in estrous cycling cattle that have a corpus luteum.

(ii) *Beef cattle and nonlactating dairy heifers*—(A) *Amount*. 25 mg as a single intramuscular injection.

(B) *Indications*. For treatment of pyometra (chronic endometritis).

(iii) *Nonlactating cattle*—(A) *Amount*. 25 mg as a single intramuscular injection during the first 100 days of gestation.

(B) *Indications*. For its abortifacient effect in nonlactating cattle.

(iv) *Lactating dairy cattle*—(A) *Amount*. 25 mg as a single intramuscular injection.

(B) *Indications*. For treatment of unobserved (silent) estrus in lactating dairy cattle that have a corpus luteum.

(v) Dinoprost injection as provided by No. 054771 in § 510.600(c) of this chapter may also be used concurrently with gonadorelin hydrochloride injection as in § 522.1077 and with progesterone intravaginal inserts as in § 529.1940 of this chapter.

[67 FR 41824, June 20, 2002, as amended at 79 FR 16187, Mar. 25, 2014; 79 FR 44278, July 31, 2014; 79 FR 64116, Oct. 28, 2014; 80 FR 61296, Oct. 13, 2015; 80 FR 76386, Dec. 9, 2015]

§ 522.723 Diprenorphine.

(a) *Specifications*. Each milliliter of solution contains 2 milligrams of diprenorphine hydrochloride.

(b) *Sponsors*. See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. It is administered intramuscularly or intravenously at a suitable dosage level depending upon the species.

(2) *Indications for use*. The drug is used for reversing the effects of etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(3) *Limitations*. For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.770

Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

[79 FR 16187, Mar. 25, 2014]

§ 522.770 Doramectin.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams of doramectin.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.225 of this chapter.

(d) *Conditions of use—(1) Cattle—(i) Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

(iii) *Limitations.* Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. Do not use in calves to be processed for veal.

(2) *Swine—(i) Amount.* 300 micrograms per kilogram (10 milligrams per 75 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.

(iii) *Limitations.* Administer as a single intramuscular injection. Do not slaughter swine within 24 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[61 FR 53321, Oct. 11, 1996, as amended at 62 FR 44410, Aug. 21, 1997; 62 FR 62242, Nov. 21, 1997; 63 FR 68183, Dec. 10, 1998; 64 FR 13509, Mar. 19, 1999; 79 FR 16187, Mar. 25, 2014]

§ 522.775 Doxapram.

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

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

21 CFR Ch. I (4–1–16 Edition)

(c) *Conditions of use—(1) Amount.* For intravenous use in dogs and cats at a dose of 2½ to 5 mg per pound (lb) body weight in barbiturate anesthesia, 0.5 mg/lb in inhalation anesthesia; for intravenous use in horses at 0.25 mg/lb body weight in barbiturate anesthesia, 0.2 mg/lb in inhalation anesthesia, 0.25 mg/lb with chloral hydrate with or without magnesium sulfate; for subcutaneous, sublingual, or umbilical vein administration in neonate puppies at a dose rate of 1 to 5 mg; for subcutaneous or sublingual use in neonate kittens at 1 to 2 mg. Dosage may be repeated in 15 to 20 minutes if necessary.

(2) *Indications for use.* Administer to dogs, cats, and horses to stimulate respiration during and after general anesthesia; or to speed awakening and return of reflexes after anesthesia. Administer to neonate dogs and cats to initiate respiration following dystocia or caesarean section; or to stimulate respiration following dystocia or caesarean section.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 261, Jan. 4, 2007, as amended at 75 FR 10167, Mar. 5, 2010; 77 FR 60302, Oct. 3, 2012]

§ 522.784 Doxylamine.

(a) *Specifications.* Each milliliter contains 11.36 milligrams (mg) of doxylamine succinate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount—(i) Horses:* Administer 25 mg per hundred pounds of body weight by intramuscular, subcutaneous, or slow intravenous injection.

(ii) *Dogs and cats:* Administer 0.5 to 1 mg per pound of body weight by intramuscular or subcutaneous injection. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect.

(2) *Indications for use.* For use in conditions in which antihistaminic therapy may be expected to alleviate some signs of disease in horses, dogs, and cats.

(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 16187, Mar. 25, 2014]

§ 522.800 Droperidol and fentanyl.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of droperidol and 0.4 mg of fentanyl citrate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.*

(i) For analgesia and tranquilization, administer as follows:

(A) 1 milliliter (mL) per 15 to 20 pounds (lbs) of body weight by intramuscular injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight; or

(B) 1 mL per 25 to 60 lbs of body weight by intravenous injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight.

(ii) For general anesthesia, administer as follows:

(A) Administer 1 mL per 40 lbs of body weight by intramuscular injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 mg per pound of body weight; or

(B) Administer 1 mL per 25 to 60 lbs of body weight by intravenous injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 mg per pound of body weight.

(2) *Indications for use.* As an analgesic and tranquilizer and for general anesthesia.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16187, Mar. 25, 2014]

§ 522.810 Embutramide, chloroquine, and lidocaine solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 135 milligrams (mg) embutramide; 45 mg chloroquine phosphate, U.S.P.; and 1.9 mg lidocaine, U.S.P.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* One mL per 5 pounds of body weight.

(2) *Indications for use.* For euthanasia.

(3) *Limitations.* Not for use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 36337, June 23, 2005, as amended at 78 FR 17597, Mar. 22, 2013; 81 FR 17608, Mar. 30, 2016]

§ 522.812 Enrofloxacin.

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

(1) 22.7 milligrams (mg) enrofloxacin or

(2) 100 mg enrofloxacin.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter:

(1) No. 000859 for use of products described in paragraph (a) as in paragraph (e) of this section; and

(2) No. 055529 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section, and use of product described in paragraph (a)(2) in this section as in paragraphs (e)(2), (e)(3)(i)(B), and (e)(3)(ii) of this section.

(3) No. 026637 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section.

(c) *Related tolerance.* See § 556.226 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

(e) *Conditions of use—(1) Dogs.* Use the product described in paragraph (a)(1) of this section as follows:

(i) *Amount.* 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days.

§522.814

21 CFR Ch. I (4–1–16 Edition)

(ii) *Indications for use.* For the management of diseases associated with bacteria susceptible to enrofloxacin.

(2) *Cattle.* Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amount—(A) Single-dose therapy:* For treatment of bovine respiratory disease (BRD), administer 7.5 to 12.5 mg/kg of body weight (3.4 to 5.7 mL per 100 pounds (100 lb)) once by subcutaneous injection. For control of BRD, administer 7.5 mg/kg of body weight (3.4 mL/100 lb) once by subcutaneous injection.

(B) *Multiple-day therapy:* For treatment of BRD, administer 2.5 to 5.0 mg/kg of body weight (1.1 to 2.3 mL/100 lb) by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 3 days. Additional treatments may be given on days 4 and 5 to animals that have shown clinical improvement but not total recovery.

(ii) *Indications for use—(A) Single-dose therapy:* For the treatment of BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and non-lactating dairy cattle; for the control of BRD in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni* and *M. bovis*.

(B) *Multiple-day therapy:* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle.

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. This product is not approved for female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Swine.* Use the product described in paragraph (a)(2) of this section as follows:

(i) *Amounts and indications for use.* (A) Administer, either by intramuscular or subcutaneous (behind the ear) injection,

a single dose of 7.5 mg/kg of body weight for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, *Streptococcus suis*, *Bordetella bronchiseptica*, and *Mycoplasma hyopneumoniae*.

(B) Administer, by subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*.

(C) Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

(ii) *Limitations.* Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.

[72 FR 10597, Mar. 9, 2007, as amended at 73 FR 17890, Apr. 2, 2008; 73 FR 21819, Apr. 23, 2008; 76 FR 22611, Apr. 22, 2011; 77 FR 55415, Sept. 10, 2012; 77 FR 76863, Dec. 31, 2012; 78 FR 19987, Apr. 3, 2013; 79 FR 37620, July 2, 2014; 80 FR 13229, Mar. 13, 2015; 80 FR 18776, Apr. 8, 2015; 80 FR 61296, Oct. 13, 2015]

§522.814 Eprinomectin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) eprinomectin.

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

(c) *Related tolerances.* See §§500.1410 and 556.227 of this chapter.

(d) *Conditions of use in cattle on pasture—(1) Amount.* Administer 1 mg/kilogram of body weight by subcutaneous injection.

(2) *Indications for use.* For the treatment and control of the following internal and external parasites: Gastrointestinal roundworms (adults and fourth-stage larvae) *Bunostomum phlebotomum*, *Cooperia oncophora*, *C. punctata*, *C. surnabada*, *Trichostrongylus axei*, *Ostertagia ostertagi* (including inhibited stage); (adults) *Haemonchus placei*, *Oesophagostomum radiatum*, *O. lyrata*, *T. colubriformis*; lungworms

(adults) *Dictyocaulus viviparus*; cattle grubs *Hypoderma bovis*; mites *Sarcoptes scabiei* var. *bovis*. Prevents reinfection with *C. oncophora*, *C. punctata*, and *T. axei* for 100 days following treatment; *H. placei*, *O. radiatum*, *O. lyrata*, and *O. ostertagi* for 120 days following treatment; and *B. phlebotomum* and *D. viviparus* for 150 days following treatment.

(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 48 days of the last treatment. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

[76 FR 72618, Nov. 25, 2011, as amended at 79 FR 37620, July 2, 2014]

§ 522.820 Erythromycin.

(a) *Specifications*—(1) Each milliliter (mL) of solution contains 100 milligrams (mg) erythromycin base.

(2) Each mL of solution contains 200 mg erythromycin base.

(b) *Sponsor*. See No. 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.230 of this chapter.

(d) *Conditions of use*—(1) *Dog*. Administer product described in paragraph (a)(1) of this section as follows:

(i) *Amount*. 3 to 5 mg per pound (lb) body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use*. For the treatment of bacterial pneumonia, upper respiratory infections (tonsillitis, bronchitis, tracheitis, pharyngitis, pleurisy), endometritis and metritis, and bacterial wound infections caused by *Staphylococcus* spp., *Streptococcus* spp., and *Corynebacterium* spp., sensitive to erythromycin.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*. Administer product described in paragraph (a)(1) of this section as follows:

(i) *Amount*. 3 to 5 mg/lb body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use*. For the treatment of bacterial pneumonia, upper respiratory infections (rhinitis, bronchitis), secondary infections associated with panleukopenia, and bacterial wound infections caused by *Staphylococcus* spp. and *Streptococcus* spp., susceptible to erythromycin.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cattle*. Administer products described in paragraph (a) of this section as follows:

(i) *Amount*. 4 mg/lb body weight by deep intramuscular injection once daily for up to 5 days.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (shipping fever complex and bacterial pneumonia) associated with *Pasteurella multocida* susceptible to erythromycin.

(iii) *Limitations*. Do not use in female dairy cattle over 20 months of age. Do not slaughter treated animals within 6 days of last treatment. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To avoid excess trim, do not slaughter within 21 days of last injection.

[72 FR 69142, Dec. 7, 2007, as amended at 79 FR 16187, Mar. 25, 2014]

§ 522.840 Estradiol.

(a) *Specifications*. Each silicone rubber implant contains 25.7 or 43.9 milligrams (mg) estradiol and is coated with not less than 0.5 mg oxytetracycline powder.

(b) *Sponsor*. See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.240 of this chapter.

(d) *Conditions of use*. For implantation in steers and heifers as follows:

(1) *Amount*. Insert one 25.7-mg implant every 200 days; insert one 43.9-mg implant every 400 days.

(2) *Indications for use*. For increased rate of weight gain in suckling and pastured growing steers; for improved feed efficiency and increased rate of weight gain in confined steers and heifers. No additional effectiveness may be

§ 522.842

expected from reimplanting in less than 200 days for the 25.7-mg implant or 400 days for the 43.9-mg implant.

(3) *Limitations.* For subcutaneous ear implantation in steers and heifers only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 67818, Nov. 22, 2004, as amended at 77 FR 31723, May 30, 2012]

§ 522.842 Estradiol benzoate and testosterone propionate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) No. 054771 for use as in paragraph (c)(1)(i), (c)(2), and (c)(3) of this section.

(2) No. 000986 for use as in paragraph (c) of this section.

(b) *Related tolerances.* See §§ 556.240 and 556.710 of this chapter.

(c) *Conditions of use.* For implantation in heifers as follows:

(1) *Amount.* (i) 20 milligrams (mg) estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 8 pellets, each pellet containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate) per implant dose.

(ii) 20 mg estradiol benzoate and 200 mg testosterone propionate (one implant consisting of 9 pellets, each of 8 pellets containing 2.5 mg estradiol benzoate and 25 mg testosterone propionate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(2) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(3) *Limitations.* For heifers weighing 400 pounds or more; for subcutaneous ear implantation, one dose per animal; not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 68252, Nov. 24, 2004, as amended at 77 FR 31723, May 30, 2012; 79 FR 16187, Mar. 25, 2014]

21 CFR Ch. I (4–1–16 Edition)

§ 522.850 Estradiol valerate and norgestomet in combination.

(a) *Specifications.* The product is a two-component drug consisting of the following:

(1) An implant containing 6.0 milligrams of norgestomet.

(2) An injectable solution (sesame oil) containing 3.0 milligrams of norgestomet and 5.0 milligrams of estradiol valerate per 2 milliliters.

(b) *Sponsor.* See 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* One implant and 2 milliliters of injection at time of implantation.

(2) *Indications for use.* For synchronization of estrus/ovulation in cycling beef cattle and non-lactating dairy heifers.

(3) *Limitations.* Insert implant subcutaneously in the ear only; then immediately inject solution intramuscularly only. Counting the day of implantation as day 1, remove the implant on day 10. Collect all implants as they are removed and burn them. While animals are restrained for artificial insemination, avoid other treatments such as vaccinations, dipping, pour-on grub and louse prevention, spraying, etc. When inseminating without estrus detection, the entire treated group should be started at 48 hours after the last implant has been removed and should be completed within 6 hours. Where estrus detection is preferred, insemination should be approximately 12 hours after first detection of estrus. Those that do not conceive can be re-bred when they return to estrus approximately 17 to 25 days after implant removal. Do not use in cows producing milk for human consumption.

[47 FR 55477, Dec. 10, 1982, as amended at 48 FR 49656, Oct. 27, 1983; 51 FR 33592, Sept. 22, 1986; 54 FR 1165, Jan. 12, 1989]

§ 522.863 Ethylisobutrazine.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of ethylisobutrazine hydrochloride.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer 2 to 5 mg per pound of body weight by intramuscular injection for profound tranquilization.

Administer 1 to 2 mg per pound of body weight by intravenous injection to effect.

(2) *Indications for use.* For use as a tranquilizer.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16187, Mar. 25, 2014]

§ 522.870 Etodolac.

(a) *Specifications.* Each milliliter contains 100 milligrams (mg) etodolac.

(b) *Sponsor.* See No. 000010 in § 510.600 of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer 4.5 to 6.8 mg/pound (10 to 15 mg/kilogram) body weight as a single, dorsoscapular subcutaneous injection. If needed, the daily dose of etodolac tablets as in § 520.870 of this chapter may be given 24 hours after the injection.

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

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 51365, Sept. 7, 2007, as amended at 75 FR 10167, Mar. 5, 2010]

§ 522.883 Etorphine.

(a) *Specifications.* Each milliliter of solution contains 1 milligram of etorphine hydrochloride.

(b) *Sponsor.* See No. 053923 in § 510.600(c) of this chapter.

(c) *Special considerations.* Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

(d) *Conditions of use—(1) Amount.* Administered intramuscularly by hand syringe or syringe dart at a suitable dosage level depending upon the species.

(2) *Indications for use.* For the immobilization of wild and exotic animals.

(3) *Limitations.* Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

§ 522.900 Euthanasia solution.

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

(1) 390 milligrams (mg) of pentobarbital sodium and 50 mg phenytoin sodium.

(2) 400 mg secobarbital sodium and 25 mg dibucaine hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(1) Nos. 000061, 051311, and 054925 for use of product described in paragraph (a)(1) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) of this section.

(c) *Special considerations.* Product labeling shall bear the following warning statements: “ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with state and local laws, to prevent consumption of carcass material by scavenging wildlife.”

(d) *Conditions of use in dogs—(1) Indications for use.* For humane, painless, and rapid euthanasia.

(2) *Amount.* One mL per 10 pounds of body weight.

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

[68 FR 42969, July 21, 2003, as amended at 68 FR 55824, Sept. 29, 2003; 70 FR 8929, Feb. 24, 2005; 71 FR 13542, Mar. 16, 2006; 79 FR 16188, Mar. 25, 2014]

§ 522.914 Fenprostalene.

(a) *Specifications.* (1) Each milliliter of solution contains 0.5 milligram (mg) fenprostalene.

(2) Each milliliter of solution contains 0.25 mg fenprostalene.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section; and for use of product described in paragraph (a)(2) as in paragraph (e)(2) of this section.

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

(d) *Special considerations.* Labeling shall bear the following statements:

§ 522.930

21 CFR Ch. I (4–1–16 Edition)

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

(e) *Conditions of use*—(1) *Cattle*—(i) *Indications for use and amount*—(A) For feedlot heifers to induce abortion when pregnant 150 days or less, administer 1 mg (2 milliliter (mL)) subcutaneously.

(B) For beef or nonlactating dairy cattle for estrus synchronization, administer a single or two 1-mg (2-mL) doses subcutaneously, 11 to 13 days apart.

(ii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount*. Administer a single injection of 0.25 mg (1 mL) subcutaneously.

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

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

§ 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 of solution contains:

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

(2) 300 mg florfenicol in the inactive vehicles n-methyl-2-pyrrolidone, propylene glycol, and polyethylene glycol.

(3) 300 mg florfenicol in the inactive vehicles 2-pyrrolidone and glycerol formal.

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter:

(1) No. 000061 for use of product described in paragraph (a)(1) as in paragraph (d)(1)(i); and

(2) Nos. 000061 and 000859 for use of product described in paragraph (a)(2) as in paragraph (d)(1)(ii).

(3) No. 055529 for use of product described in paragraph (a)(3) as in paragraph (d)(1)(ii).

(c) *Related tolerances*. See §§ 500.1410 and 556.283 of this chapter.

(d) *Conditions of use*—(1) *Beef and nonlactating dairy cattle*—(i) 300 mg per milliliter (mL) florfenicol in the inactive vehicles 2-pyrrolidone and triacetin:

(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*. Animals intended for human consumption must not be slaughtered within 44 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 pre-ruminating 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 the inactive vehicles n-methyl-2-pyrrolidone, propylene glycol, and polyethylene glycol, or in 2-pyrrolidone and glycerol formal:

(A)(I) *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.* Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. Animals intended for human consumption must not be slaughtered within 33 days of subcutaneous treatment. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in pre-ruminating 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 at 74 FR 66574, Dec. 16, 2009; 79 FR 18158, Apr. 1, 2014; 79 FR 53136, Sept. 8, 2014; 80 FR 61296, Oct. 13, 2015; 80 FR 76386, Dec. 9, 2015]

§ 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.* Animals intended for human consumption must not be slaughtered within 38 days of treatment. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in prerinuating 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.

[75 FR 1275, Jan. 11, 2010, as amended at 75 FR 54018, Sept. 3, 2010; 79 FR 18158, Apr. 1, 2014]

§ 522.960 Flumethasone injectable dosage forms.

§ 522.960a Flumethasone suspension.

(a) *Specifications.* Each milliliter of suspension contains 2 milligrams (mg) of flumethasone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 6 to 10 mg by intra-articular injection. Dosage is limited to a single injection per week in any one synovial structure.

(2) *Indications for use.* For use 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.

(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 16188, Mar. 25, 2014]

§ 522.960b Flumethasone acetate solution.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) of flumethasone acetate.

§ 522.960c

21 CFR Ch. I (4–1–16 Edition)

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer by intramuscular injection as follows: Dogs weighing up to 10 pounds (lbs): 2 mg; dogs weighing 10 to 25 lbs: 4 mg; dogs weighing over 25 lbs: 8 mg. 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 conditions intramuscular therapy may be followed by oral administration of flumethasone tablets at a daily dose of from 0.0625 to 0.25 mg per animal.

(2) *Indications for use.* For use in certain acute and chronic canine dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

§ 522.960c **Flumethasone solution.**

(a) *Specifications.* Each milliliter of solution contains 0.5 milligrams (mg) of flumethasone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Amount.* Administer 1.25 to 2.5 milligrams (mg) daily by intravenous, intramuscular, or intra-articular injection.

(ii) *Indications for use.* For use in the treatment of musculoskeletal conditions due to inflammation, where permanent structural changes do not exist, e.g., bursitis, carpalis, osselets, and myositis; and allergic states, e.g., hives, urticaria, and insect bites.

(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.

(2) *Dogs*—(i) *Amount.* Administer 0.0625 to 0.25 mg daily by intravenous, intramuscular, or subcutaneous injection; 0.125 to 1.0 mg daily by intralesional injection, depending on the size and location of the lesion; or 0.166 to 1.0 mg daily by intra-articular injection, depending on the severity of the

condition and the size of the involved joint.

(ii) *Indications for use.* For use in the treatment of musculoskeletal conditions due to inflammation of muscles or joints and accessory structures where permanent structural changes do not exist, e.g., arthritis, osteoarthritis, disc syndrome, and myositis (in septic arthritis, appropriate antibacterial therapy should be concurrently administered); certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation; otitis externa in conjunction with topical medication; allergic states, e.g., hives, urticaria, and insect bites; and shock and shock-like states by intravenous administration.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cats*—(i) *Amount.* Administer 0.03125 to 0.125 mg daily by intravenous, intramuscular, or subcutaneous injection.

(ii) *Indications for use.* For use in the treatment of certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

§ 522.970 **Flunixin.**

(a) *Specifications.* Each milliliter of solution contains flunixin meglumine equivalent to 50 milligrams (mg) flunixin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) See Nos. 000061, 055529, and 061623 for use as in paragraph (e) of this section.

(2) See No. 054771 for use as in paragraph (e)(1) of this section.

(3) See Nos. 057561 and 059130 for use as in paragraphs (e)(1) and (2) of this section.

(c) *Related tolerances.* See § 556.286 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Horses*—(i) *Amount*. 0.5 mg per pound (lb) of body weight per day, intravenously or intramuscularly, for up to 5 days.

(ii) *Indications for use*. For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic.

(iii) *Limitations*. Do not use in horses intended for human consumption.

(2) *Cattle*—(i) *Amounts and indications for use*—(A) Administer 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day intravenously, as a single dose or divided into two doses administered at 12-hour intervals, for up to 3 days for control of pyrexia associated with bovine respiratory disease and endotoxemia or for control of inflammation in endotoxemia.

(B) Administer 2.2 mg/kg (1.0 mg/lb) of body weight once intravenously for control of pyrexia associated with acute bovine mastitis.

(ii) *Limitations*. Cattle must not be slaughtered for human consumption within 4 days of last treatment. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. Do not use in dry dairy cows. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal.

(B) For control of pyrexia associated with acute bovine mastitis.

(iii) *Limitations*. Do not slaughter for food use within 4 days of last treatment. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. For Nos. 000061, 055529, 059130, and 061623: Do not use in dry dairy cows. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. For No. 057561: Not for use in lactating or dry dairy cows.

(3) *Swine*—(i) *Amount*. Administer 2.2 mg/kg (1.0 mg/lb) of body weight as a single intramuscular injection.

(ii) *Indications for use*. For the control of pyrexia associated with swine respiratory disease.

(iii) *Limitations*. Swine must not be slaughtered for human consumption within 12 days of last treatment.

[42 FR 39103, Aug. 2, 1977, as amended at 52 FR 7832, Mar. 13, 1987; 60 FR 54942, Oct. 27, 1995; 62 FR 22888, Apr. 28, 1997; 63 FR 38749, July 20, 1998; 67 FR 9400, Mar. 1, 2002; 68 FR 70701, Dec. 19, 2003; 69 FR 53618, Sept. 2, 2004; 69 FR 60308, Oct. 8, 2004; 70 FR 48868, Aug. 22, 2005; 70 FR 70998, Nov. 25, 2005; 71 FR 15564, Mar. 29, 2006; 71 FR 16222, Mar. 31, 2006; 73 FR 2809, Jan. 16, 2008; 73 FR 28037, May 15, 2008; 74 FR 6994, Feb. 12, 2009; 74 FR 34236, July 15, 2009; 75 FR 13225, Mar. 19, 2010; 75 FR 76260, Dec. 8, 2010; 79 FR 16189, Mar. 25, 2014]

§ 522.995 Fluprostenol.

(a) *Specifications*. Each milliliter of solution contains fluprostenol sodium equivalent to 50 micrograms (µg) of fluprostenol.

(b) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 0.55 µg fluprostenol per kilogram of body weight by intramuscular injection.

(2) *Indications for use*. For use in mares for its luteolytic effect to control the timing of estrus in estrous cycling and in clinically anestrous mares that have a corpus luteum.

(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 16189, Mar. 25, 2014]

§ 522.1002 Follicle stimulating hormone.

(a)(1) *Specifications*. Each package contains 2 vials. One vial contains dry, powdered, porcine pituitary gland equivalent to 75 units (NIH-FSH-S1) of follicle stimulating hormone. The other vial contains 10 milliliters of aqueous diluent.

(2) *Sponsor*. See No. 052923 in § 510.600(c) of this chapter.

(3) *Conditions of use*. (i) *Dosage*. 12.5 units of follicle stimulating hormone twice a day for 3 days (a total of 75 units). To effect regression of the corpus luteum, prostaglandin should be given with the 5th dose.

(ii) *Indications for use*. For induction of superovulation in cows for procedures requiring the production of multiple ova at a single estrus.

§522.1010

21 CFR Ch. I (4–1–16 Edition)

(iii) *Limitations.* For intramuscular use in cows that are not pregnant and have a normal corpus luteum. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* The drug is a lyophilized pituitary extract material. Each 10-milliliter vial contains an amount equivalent to 50 milligrams of standard porcine follicle stimulating hormone and is reconstituted for use by addition of 10 milliliters of 0.9 percent aqueous sodium chloride solution.

(2) *Sponsor.* See 063112 in §510.600(c) of this chapter.

(3) *Conditions of use.* (i) *Dosage.* Cattle and horses, 10–50 milligrams; sheep and swine, 5–25 milligrams; dogs, 5–15 milligrams.

(ii) *Indications for use.* The drug is used as a supplemental source of follicle stimulating hormone where there is a general deficiency in cattle, horses, sheep, swine, and dogs.

(iii) *Limitations.* Administer intramuscularly, subcutaneously, or intravenously. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each package contains 2 vials. One vial contains 700 international units (IU) porcine-pituitary derived follicle stimulating hormone (FSH) equivalent to 400 milligrams NIH-FSH-P1, as a dry powder. The other vial contains 20 milliliters (mL) of bacteriostatic sodium chloride injection. When reconstituted, each milliliter of constituted solution contains 35 IU FSH.

(2) *Sponsor.* See No. 017030 in §510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* Administer 2.5 mL (87.5 IU) intramuscularly, twice daily at 12-hour intervals, for 4 consecutive days. In conjunction with the 6th dose, administer an approved prostaglandin product for cattle (cloprostenol sodium or dinoprost tromethamine), using the labeled dosage and administration instructions to cause luteolysis and induce estrus. See §522.460 for use of cloprostenol sodium or §522.690 for use of dinoprost tromethamine.

(ii) *Indications for use.* For the induction of superovulation in beef and dairy heifers and cows.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 47377, Sept. 9, 1993, as amended at 62 FR 62242, Nov. 21, 1997; 76 FR 2808, Jan. 18, 2011; 79 FR 53136, Sept. 8, 2014; 79 FR 74020, Dec. 15, 2014]

§522.1010 Furosemide.

(a) *Specifications—(1)* Each milliliter (mL) of solution contains 50 milligrams (mg) furosemide monoethanolamine.

(2) Each mL of solution contains 50 mg furosemide diethanolamine.

(b) *Sponsors.* See sponsors in §510.600(c) of this chapter for use of products described in paragraph (a) of this section for use as in paragraph (d) of this section.

(1) No. 000010 as described in paragraph (a)(1) of this section for use as in paragraphs (d)(1) and (d)(2)(ii) of this section.

(2) No. 061623 as described in paragraph (a)(2) of this section for use as in paragraph (d)(2)(ii) of this section.

(3) No. 000859 as described in paragraph (a)(2) for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

(4) No. 000061 as described in paragraph (a)(2) for use as in paragraphs (d)(1), (d)(2)(iii), and (d)(3) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use—(1) Dogs and cats—(i) Amount.* 1.25 to 2.5 mg per pound (1b) body weight once or twice daily, intramuscularly or intravenously.

(ii) *Indications for use.* For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

(2) *Horses—(i) Amount.* 250 to 500 mg per animal once or twice daily, intramuscularly or intravenously.

(A) *Indications for use.* For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency, and acute noninflammatory tissue edema.

(B) *Limitations.* Do not use in horses intended for human consumption.

(ii) *Amount.* 0.5 mg/lb body weight once or twice daily, intramuscularly or intravenously.

(A) *Indications for use.* For treatment of acute noninflammatory tissue edema.

(B) *Limitations.* Do not use in horses intended for human consumption.

(iii) *Amount.* 250 to 500 mg/animal once or twice daily, intramuscularly or intravenously.

(A) *Indications for use.* For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency, and acute noninflammatory tissue edema.

(B) *Limitations.* Do not use in horses intended for human consumption.

(3) *Cattle*—(i) *Amount.* 500 mg/animal once daily, intramuscularly or intravenously; or 250 mg/animal twice daily at 12-hour intervals, intramuscularly or intravenously.

(ii) *Indications for use.* For the treatment of physiological parturient edema of the mammary gland and associated structures.

(iii) *Limitations.* Treatment not to exceed 48 hours post-parturition. Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.

[66 FR 47961, Sept. 17, 2001, as amended at 67 FR 18086, Apr. 15, 2002; 68 FR 59881, Oct. 20, 2003; 69 FR 17585, Apr. 5, 2004; 71 FR 39548, July 13, 2006; 74 FR 61516, Nov. 25, 2009; 76 FR 17338, Mar. 29, 2011; 78 FR 17597, Mar. 22, 2013; 79 FR 16189, Mar. 25, 2014]

§ 522.1014 Gamithromycin.

(a) *Specifications.* Each milliliter (mL) of solution contains 150 milligrams (mg) gamithromycin.

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

(c) *Related tolerances.* See § 556.292 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer 6 mg/kilogram of body weight (2 mL per 110 pounds) one time by subcutaneous injection in the neck.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*,

Histophilus somni, and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida*.

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 35 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product 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]

[76 FR 57906, Sept. 19, 2011, as amended at 77 FR 26162, May 3, 2012]

§ 522.1020 Gelatin.

(a) *Specifications.* Each 100 milliliters contains 8 grams of gelatin in a 0.85 percent sodium chloride solution.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* The exact dosage to be administered must be determined after evaluating the animal's condition and will vary according to the size of the animal and the degree of shock. A suggested dosage range for small animals such as dogs is 4 to 8 cubic centimeters per pound body weight. The suggested dosage range for large animals such as sheep, calves, cows, or horses is 2 to 4 cubic centimeters per pound of body weight.

(2) *Indications for use.* For use to restore circulatory volume and maintain blood pressure in animals being treated for shock.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16189, Mar. 25, 2014]

§ 522.1044 Gentamicin.

(a) *Specifications.* Each milliliter of solution contains gentamicin sulfate equivalent to 5, 50, or 100 milligrams (mg) gentamicin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000061 for use of 5 mg per milliliter (mL) solution in swine as in paragraph (d)(4), 50 mg/mL solution in dogs and cats as in paragraph (d)(1), 50 mg/mL and 100 mg/mL solution in chickens and turkeys as in paragraphs (d)(2) and (d)(3) of this section.

(2) No. 058005 for use of 5 mg/mL solution in swine as in paragraph (d)(4) of this section.

(3) No. 054628 for use of 50 mg/mL solution in dogs as in paragraph (d)(5) of this section.

(4) Nos. 000859 and 061623 for use of 100 mg/mL solution in turkeys as in paragraph (d)(2) and in chickens as in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.300 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* Two milligrams of gentamicin per pound of body weight, twice daily on the first day, once daily thereafter, using a 50 milligram-per-milliliter solution.

(ii) *Indications for use*—(a) *Dogs.* For the treatment of infections of urinary tract (cystitis, nephritis), respiratory tract (tonsillitis, pneumonia, tracheobronchitis), skin and soft tissue (pyodermatitis, wounds, lacerations, peritonitis).

(b) *Cats.* For the treatment of infections of urinary tract (cystitis, nephritis), respiratory tract (pneumonitis, pneumonia, upper respiratory tract infections), skin and soft tissue (wounds, lacerations, peritonitis), and as supportive therapy for secondary bacterial infections associated with panleucopenia.

(iii) *Limitations.* Administer intramuscularly or subcutaneously. If response is not noted after 7 days, the antibiotic sensitivity of the infecting organism should be retested. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Turkeys*—(i) *Amount.* One milligram of gentamicin per 0.2 milliliter dose, using the 50- or 100-milligrams-per-milliliter product diluted with sterile saline to a concentration of 5 milligrams-per-milliliter.

(ii) *Indications for use.* As an aid in the prevention of early mortality due to Arizona paracolon infections susceptible to gentamicin.

(iii) *Limitations.* For 1- to 3-day old turkey poults. Administer subcutaneously in the neck. Injected poults must not be slaughtered for food for at least 9 weeks after treatment.

(3) *Chickens*—(i) *Amount.* 0.2 milligram of gentamicin per 0.2 milliliter dose, using the 50- or 100-milligrams-per-milliliter product diluted with sterile saline to a concentration of 1.0 milligram-per-milliliter.

(ii) *Indications for use.* In day-old chickens, for prevention of early mortality caused by *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* that are susceptible to gentamicin.

(iii) *Limitations.* For use in day-old chickens only. Administer aseptically, injecting the diluted product subcutaneously in the neck. Do not slaughter treated animals for food for at least 5 weeks after treatment.

(4) *Swine*—(i) *Amount.* 5 milligrams of gentamicin as a single intramuscular dose using 5 milligram-per-milliliter solution.

(ii) *Indications for use.* In piglets up to 3 days old for treatment of porcine colibacillosis caused by strains of *E. coli* sensitive to gentamicin.

(iii) *Limitations.* For single intramuscular dose in pigs up to 3 days of age only. Do not slaughter treated animals for food for at least 40 days following treatment.

(5) *Dogs*—(i) *Amount.* 2 milligrams of gentamicin per pound of body weight, twice daily on the first day, then once daily.

(ii) *Indications for use.* For use in the treatment of urinary tract infections (cystitis) caused by *Proteus mirabilis*, *Escherichia coli*, and *Staphylococcus aureus*.

(iii) *Limitations.* Administer intramuscularly or subcutaneously. If no improvement is seen after 3 days, treatment should be discontinued and the diagnosis reevaluated. Treatment

not to exceed 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 1942, Jan. 13, 1978, as amended at 48 FR 791, Jan. 7, 1983; 51 FR 15606, Apr. 25, 1986; 52 FR 7832, Mar. 13, 1987; 53 FR 40727, Oct. 18, 1988; 60 FR 29985, June 7, 1995; 61 FR 24441, May 15, 1996; 62 FR 45157, Aug. 26, 1997; 63 FR 59714, Nov. 5, 1998; 63 FR 68182, Dec. 10, 1998; 65 FR 45877, July 26, 2000; 71 FR 76901, Dec. 22, 2006; 78 FR 17597, Mar. 22, 2013; 78 FR 21060, Apr. 9, 2013; 79 FR 21127, Apr. 15, 2014]

§ 522.1066 Glycopyrrolate.

(a) *Specifications.* Each milliliter of solution contains 0.2 milligram glycopyrrolate.

(b) *Sponsors.* See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—*
(1) *Amount.* 5 micrograms per pound of body weight (0.25 milliliter per 10 pounds of body weight) by intravenous, intramuscular, or subcutaneous injection in dogs or by intramuscular injection in cats.

(2) *Indications for use.* As a preanesthetic agent.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[71 FR 64451, Nov. 2, 2006, as amended at 78 FR 17597, Mar. 22, 2013; 79 FR 16189, Mar. 25, 2014; 81 FR 17608, Mar. 30, 2016]

§ 522.1077 Gonadorelin.

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

(1) 43 micrograms (µg) of gonadorelin as gonadorelin acetate;

(2) 100 µg of gonadorelin as gonadorelin acetate;

(3) 50 µg of gonadorelin as gonadorelin diacetate tetrahydrate; or

(4) 50 µg of gonadorelin as gonadorelin hydrochloride.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 000061 for use of the 43-µg/mL product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(iv), and (d)(2) of this section.

(2) No. 068504 for use of the 100-µg/mL product described in paragraph (a)(2) as in paragraphs (d)(1)(ii), (d)(1)(v), and (d)(2) of this section.

(3) Nos. 000859 and 050604 for use of the 50-µg/mL product described in para-

graph (a)(3) as in paragraphs (d)(1)(ii) and (d)(2) of this section.

(4) No. 054771 for use of the 50-µg/mL product described in paragraph (a)(4) as in paragraphs (d)(1)(iii), (d)(1)(vi), and (d)(2) of this section.

(c) *Special considerations.* Concurrent luteolytic drug use is approved as follows:

(1) Cloprostenol injection for use as in paragraph (d)(1)(iv) of this section as provided by No. 000061 in § 510.600(c) of this chapter.

(2) Cloprostenol injection for use as in paragraph (d)(1)(v) of this section as provided by No. 000061 or No. 068504 in § 510.600(c) of this chapter.

(3) Dinoprost injection for use as in paragraph (d)(1)(vi) of this section as provided by No. 054771 in § 510.600(c) of this chapter.

(d) *Conditions of use in cattle—*(1) *Indications for use and amounts—*(i) For the treatment of ovarian follicular cysts in dairy cattle: Administer 86 µg gonadorelin by intramuscular or intravenous injection.

(ii) For the treatment of ovarian follicular cysts in dairy cattle: Administer 100 µg gonadorelin by intramuscular or intravenous injection.

(iii) For the treatment of ovarian follicular cysts in cattle: Administer 100 µg gonadorelin by intramuscular injection.

(iv) For use with cloprostenol injection to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows: Administer to each cow 86 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 86 µg gonadorelin by intramuscular injection.

(v) For use with cloprostenol injection to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows and beef cows: Administer to each cow 100 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 100 µg gonadorelin by intramuscular injection.

§ 522.1079

21 CFR Ch. I (4–1–16 Edition)

(vi) For use with dinoprost injection to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows: Administer to each cow 100 to 200 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 25 mg dinoprost by intramuscular injection, followed 30 to 72 hours later by 100 to 200 µg gonadorelin by intramuscular injection.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[80 FR 34279, June 16, 2015]

§ 522.1079 Serum gonadotropin and chorionic gonadotropin.

(a) *Specifications.* Each dose consists of 400 international units (I.U.) serum gonadotropin and 200 I.U. chorionic gonadotropin as a freeze-dried powder to be reconstituted with 5 milliliters of sterile aqueous diluent.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine—(1) Amount.* 400 I.U. serum gonadotropin with 200 I.U. chorionic gonadotropin per 5 milliliters dose per animal.

(2) *Indications for use.* (i) *Gilts.* For induction of fertile estrus (heat) in healthy prepuberal (nonycling) gilts.

(ii) *Sows.* For induction of estrus in healthy weaned sows experiencing delayed return to estrus.

(3) *Limitations.* For subcutaneous use only.

(i) *Gilts.* For use only in gilts over 5½ months of age and weighing at least 85 kilograms (187 pounds).

(ii) *Sows.* Delayed return to estrus is most prevalent after the first litter. The effectiveness has not been established after later litters. Delayed return to estrus often occurs during periods of adverse environmental conditions, and sows mated under such conditions may farrow smaller than normal litters.

[55 FR 1405, Jan. 16, 1990, as amended at 58 FR 52222, Oct. 7, 1993; 74 FR 61516, Nov. 25, 2009]

§ 522.1081 Chorionic gonadotropin.

(a) *Specifications.* Each vial contains 5,000, 10,000 or 20,000 USP units of lyophilized powder for constitution

with accompanying diluent to a 10-milliliter solution.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) Nos. 000402 and 054771 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B) and (d)(1)(i)(C) of this section.

(2) [Reserved]

(3) No. 000061 for use as in paragraphs (d)(1)(i)(A) and (d)(2) of this section.

(c) *Related tolerances.* See § 556.304 of this chapter.

(d) *Conditions of use—(1) Cattle—(i) Amount.* As a single dose. Dosage may be repeated in 14 days if the animal's behavior or examination of the ovaries *per rectum* indicates retreatment.

(A) 10,000 USP units by intramuscular injection.

(B) 500 to 2,500 USP units by intrafollicular injection.

(C) 2,500 to 5,000 USP units by intravenous injection.

(ii) *Indications for use.* For parenteral use in cows for treatment of nymphomania (frequent or constant heat) due to cystic ovaries.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Finfish—(i) Amount.* 50 to 510 IU per pound of body weight for males, 67 to 1,816 IU per pound of body weight for females, by intramuscular injection. Up to three doses may be administered.

(ii) *Indications for use.* An aid in improving spawning function in male and female brood finfish.

(iii) *Limitations.* In fish intended for human consumption, the total dose administered per fish (all injections combined) should not exceed 25,000 IU chorionic gonadotropin. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[74 FR 61516, Nov. 25, 2009, as amended at 76 FR 17778, Mar. 31, 2011; 77 FR 55414, Sept. 10, 2012; 79 FR 16189, Mar. 25, 2014]

§ 522.1083 Gonadotropin releasing factor analog-diphtheria toxoid conjugate.

(a) *Specifications.* Each milliliter of solution contains 0.2 milligrams (mg) gonadotropin releasing factor analog-diphtheria toxoid conjugate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Amount*. Administer 0.4 mg (2 milliliter (mL)) by subcutaneous injection no earlier than 9 weeks of age. A second subcutaneous injection of 0.4 mg (2 mL) should be administered at least 4 weeks after the first dose.

(2) *Indications for use*. For the temporary immunological castration (suppression of testicular function) and reduction of boar taint in intact male pigs intended for slaughter.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Pigs should be slaughtered no earlier than 3 weeks and no later than 10 weeks after the second dose.

[76 FR 27889, May 13, 2011, as amended at 77 FR 4227, Jan. 27, 2012; 79 FR 16189, Mar. 25, 2014]

§ 522.1085 Guaifenesin powder for injection.

(a) *Specifications*. The product is a sterile powder containing guaifenesin. A solution is prepared by dissolving the drug in sterile water for injection to make a solution containing 50 milligrams of guaifenesin per milliliter of solution.

(b) *Sponsors*. See Nos. 037990 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 1 milliliter of prepared solution per pound of body weight by rapid intravenous infusion.

(2) *Indications for use*. For use as a muscle relaxant.

(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 16189, Mar. 25, 2014]

§ 522.1086 Guaifenesin solution.

(a) *Specifications*. Each milliliter of solution contains 50 milligrams (mg) of guaifenesin and 50 mg of dextrose.

(b) *Sponsors*. See Nos. 000859 and 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 1 milliliter per pound of body weight by rapid intravenous infusion.

(2) *Indications for use*. For use as a skeletal muscle relaxant.

(3) *Limitations*. Do not use in horses intended for human consumption. Fed-

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

[79 FR 16189, Mar. 25, 2014]

§ 522.1125 Hemoglobin glutamer-200 (bovine).

(a) *Specifications*. Each 125 milliliter bag contains 13 grams per deciliter of polymerized hemoglobin of bovine origin in modified Lactated Ringer's Solution. It is a sterile, clear, dark purple solution.

(b) *Sponsor*. See No. 063075 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount*. One-time dose of 10 to 30 milliliters per kilogram of body weight administered intravenously at a rate of up to 10 milliliters per kilogram per hour.

(2) *Indications for use*. For the treatment of anemia in dogs by increasing systemic oxygen content (plasma hemoglobin concentration) and improving the clinical signs associated with anemia, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis).

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[63 FR 11598, Mar. 10, 1998, as amended at 65 FR 20732, Apr. 18, 2000; 79 FR 16189, Mar. 25, 2014]

§ 522.1145 Hyaluronate.

(a)(1) *Specifications*. Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor*. See 054771 in § 510.600(c).

(3) *Conditions of use*—(i) *Amount*. Small and medium-size joints (carpal, fetlock): 20 mg; larger joint (hock): 40 mg. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use*. Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(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.

(b)(1) *Specifications*. Each milliliter of sterile aqueous solution contains 5 milligrams of hyaluronate sodium.

(2) *Sponsor*. See 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. Small and medium-size joints (carpal, fetlock): 10 mg; larger joint (hock): 20 mg. Treatment may be repeated at weekly intervals for a total of four treatments.

(ii) *Indications for use*. Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(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.

(c)(1) *Specifications*. Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

(2) *Sponsor*. See No. 000010 in §510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. Small and medium-size joints (carpal, fetlock): 20 mg. Treatment may be repeated after 1 or more weeks but not to exceed 2 injections per week for a total of 4 weeks.

(ii) *Indications for use*. For the intra-articular treatment of carpal or fetlock joint dysfunction in horses due to acute or chronic, non-infectious synovitis associated with equine osteoarthritis.

(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.

(d)(1) *Specifications*. Each milliliter of sterile aqueous solution contains 10 milligrams of hyaluronate sodium.

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

(3) *Conditions of use*—(i) *Amount*. 50 milligrams in carpal and fetlock joints.

(ii) *Indications for use*. For treatment of equine carpal and fetlock joint dysfunction caused by traumatic and/or degenerative joint disease of mild to moderate severity.

(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.

(e)(1) *Specifications*. Each milliliter of solution contains:

(i) 10 milligrams (mg) hyaluronate sodium; or

(ii) 10 mg hyaluronate sodium with benzyl alcohol as a preservative.

(2) *Sponsors*. See sponsors in §510.600(c) of this chapter:

(i) No. 050604 for use of products described in paragraph (e)(1) as in paragraph (e)(3) of this section.

(ii) No. 017030 for use of product described in paragraph (e)(1)(i) as in paragraph (e)(3) of this section.

(3) *Conditions of use*—(i) *Amount*. 20 mg of the product described in paragraph (e)(1)(i) of this section by intra-articular injection into the carpus or fetlock; or 40 mg of the product described in paragraph (e)(1)(i) or (e)(1)(ii) of this section by slow intravenous injection into the jugular vein. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use*. For treatment of carpal or fetlock joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis.

(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.

(f)(1) *Specifications*. Each milliliter of sterile aqueous solution contains 11 milligrams of hyaluronate sodium.

(2) *Sponsor*. See 060865 in §510.600(c).

(3) *Conditions of use*—(i) *Amount*. Small and medium-size joints (carpal, fetlock): 22 mg; larger joint (hock): 44 mg. Treatment may be repeated at weekly intervals for a total of three treatments.

(ii) *Indications for use*. Treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

(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.

[49 FR 45124, Nov. 15, 1984, as amended at 51 FR 11438, Apr. 3, 1986; 51 FR 25032, July 10, 1986; 53 FR 19773, May 31, 1988; 53 FR 22297, June 15, 1988; 56 FR 50814, Oct. 9, 1991; 57 FR 2837, Jan. 24, 1992; 59 FR 33198, June 28, 1994; 61 FR 59003, Nov. 20, 1996; 63 FR 59216, Nov. 3, 1998; 71 FR 1689, Jan. 11, 2006; 71 FR 39204, July 12, 2006; 75 FR 1274, Jan. 11, 2010; 75 FR 10167, Mar. 5, 2010; 78 FR 73698, Dec. 9, 2013; 79 FR 16189, Mar. 25, 2014; 79 FR 74020, Dec. 15, 2014; 80 FR 34279, June 16, 2015]

§522.1150 Hydrochlorothiazide.

(a) *Specifications*. Each milliliter of solution contains 25 milligrams of hydrochlorothiazide.

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

(c) *Conditions of use*—(1) *Amount*. 5 to 10 milliliters (125 to 250 milligrams) intravenously or intramuscularly once or twice a day. After onset of diuresis, treatment may be continued with an orally administered maintenance dose.

(2) *Indications for use*. For use in cattle as an aid in the treatment of postparturient udder edema.

(3) *Limitations*. Milk taken from dairy animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 59058, Dec. 19, 1978, as amended at 62 FR 63271, Nov. 28, 1997; 79 FR 16190, Mar. 25, 2014]

§ 522.1155 Imidocarb powder for injection.

(a) *Specifications*. The product is a sterile powder containing imidocarb dipropionate. Each milliliter of constituted solution contains 100 milligrams (mg) of imidocarb base.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations*. Imidocarb dipropionate is sold only under permit issued by the Director of the National Program Planning Staff, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, to licensed or full-time State, Federal, or military veterinarians.

(d) *Conditions of use in horses and zebras*—(1) *Amount*. For *Babesia caballi* infections, administer 2 mg of imidocarb base per kilogram of body weight by intramuscular injection in the neck region, repeating dosage once after 24 hours. For *Babesia equi* infections, administer 4 mg of imidocarb base per kilogram of body weight by intramuscular injection in the neck region, repeating dosage four times at 72-hour intervals.

(2) *Indications for use*. For the treatment of babesiosis (piroplasmosis) caused by *Babesia caballi* and *Babesia equi*.

(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 16190, Mar. 25, 2014]

§ 522.1156 Imidocarb solution.

(a) *Specifications*. Each milliliter of solution contains 120 milligrams (mg) of imidocarb dipropionate.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer 6.6 mg per kilogram (3 mg per pound) of body weight by intramuscular injection. Repeat the dose after 2 weeks for a total of two treatments.

(2) *Indications for use*. For the treatment of clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16190, Mar. 25, 2014]

§ 522.1160 Insulin.

(a) *Specifications*—(1) Each milliliter (mL) of porcine insulin zinc suspension contains 40 international units (IU) of insulin.

(2) Each mL of protamine zinc recombinant human insulin suspension contains 40 IU of insulin.

(b) *Sponsors*. See sponsors in § 510.600 of this chapter for use as in paragraph (c) of this section.

(1) No. 000061 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

(2) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraphs (c)(2)(i)(B), (c)(2)(ii), and (c)(2)(iii) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer an initial once-daily dose of 0.5 IU per kilogram of body weight by subcutaneous injection concurrently with or right after a meal. Adjust this once-daily dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

(ii) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*—(A) *Porcine insulin zinc.* Administer an initial dose of 1 to 2 IU by subcutaneous injection. Injections should be given twice daily at approximately 12-hour intervals. For cats fed twice daily, the injections should be concurrent with or right after a meal. For cats fed ad libitum, no change in feeding is needed. Adjust the dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained.

(B) *Protamine zinc recombinant human insulin.* Administer an initial dose of 0.1 to 0.3 IU/pound of body weight (0.2 to 0.7 IU/kilogram) every 12 hours. The dose should be given concurrently with or right after a meal. Re-evaluate the cat at appropriate intervals and adjust the dose based on both clinical signs and glucose nadirs until adequate glycemic control has been attained.

(ii) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 25827, May 10, 2004, as amended at 73 FR 21042, Apr. 18, 2008; 74 FR 61517, Nov. 25, 2009; 74 FR 66048, Dec. 14, 2009]

§522.1182 Iron injection.

(a) *Specifications.* See §510.440 of this chapter. Each milliliter (mL) of solution contains the equivalent of:

(1) 100 milligrams (mg) of elemental iron derived from:

- (i) Ferric hydroxide;
- (ii) Ferric oxide; or
- (iii) Elemental iron.

(2) 200 mg of elemental iron derived from ferric hydroxide.

(b) *Sponsors and conditions of use.* It is used in baby pigs by sponsors in §510.600(c) of this chapter as follows:

(1) Nos. 000859 and 042552 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For prevention of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection at 2 to 4 days of age.

(ii) For treatment of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection. Dosage may be repeated in approximately 10 days.

(2) No. 054771 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For the prevention of anemia due to iron deficiency, administer an initial intramuscular injection of 100 mg at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 mg.

(3) Nos. 000061 and 059120 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For the prevention of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 150 mg of elemental iron to animals from 1 to 3 days of age.

(ii) For the treatment of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 200 mg of elemental iron per animal. Dosage may be repeated in 10 days to 2 weeks.

(4) Nos. 051311 and 054771 for use of product described in paragraph (a)(1)(ii) of this section as follows:

(i) For prevention of iron deficiency anemia, administer 1 mL by intramuscular injection at 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For treatment of iron deficiency anemia, administer 1 to 2 mL by intramuscular injection at 5 to 28 days of age.

(5) No. 054771 for use of product described in paragraph (a)(1)(iii) of this section as follows:

(i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection at 2 to 4 days of age.

(ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection up to 4 weeks of age.

(6) Nos. 000859 and 058005 for use of product described in paragraph (a)(1)(iii) of this section as follows:

(i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular injection at 2 to 4 days of age.

(ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular injection. Treatment may be repeated in 10 days.

(7) Nos. 000859 and 042552 for use of product described in paragraph (a)(2) of this section as follows:

(i) For prevention of baby pig anemia due to iron deficiency, intramuscularly inject 200 mg of elemental iron (1 mL) at 1 to 3 days of age.

(ii) For treatment of baby pig anemia due to iron deficiency, intramuscularly inject 200 mg of elemental iron at the first sign of anemia.

(8) No. 059120 for use of product described in paragraph (a)(2) of this section as follows:

(i) For prevention of iron deficiency anemia, administer 200 mg intramuscularly on or before 3 days of age.

(ii) For treatment of iron deficiency anemia, administer 200 mg intramuscularly.

[73 FR 12635, Mar. 10, 2008, as amended at 73 FR 14385, Mar. 18, 2008; 78 FR 17597, Mar. 22, 2013; 78 FR 44433, July 24, 2013; 79 FR 16190, Mar. 25, 2014]

§ 522.1185 Isoflupredone.

(a) *Specifications.* Each milliliter of suspension contains 2 milligrams (mg) of isoflupredone acetate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer 10 to 20 mg by intramuscular injection.

(ii) *Indications for use.* For use in the treatment of bovine ketosis. For alleviation of pain associated with generalized and acute localized arthritic conditions; for treating acute hypersensitivity reactions; and as an aid in correcting circulatory defects associated with severe toxicity and shock.

(iii) *Limitations.* Animals intended for human consumption should not be slaughtered within 7 days of last treatment. A withdrawal period has not been established for this product 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) *Horses and swine*—(i) *Amount*—(A) *Horses.* Administer 5 to 20 mg by intramuscular injection for systemic effect or by intrasynovial injection into a joint cavity, tendon sheath, or bursa for local effect.

(B) *Swine.* The usual dose for a 300-pound animal is 5 mg by intramuscular injection.

(ii) *Indications for use.* For alleviation of pain associated with generalized and acute localized arthritic conditions; for treating acute hypersensitivity reactions; and as an aid in correcting circulatory defects associated with severe toxicity and shock.

(iii) *Limitations.* Animals intended for human consumption should not be slaughtered within 7 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16190, Mar. 25, 2014]

§ 522.1192 Ivermectin.

(a) *Specifications*—(1) Each milliliter (mL) of solution contains 20 milligrams (mg) ivermectin.

(2) Each mL of solution contains 10 mg ivermectin.

(3) Each mL of solution contains 2.7 mg ivermectin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 050604 for use of the product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section; and the product described in paragraph (a)(3) of this section as in paragraphs (e)(3) and (e)(6) of this section.

(2) Nos. 000859 055529, 058005, and 061623 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2), (e)(3), (e)(4), and (e)(5) of this section.

(d) *Special considerations*—(1) See § 500.25 of this chapter.

(2) Labeling shall bear the following precaution: “This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.”

(e) *Conditions of use*—(1) *Horses*—(i) *Amount*. 200 micrograms per kilogram ($\mu\text{g}/\text{kg}$) of body weight by intramuscular injection.

(ii) *Indications for use*. For the treatment and control of large strongyles (adult) (*Strongylus vulgaris*, *S. edentatus*, *Triodontophorus* spp.), small strongyles (adult and fourth stage larvae) (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (adult and fourth-stage larvae) (*Oxyuris equi*), large roundworms (adult) (*Parascaris equorum*), hairworms (adult) (*Trichostrongylus axei*), large mouth stomach worms (adult) (*Habronema muscae*), neck threadworms (microfilariae) (*Onchocerca* spp.), and stomach bots (*Gastrophilus* spp.).

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

(2) *Cattle*—(i) *Amount*. 200 $\mu\text{g}/\text{kg}$ of body weight by subcutaneous injection.

(ii) *Indications for use*. For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*); lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*scabies*) (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*). For control of infections and to protect from reinfection with *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; *H. placei* and *C. oncophora* for 14 days after treatment.

(iii) *Limitations*. Do not treat cattle within 35 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do

not use in calves to be processed for veal.

(3) *Swine*—(i) *Amount*. 300 $\mu\text{g}/\text{kg}$ of body weight by subcutaneous injection.

(ii) *Indications for use*. For the treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (large roundworm, *Ascaris suum*; red stomach worm, *Hyostrogylus rubidus*; nodular worm, *Oesophagostomum* spp.; threadworm, *Strongyloides ransomi* (adults only)); somatic roundworm larvae (threadworm, *S. ransomi* (somatic larvae)); lungworms (*Metastrongylus* spp. (adults only)); lice (*H. suis*); and mites (*S. scabiei* var. *suis*).

(iii) *Limitations*. Do not treat swine within 18 days of slaughter.

(4) *American bison*—(i) *Amount*. 200 $\mu\text{g}/\text{kg}$ of body weight by subcutaneous injection.

(ii) *Indications for use*. For the treatment and control of grubs (*H. bovis*).

(iii) *Limitations*. Do not slaughter within 56 days of last treatment.

(5) *Reindeer*—(i) *Amount*. 200 $\mu\text{g}/\text{kg}$ of body weight by subcutaneous injection.

(ii) *Indications for use*. For the treatment and control of warbles (*Oedemagena tarandi*).

(iii) *Limitations*. Do not treat reindeer within 56 days of slaughter.

(6) *Ranch-raised foxes*—(i) *Amount*. 200 $\mu\text{g}/\text{kg}$ of body weight by subcutaneous injection. Repeat in 3 weeks.

(ii) *Indications for use*. For treatment and control of ear mites (*Otodectes cynotis*).

[72 FR 27735, May 17, 2007, as amended at 72 FR 62771, Nov. 7, 2007; 74 FR 9049, Mar. 2, 2009; 75 FR 26647, May 12, 2010; 76 FR 57906, Sept. 19, 2011; 78 FR 17597, Mar. 22, 2013]

§522.1193 Ivermectin and clorsulon.

(a) *Specifications*. Each milliliter (mL) of solution contains 10 milligrams (mg) (1 percent) ivermectin and 100 mg (10 percent) clorsulon.

(b) *Sponsors*. See Nos. 050604, 055529, and 058005 in §510.600(c) of this chapter.

(c) *Related tolerances*. See §§556.163 and 556.344 of this chapter.

(d) *Special considerations*. See §500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount*. Administer 1 mL (10 mg ivermectin and 100 mg clorsulon) per 50 kilograms (110 pounds) by subcutaneous injection.

(2) *Indications for use.* For the treatment and control of gastrointestinal nematodes (adults and fourth-stage larvae) (*Haemonchus placei*, *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia oncophora*, *C. punctata*, *C. pectinata*, *Oesophagostomum radiatum*, *Nematodirus helvetianus* (adults only), *N. spathiger* (adults only), *Bunostomum phlebotomum*; lungworms (adults and fourth-stage larvae) (*Dictyocaulus viviparus*); liver flukes (adults only) (*Fasciola hepatica*); grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mites (*Psoroptes ovis* (syn. *P. communis* var. *bovis*), *Sarcoptes scabiei* var. *bovis*); and for control of infections of *D. viviparus* and *O. radiatum* for 28 days after treatment; *O. ostertagi*, *T. axei*, and *C. punctata* for 21 days after treatment; and *H. placei* and *C. oncophora* for 14 days after treatment.

(3) *Limitations.* For No. 050604: Do not treat cattle within 21 days of slaughter. For Nos. 055529 and 058005: Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

[55 FR 38984, Sept. 24, 1990, as amended at 62 FR 14302, Mar. 26, 1997; 62 FR 63271, Nov. 28, 1997; 64 FR 26671, May 17, 1999; 69 FR 31735, June 7, 2004; 72 FR 27734, May 17, 2007; 77 FR 64717, Oct. 23, 2012; 79 FR 64116, Oct. 28, 2014]

§ 522.1204 Kanamycin.

(a) *Specifications.* Each milliliter of solution contains 50 or 200 milligrams (mg) of kanamycin as kanamycin 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 5 mg per pound of body weight per day in equally divided doses at 12-hour intervals.

(2) *Indications for use.* For the treatment of bacterial infections due to kanamycin sensitive organisms in dogs and cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16190, Mar. 25, 2014]

§ 522.1222 Ketamine.

(a) *Specifications.* Each milliliter contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity.

(b) *Sponsors.* See Nos. 000859, 026637, 054628, 054771, 059399, and 063286 in § 510.600(c) of this chapter.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use—*(1) *Cats—*(i) *Amount.* 5 to 15 mg/pound body weight intramuscularly, depending on the effect desired.

(ii) *Indications for use.* For restraint or as the sole anesthetic agent in diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation.

(2) *Subhuman primates—*(i) *Amount.* 3 to 15 mg/kilogram body weight intramuscularly, depending upon the species, general condition, and age of the subject.

(ii) *Indications for use.* For restraint.

[67 FR 17283, Apr. 10, 2002, as amended at 73 FR 8192, Feb. 13, 2008. Redesignated at 79 FR 16191, Mar. 25, 2014, as amended at 80 FR 13229, Mar. 13, 2015]

§ 522.1223 Ketamine, promazine, and aminopentamide.

(a) *Specifications.* Each milliliter of solution contains ketamine hydrochloride equivalent to 100 milligrams (mg) ketamine base activity, 7.5 (mg) of promazine hydrochloride, and 0.0625 mg of aminopentamide hydrogen sulfate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats—*(1) *Amount.* Administer by intramuscular injection 15 to 20 mg ketamine base per pound of body weight, depending on the effect desired.

(2) *Indications for use.* It is used in cats as the sole anesthetic agent for ovariohysterectomy and general surgery.

§ 522.1225

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16191, Mar. 25, 2014]

§ 522.1225 Ketoprofen.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) of ketoprofen.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer by intravenous injection 1.0 mg per pound of body weight once daily for up to 5 days.

(2) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders in horses.

(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 16191, Mar. 25, 2014]

§ 522.1242 Levamisole.

(a) *Specifications.* Each milliliter of solution contains levamisole phosphate equivalent to 136.5 or 182 milligrams of levamisole hydrochloride (13.65 or 18.2 percent).

(b) *Sponsor.* See Nos. 000061 and 057561 in § 510.600 of this chapter for use of 13.65 percent injection, and see No. 054771 for use of 13.65 and 18.2 percent injection.

(c) *Conditions of use—(1) Amount.* 2 milliliters per 100 pounds of body weight, subcutaneously in the neck.

(2) *Indications for use.* (i) The 13.65 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(ii) The 18.2 percent injection is used as an anthelmintic in cattle for treatment of the following parasites: stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*) and lungworms (*Dictyocaulus*).

21 CFR Ch. I (4–1–16 Edition)

(3) *Limitations.* Do not administer more than 10 milliliters per site. Cattle that are severely parasitized or maintained under conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after first treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Consult your veterinarian before using in severely debilitated animals or animals under severe stress. Do not administer to cattle within 7 days of slaughter. Do not administer to dairy animals of breeding age.

[43 FR 20489, May 12, 1978, as amended at 43 FR 29289, July 7, 1978; 43 FR 60895, Dec. 29, 1978; 47 FR 10807, Mar. 12, 1982; 62 FR 61625, Nov. 19, 1997; 65 FR 61090, Oct. 16, 2000; 67 FR 63055, Oct. 10, 2002. Redesignated and amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1260 Lincomycin.

(a) *Specifications.* Each milliliter of solution contains lincomycin hydrochloride monohydrate equivalent to:

(1) 25, 50, 100, or 300 milligrams (mg) lincomycin.

(2) 25, 100, or 300 mg lincomycin.

(3) 300 mg lincomycin.

(4) 100 or 300 mg lincomycin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (e) of this section.

(1) No. 054771 for use of concentrations in paragraph (a)(1) of this section as in paragraph (e) of this section.

(2) Nos. 000859 and 058005 for use of concentrations in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

(3) No. 054771 for use of concentration in paragraph (a)(3) of this section as in paragraph (e)(2) of this section.

(4) No. 061623 for use of concentrations in paragraph (a)(4) of this section as in paragraph (e)(2) of this section.

(c) *Special considerations.* When common labeling for use of the drug in dogs, cats, and swine is included with the drug, all such uses are subject to the labeling requirements of § 201.105 of this chapter.

(d) *Related tolerances.* See § 556.360 of this chapter.

(e) *Conditions of use.* It is used for animals as follows:

(1) *Dogs and cats—(i) Amount.* 5 mg per pound (lb) of body weight twice

daily or 10 mg/lb body weight once daily by intramuscular injection; 5 to 10 mg/lb body weight one or two times daily by slow intravenous injection.

(ii) *Indications for use.* Infections caused by Gram-positive organisms, particularly streptococci and staphylococci.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* 5 mg/lb body weight once daily by intramuscular injection for 3 to 7 days.

(ii) *Indications for use.* Treatment of infectious arthritis and mycoplasma pneumonia.

(iii) *Limitations.* Do not treat within 48 hours of slaughter.

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 31351, Aug. 2, 1985; 67 FR 34388, May 14, 2002; 68 FR 51705, Aug. 28, 2003; 69 FR 11507, Mar. 11, 2004; 69 FR 47361, Aug. 5, 2004; 71 FR 51996, Sept. 1, 2006; 78 FR 17597, Mar. 22, 2013; 79 FR 16191, Mar. 25, 2014]

§ 522.1289 Lufenuron.

(a) *Specifications.* Each milliliter of suspension contains 100 milligrams (mg) of lufenuron.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* 10 mg per kilogram (4.5 mg per pound) of body weight every 6 months, by subcutaneous injection.

(2) *Indications for use.* For control of flea populations in cats 6 weeks of age and older.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16191, Mar. 25, 2014, as amended at 80 FR 61297, Oct. 13, 2015]

§ 522.1290 Luprostirol.

(a) *Specifications.* Each milliliter of solution contains 7.5 milligrams (mg) luprostirol.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Special considerations.* Labeling shall bear the following statements: *Warning:* Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their preg-

nancies. Luprostirol is readily absorbed through the skin and can cause abortion and/or bronchospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) *Conditions of use in horses*—(1) *Amount.* 7.5 mg by intramuscular injection.

(2) *Indications for use.* For estrus control and termination of pregnancy in mares.

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

[55 FR 1185, Jan. 12, 1990, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 61 FR 66582, Dec. 18, 1996; 74 FR 25146, May 27, 2009]

§ 522.1315 Maropitant.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) maropitant as maropitant citrate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 1.0 mg per kilogram (mg/kg) of body weight by subcutaneous injection once daily for up to 5 consecutive days.

(ii) *Indications for use.* For the prevention and treatment of acute vomiting.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* Administer 1.0 mg/kg of body weight by subcutaneous injection once daily for up to 5 consecutive days.

(ii) *Indications for use.* For the treatment of vomiting.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 9243, Mar. 1, 2007, as amended at 77 FR 39391, July 3, 2012; 79 FR 16191, Mar. 25, 2014]

§ 522.1335 Medetomidine.

(a) *Specifications.* Each milliliter of solution contains 1.0 milligrams of medetomidine hydrochloride.

(b) *Sponsor.* See 052483 in § 510.600(c) of this chapter.

§ 522.1350

(c) *Conditions of use*—(1) *Amount*. 750 micrograms intravenously (IV) or 1,000 micrograms intramuscularly per square meter of body surface. The IV route is more efficacious for dental care.

(2) *Indications for use*. As a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations, clinical procedures, minor surgical procedures not requiring muscle relaxation, and minor dental procedures not requiring intubation. The intravenous route of administration is more efficacious for dental care.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 21075, May 9, 1996, as amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1350 Melatonin implant.

(a) *Specifications*. The drug is a silicone rubber elastomer implant containing 2.7 milligrams of melatonin.

(b) *Sponsor*. See No. 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. One implant per mink.

(2) *Indications for use*. For use in healthy male and female kit and adult female mink (*Mustela vison*) to accelerate the fur priming cycle.

(3) *Limitations*. For subcutaneous implantation in mink only. Do not implant potential breeding stock. Do not use in food-producing animals.

[59 FR 37422, July 22, 1994]

§ 522.1362 Melarsomine powder for injection.

(a) *Specifications*. The drug consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride which is reconstituted with the provided 2 milliliters of sterile water for injection.

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

(c) *Conditions of use*—(1) *Amount*. Administer only by deep intramuscular injection in the lumbar muscles (L₃–L₅).

(2) *Indications*. Treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L₅) to ma-

21 CFR Ch. I (4–1–16 Edition)

ture adult infections of *Dirofilaria immitis* in dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 49340, Sept. 25, 1995, as amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1367 Meloxicam.

(a) *Specifications*. Each milliliter of solution contains 5.0 milligrams (mg) meloxicam.

(b) *Sponsors*. See Nos. 000010, 016729, 026637, and 055529 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.045 mg/lb (0.1 mg/kg) body weight once daily as in § 520.1350(c) of this chapter.

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

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. Administer 0.14 mg/lb (0.3 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use*. For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 68724, Dec. 10, 2003, as amended at 69 FR 69523, Nov. 30, 2004; 78 FR 5715, Jan. 28, 2013; 79 FR 74020, Dec. 15, 2014]

§ 522.1372 Mepivacaine.

(a) *Specifications*. Each milliliter (mL) of solution contains 20 milligrams mepivacaine hydrochloride.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. For nerve block, 3 to 5 mL; for epidural anesthesia, 5 to 20 mL; for intra-articular anesthesia, 10 to 15 mL; for infiltration, as required; for anesthesia of the laryngeal mucosa prior to

ventriculectomy, by topical spray, 25 to 40 mL, by infiltration, 20 to 50 mL.

(2) *Indications for use.* For use as a local anesthetic for infiltration, nerve block, intra-articular and epidural anesthesia, and topical and/or infiltration anesthesia of the laryngeal mucosa prior to ventriculectomy.

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

[71 FR 39547, July 13, 2006, as amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1380 Methocarbamol.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) of methocarbamol.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount—(i) Dogs and cats.* Administer by intravenous injection 20 mg per pound of body weight for moderate conditions or 25 to 100 mg per pound of body weight for severe conditions (tetanus and strychnine poisoning). The total cumulative dose should not to exceed 150 mg per pound of body weight.

(ii) *Horses.* Administer by intravenous injection 2 to 10 mg per pound of body weight for moderate conditions or 10 to 25 mg per pound of body weight for severe conditions (tetanus). Additional amounts may be needed to relieve residual effects and to prevent recurrence of symptoms.

(2) *Indications for use.* As an adjunct for treating acute inflammatory and traumatic conditions of the skeletal muscles and to reduce muscular spasms.

(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 16191, Mar. 25, 2014]

§ 522.1410 Methylprednisolone.

(a) *Specifications.* Each milliliter of suspension contains 20 or 40 milligrams (mg) of methylprednisolone acetate.

(b) *Sponsors.* See Nos. 054628 and 054771 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Dogs—(i) Amount.* Administer 2 to 40 mg (up to

120 mg in extremely large breeds or dogs with severe involvement) by intramuscular injection or up to 20 mg by intrasynovial injection.

(ii) *Indications for use.* For treatment of inflammation and related disorders; treatment of allergic and dermatologic disorders; and as supportive therapy to antibacterial treatment of severe infections.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats—(i) Amount.* Administer 10 to 20 mg by intramuscular injection.

(ii) *Indications for use.* For treatment of inflammation and related disorders; treatment of allergic and dermatologic disorders; and as supportive therapy to antibacterial treatment of severe infections.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Horses—(i) Amount.* Administer 200 mg by intramuscular injection or 40 to 240 mg by intrasynovial injection.

(ii) *Indications for use.* For treatment of inflammation and related disorders.

(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.

[43 FR 59058, Dec. 19, 1978, as amended at 51 FR 741, Jan. 8, 1986; 53 FR 40728, Oct. 18, 1988; 62 FR 35076, June 30, 1997; 76 FR 53051, Aug. 25, 2011; 78 FR 21060, Apr. 9, 2013; 79 FR 16191, Mar. 25, 2014]

§ 522.1450 Moxidectin solution.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) moxidectin.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.426 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in beef and non-lactating dairy cattle—(1) Amount.* Administer 0.2 mg/kg of body weight (0.2 mg/2.2 pound) as a single, subcutaneous injection.

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms: *Ostertagia ostertagi* (adults, fourth-stage larvae, and inhibited larvae), *Haemonchus placei*

§522.1451

(adults), *Trichostrongylus axei* (adults and fourth-stage larvae), *Trichostrongylus colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults), *Cooperia pectinata* (adults), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia spatulata* (adults), *Cooperia surnabada* (adults and fourth-stage larvae), *Nematodirus helvetianus* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); grubs: *Hypoderma bovis* and *Hypoderma lineatum*; mites: *Psoroptes ovis* (*Psoroptes communis* var. *bovis*); lice: *Linognathus vituli* and *Solenopotes capillatus*; for protection of cattle from reinfection with *D. viviparus* and *O. radiatum* for 42 days after treatment, with *H. placei* for 35 days after treatment, and with *O. ostertagi* and *T. axei* for 14 days after treatment.

(3) *Limitations.* Do not slaughter cattle within 21 days of treatment. Because a withholding time for milk has not been established, do not use in female dairy cattle 20 months of age and older. A withdrawal period has not been established for pre-ruminating calves. Do not use in calves to be processed for veal.

[70 FR 36337, June 23, 2005, as amended at 71 FR 7414, Feb. 13, 2006; 76 FR 48714, Aug. 9, 2011]

§522.1451 Moxidectin microspheres for injection.

(a) *Specifications.* The drug product consists of two separate vials. One contains 10 percent moxidectin microspheres, and the other contains a vehicle for constitution of the moxidectin microspheres. Each milliliter of constituted, sustained-release suspension contains 3.4 milligrams (mg) of moxidectin.

(b) *Sponsor.* See No. 054771 in §510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use; dogs*—(1) *Amount.* 0.17 mg per kilogram body weight (0.0773 mg per pound) as a single subcutaneous injection.

(2) *Indications for use.* For prevention of heartworm disease caused by *Dirofilaria immitis*; for treatment of existing larval and adult hookworm

21 CFR Ch. I (4–1–16 Edition)

(*Ancylostoma caninum*) and *Uncinaria stenocephala* infections.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 35756, July 9, 2001, as amended at 67 FR 57944, Sept. 13, 2002; 79 FR 16191, Mar. 25, 2014]

§522.1452 Nalorphine.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams of nalorphine hydrochloride.

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

(c) *Conditions of use in dogs*—(1) *Amount.* One milligram per 5 pounds; intravenously, intramuscularly, or subcutaneously.

(2) *Indications for use.* Respiratory and circulatory depression in dogs resulting from overdosage of, or unusual sensitivity to, morphine and certain other narcotics. Not for depression due to any other cause.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 6707, Feb. 2, 1979, as amended at 47 FR 36418, Aug. 20, 1982; 62 FR 63271, Nov. 28, 1997; 79 FR 16191, Mar. 25, 2014]

§522.1465 Naltrexone.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams of naltrexone hydrochloride.

(b) *Sponsor.* See 053923 in §510.600(c) of this chapter.

(c) *Conditions of use in elk and moose*—

(1) *Amount.* 100 milligrams of naltrexone hydrochloride for each milligram of carfentanil citrate administered. One-quarter of the dose should be administered intravenously and three-quarters of the dose should be administered subcutaneously.

(2) *Indications for use.* As an antagonist to carfentanil citrate immobilization in free-ranging or confined elk and moose (*Cervidae*).

(3) *Limitations.* Do not use in domestic food-producing animals. Do not use in free-ranging animals for 45 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[62 FR 5320, Feb. 5, 1997, as amended at 79 FR 16191, Mar. 25, 2014]

§ 522.1468 Naproxen for injection.

(a) *Specifications.* The drug is a lyophilized powder which is reconstituted with sterile water for injection to form a 10 percent sterile aqueous solution (100 milligrams per milliliter).

(b) *Sponsor.* See 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Dosage.* Five milligrams per kilogram of body weight intravenously followed by maintenance oral therapy of 10 milligrams per kilogram of body weight twice daily for up to 14 consecutive days.

(2) *Indications for use.* For the relief of inflammation and associated pain and lameness exhibited with arthritis, as well as myositis and other soft tissue diseases of the musculoskeletal system of the horse.

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

[46 FR 26763, May 15, 1981. Redesignated and amended at 51 FR 24525, July 7, 1986; 61 FR 5507, Feb. 13, 1996; 79 FR 16192, Mar. 25, 2014]

§ 522.1484 Neomycin.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of neomycin sulfate (equivalent to 35 mg of neomycin base).

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—(1) Amount.* Administer 5 mg per pound of body weight daily by intramuscular or intravenous injection, divided into portions administered every 6 to 8 hours for 3 to 5 days.

(2) *Indications for use.* For the treatment of acute and chronic bacterial infections due to organisms susceptible to neomycin.

(3) *Limitations.* Not for parenteral use in food-producing animals because of prolonged residues in edible tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16192, Mar. 25, 2014]

§ 522.1503 Neostigmine.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) neostigmine methylsulfate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Administer to cattle and horses at a dosage level of 1 mg per (l) 100 pounds (lbs) of body weight subcutaneously. Administer to sheep at a dosage level of 1 to 1½ mg/100 lbs body weight subcutaneously. Administer to swine at a dosage level of 2 to 3 mg/100 lbs body weight intramuscularly. These doses may be repeated as indicated.

(2) *Indications for use.* For treating rumen atony; initiating peristalsis which causes evacuation of the bowel; emptying the urinary bladder; and stimulating skeletal muscle contractions.

(3) *Limitations.* Not for use in animals producing milk, since this use will result in contamination of the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 62 FR 61625, Nov. 19, 1997; 79 FR 16192, Mar. 25, 2014]

§ 522.1610 Oleate sodium.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of sodium oleate.

(b) *Sponsor.* See No. 037990 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer by parenteral injection depending on the area of response desired. An injection of 1 milliliter (mL) will produce a response of approximately 15 square centimeters. Do not inject more than 2 mL per injection site. Regardless of the number of injection sites, the total volume used should not exceed 10 mL.

(2) *Indications for use.* It is used in horses to stimulate infiltration of cellular blood components that subsequently differentiate into fibrous and/or fibrocartilagenous tissue.

(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.

[41 FR 27034, July 1, 1976, as amended at 50 FR 40966, Oct. 8, 1985; 79 FR 16192, Mar. 25, 2014]

§ 522.1620 Orgotein for injection.

(a) *Specifications.* Orgotein for injection is packaged in a vial containing 5

§522.1660

21 CFR Ch. I (4-1-16 Edition)

milligrams of orgotein and 10 milligrams of sucrose as lyophilized sterile nonpyrogenic powder with directions for dissolving the contents of the vial in 2 milliliters of diluent which is sodium chloride injection, U.S.P.

(b) *Sponsor.* See No. 024991 in §510.600(c) of this chapter.

(c) *Conditions of use—(1) Horses—(i) Amount.* Administer by deep intramuscular injection at a dosage level of 5 milligrams (mg) every other day for 2 weeks and twice weekly for 2 to 3 more weeks. Severe cases, both acute and chronic, may benefit more from daily therapy initially. Dosage may be continued beyond 5 weeks if satisfactory improvement has not been achieved.

(ii) *Indications for use.* It is used in the treatment of soft tissue inflammation associated with the musculo-skeletal system.

(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.

(2) *Dogs—(i) Amount.* Administer by subcutaneous injection 5 mg daily for 6 days, and thereafter, every other day for 8 days. In less severe conditions, shorter courses of therapy may be indicated.

(ii) *Indications for use.* It is used for the relief of inflammation associated with ankylosing spondylitis, spondylosis, and disc disease. When severe nerve damage is present, response will occur much more slowly, if at all.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 32583, Aug. 4, 1976; 79 FR 16192, Mar. 25, 2014]

§ 522.1660 Oxytetracycline injectable dosage forms.

§ 522.1660a Oxytetracycline solution, 200 milligrams/milliliter.

(a) *Specifications.* Each milliliter of sterile solution contains 200 milligrams of oxytetracycline base.

(b) *Sponsors.* See Nos. 000010, 000859, 048164, 054771, 055529, 057561, and 061623 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.500 of this chapter.

(d) *Special considerations.* When labeled for the treatment of anaplasmosis or anthrax, labeling shall also bear the following: "Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(e) *Conditions of use—(1) Beef cattle, dairy cattle, and calves including prerumenative (veal) calves—(i) Amounts and indications for use—(A) 3 to 5 mg per pound of body weight (mg/lb BW) per day (/day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp., and anthrax caused by *Bacillus anthracis*.*

(B) 5 mg/lb BW/day intramuscularly or intravenously for treatment of anaplasmosis caused by *Anaplasma marginale*, severe foot-rot, and advanced cases of other indicated diseases.

(C) 9 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical, for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*, or where retreatment for anaplasmosis is impractical.

(ii) *Limitations.* Exceeding the highest recommended level of drug per pound of bodyweight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site may result in antibiotic residues beyond the withdrawal time. Rapid intravenous administration in cattle may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. Discontinue treatment at least 28 days prior to slaughter. Milk taken from animals during treatment and for 96 hours after the last treatment must not be used for food.

(2) *Swine*—(i) *Amounts and indications for use*—(A) Sows: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*.

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(i) *Limitations.* Administer intramuscularly. Do not inject more than 5 mL per site in adult swine. Discontinue treatment at least 28 days prior to slaughter.

[45 FR 16479, Mar. 14, 1980. Redesignated and amended at 69 FR 31879, June 8, 2004]

EDITORIAL NOTE: FOR FEDERAL REGISTER citations affecting § 522.1660a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 522.1660b Oxytetracycline solution, 300 milligrams/milliliter.

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Special considerations.* When labeled for use as in paragraph (e)(1)(i)(D) or (e)(1)(i)(E) of this section, labeling shall also bear the following: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(e) *Conditions of use*—(1) *Beef cattle, nonlactating dairy cattle, and calves including preruminating (veal) calves*—(i) *Amounts and indications for use*—(A) 3 to 5 mg per pound of bodyweight (mg/lb BW) per day (/day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Histophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by

Actinobacillus lignieresii, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp.

(B) 5 mg/lb BW/day intramuscularly, subcutaneously, or intravenously for treatment of severe foot-rot, and advanced cases of other indicated diseases.

(C) 9 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

(D) 9 to 13.6 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

(E) 13.6 mg/lb BW intramuscularly or subcutaneously as a single dosage for control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia (Pasteurella) haemolytica*.

(i) *Limitations.* Treatment should be continued 24 to 48 hours following remission of disease signs, however, not to exceed a total of four consecutive days. Do not inject more than 10 mL per site in adult cattle, reducing the volume according to age and body size to 1 to 2 mL in small calves. Exceeding the highest recommended level of drug/lb BW/day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site may result in antibiotic residues beyond the withdrawal time. Rapid intravenous administration may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. Discontinue treatment at least 28 days prior to slaughter. Not for use in lactating dairy animals.

(2) *Swine*—(i) *Amounts and indications for use*—(A) Sows: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby

§ 522.1662

21 CFR Ch. I (4-1-16 Edition)

pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*.

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(ii) *Limitations.* Administer intramuscularly. Treatment should be continued 24 to 48 hours beyond remission of disease signs, however, not to exceed a total of 4 consecutive days. Exceeding the highest recommended level of drug/lb BW/day, administering more than the recommended number of treatments, and/or exceeding 5 mL intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 28 days prior to slaughter.

[68 FR 54805, Sept. 19, 2003. Redesignated and amended at 69 FR 31879, June 8, 2004; 73 FR 14926, Mar. 20, 2008]

§ 522.1662 **Oxytetracycline hydrochloride implantation or injectable dosage forms.**

§ 522.1662a **Oxytetracycline hydrochloride injection.**

(a)(1) *Specifications.* The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves for treatment of disease conditions caused by one or more of the following oxytetracycline sensitive pathogens listed as follows: pneumonia and shipping fever complex (*Pasteurella spp.*; *Haemophilis spp.*; *Klebsiella spp.*), bacterial enteritis (scours) (*E. coli*), foot-rot (*Spherophorus necrophorus*), diphtheria (*Spherophorus necrophorus*), wooden tongue (*Actinobacillus lignieresii*), leptospirosis (*Leptospira pomona*), and wound infections; acute metritis; traumatic injury (caused by a variety of bacterial organisms (such as

streptococcal and staphylococcal organisms).)

(ii) It is administered by intramuscular injection of 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Leptospirosis, severe foot-rot and severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight per day. Treatment should be continued for 24 to 48 hours following remission of disease symptoms; however, not to exceed a total of 4 consecutive days. Only 2 milliliters of the drug should be injected per site in case of calves weighing 100 pounds or less and not more than 10 milliliters should be injected per site in adult cattle.

(iii) Discontinue treatment with the drug at least 20 days prior to slaughter of the animal. When administered to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of injection site and surrounding tissues.

(iv) For use only in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves.

(b)(1) *Specifications.* Each milliliter of sterile solution contains 50 or 100 milligrams of oxytetracycline (as oxytetracycline hydrochloride).

(2) *Sponsor.* See 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Beef cattle and nonlactating dairy cattle*—(a) *Amount.* Three to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for the treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases.

(b) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella spp.*, *Haemophilus spp.*, and *Klebsiella spp.*, foot-rot and diphtheria caused by *Spherophorus necrophorus*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, and wound infections and acute metritis caused by *Staphylococcus spp.* and *Streptococcus spp.* If labeled for use by or on the order of a licensed veterinarian, it may

be used for the treatment of anaplasmosis caused by *Anaplasma marginale*.

(c) *Limitations.* For 50-milligram-per-milliliter solution, administer intramuscularly or intravenously; for 100-milligram-per-milliliter solution, administer intramuscularly only. Treatment of all diseases should be instituted early and continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Consult your veterinarian if no improvement is noted within 48 hours. Do not inject more than 10 milliliters per site in adult cattle, reducing the volume according to age and body size to 0.5 to 2 milliliters in small calves. Exceeding the highest recommended dose of 5 milligrams per pound of body weight, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 milliliters intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 18 days prior to slaughter. Not for use in lactating dairy cattle.

(ii) *Swine—(a) Amount.* Three to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(b) *Indications for use.* For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(c) *Limitations.* Administer intramuscularly. Do not inject more than 5 milliliters per site. Do not use for more than 4 consecutive days. Discontinue treatment at least 26 days before slaughter.

(c)(1) *Specifications.* The drug contains 50 or 100 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is intended for use in the treatment of

disease due to oxytetracycline-susceptible organisms in beef cattle and non-lactating dairy cattle. It is indicated in the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.*, *Haemophilus spp.*, *Klebsiella spp.*, foot-rot and diphtheria caused by *Spherophorus necrophorus*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, acute metritis, and wound infections caused by staphylococcal and streptococcal organisms.

(ii) It is administered to cattle at a dosage level of 3 to 5 milligrams per pound of body weight per day. It may be administered intramuscularly or intravenously from a 50 milligram per milliliter solution. It is administered intravenously from a 100 milligram per milliliter solution. Severe foot-rot and the severe forms of the indicated diseases should be treated with 5 milligrams per pound of body weight. Treatment should be continued 24 to 48 hours following remission of disease symptoms, however, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 hours, consult a veterinarian. When injecting the drug intramuscularly, do not inject more than 10 milliliters per site in adult cattle. Reduce the amount injected at each site according to the size of the animal. For very small calves do not use more than 2 milliliters per injection site.

(iii) Not for use in lactating dairy cattle. Discontinue treatment at least 19 days prior to slaughter. When administered intramuscularly within 30 days of slaughter, muscle discoloration may necessitate trimming of the injection site and surrounding tissues.

(d)(1) *Specifications.* The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) In beef cattle and nonlactating dairy cattle as follows:

(a) It is used for the treatment of pneumonia and shipping fever complex associated with *Pasteurella spp.* and *Haemophilus spp.*; foot-rot and diphtheria caused by *Spherophorus*

necrophorus; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; wound infections and acute metritis caused by staphylococcal and streptococcal organisms.

(b) Administer by intravenous or intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day. In the treatment of severe foot-rot and severe forms of the indicated diseases, a dosage level of 5 milligrams per pound of body weight per day is recommended.

(c) If the labeling of the drug bears the statement "Federal law restricts this drug to use by or on the order of a licensed veterinarian," it may include additional directions for use in beef cattle and nonlactating dairy cattle for the treatment of anaplasmosis caused by *Anaplasma marginale*, and anthrax caused by *Bacillus anthracis* in which case the drug is given at 3 to 5 milligrams of oxytetracycline per pound of body weight per day for anthrax, and at 5 milligrams per pound of body weight per day for anaplasmosis.

(ii) In swine as follows:

(a) It is used for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. Administered to sows as an aid in the control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(b) Administer by intramuscular injection at 3 to 5 milligrams of oxytetracycline per pound of body weight per day to swine. Administered to sows at 3 milligrams of oxytetracycline per pound of body weight approximately 8 hours before farrowing or immediately after farrowing.

(iii) In poultry (broilers, turkeys, and breeding chickens) as follows:

(a) It is used for the treatment of air sacculitis (air-sac disease, chronic respiratory disease) caused by *Mycoplasma gallisepticum* and *Escherichia coli*; fowl cholera caused by *Pasteurella multocida*; infectious sinusitis caused by *Mycoplasma gallisepticum*; and infectious synovitis caused by *Mycoplasma synoviae*.

(b) Administered subcutaneously to chickens 1 day to 2 weeks of age at 6.25 milligrams of oxytetracycline per bird per day diluted with 1 part of the drug to 3 parts of sterile water; to chickens 2 to 4 weeks of age using the same diluted product at 12.5 milligrams of oxytetracycline per bird; to chickens 4 to 8 weeks of age without dilution at 25 milligrams of oxytetracycline per bird; to chickens 8 weeks of age (broilers and light pullets) at 50 milligrams of oxytetracycline per bird; to adult chickens at 100 milligrams of oxytetracycline per bird.

(c) Administered subcutaneously to turkeys 1 day to 2 weeks of age and 2 to 4 weeks of age at the same dosage as chickens; to turkeys 4 to 6 weeks of age at 50 milligrams of oxytetracycline as the undiluted product per bird; to turkeys 6 to 9 weeks of age at 100 milligrams of oxytetracycline per bird; to turkeys 9 to 12 weeks of age at 150 milligrams of oxytetracycline per bird; to turkeys 12 weeks of age and older at 200 milligrams of oxytetracycline per bird. In light turkey breeds, no more than 25 milligrams per pound of body weight is administered. For the treatment of infectious sinusitis in turkeys, $\frac{1}{4}$ to $\frac{1}{2}$ milliliter of the drug is injected directly into each swollen sinus depending upon the age of the bird and the severity of the condition. At the time that the sinuses are treated, the drug should also be administered subcutaneously to the birds according to the dosage schedule given in paragraph (d)(3)(iii)(c) of this section. If refilling of the sinuses occurs, the treatment may be repeated in 5 to 7 days.

(iv) Treatment of all diseases should be instituted early. Treatment should continue for 24 to 48 hours beyond the remission of disease symptoms, but not exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, diagnosis and therapy should be reevaluated.

(v) When injecting intramuscularly in adult livestock, do not inject more than 10 milliliters at any one site. The volume administered per injection site should be reduced according to age and body size so that 1 or 2 milliliters are injected in smaller animals such as small calves and young pigs. Intravenous administration is recommended

in cattle when daily dosage exceeds 50 milliliters.

(vi) Treatment must be discontinued at least 5 days prior to slaughter for chickens and turkeys and at least 22 days prior to slaughter for cattle and swine.

When administered intramuscularly to animals within 30 days of slaughter, muscle discoloration may necessitate trimming of the injection site(s) and surrounding tissues during the dressing procedure.

(vii) Not for use in lactating dairy animals. Do not administer to laying hens unless the eggs are used for hatching only.

(e)(1) *Specifications.* Each milliliter of sterile solution contains 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Beef cattle and nonlactating dairy cattle—(a) Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day; 5 milligrams per pound of body weight per day for treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases.

(b) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp. If labeled for use by or on the order of a licensed veterinarian, it may be used for the treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(c) *Limitations.* Administer intramuscularly. Treatment of all diseases should be instituted early and continue for 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 4 consecutive days. Consult your veterinarian if no improvement is noted within 48 hours. Do not inject more than 10 milliliters per site in adult cattle, reducing the volume according to age and body size to

1 to 2 milliliters in small calves. Exceeding the highest recommended dose of 5 milligrams per pound of body weight, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 milliliters intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 15 days prior to slaughter. Not for use in lactating dairy cattle.

(ii) *Swine—(a) Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: 3 milligrams of oxytetracycline per pound of body weight, administered once, approximately 8 hours before farrowing or immediately after completion of farrowing.

(b) *Indications for use.* For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: as an aid in control of infections enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(c) *Limitations.* Administer intramuscularly. Do not inject more than 5 milliliters per site in adult swine, reducing the volume according to age and body size to 1 to 2 milliliters in young pigs. Discontinue treatment at least 22 days prior to slaughter.

(f) [Reserved]

(g)(1) *Specifications.* Each milliliter of sterile solution contains 100 milligrams of oxytetracycline as oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 054628 in § 510.600(c) of this chapter.

(3) *Conditions of use.* The drug is used for the treatment of diseases due to oxytetracycline-susceptible organisms as follows:

(i) *Beef cattle, beef calves, nonlactating dairy cattle, and dairy calves—(a) Amount.* 3 to 5 milligrams of oxytetracycline per pound of body weight per day.

(b) *Indications for use.* For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., *Haemophilus* spp., or *Klebsiella* spp.

(c) *Limitations.* Administer by intramuscular, intravenous, or subcutaneous injection. In severe forms of

the indicated diseases, administer 5 milligrams of oxytetracycline per pound of body weight per day. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 48 hours, consult a veterinarian. Do not inject more than 10 milliliters per injection site intramuscularly in adult cattle; no more than 1 milliliter per site in calves weighing 100 pounds or less. Do not slaughter cattle for 13 days after intramuscular or intravenous treatment, or 2 days after subcutaneous treatment. Exceeding the highest recommended dosage or duration of treatment (not more than 4 consecutive days) may result in residues beyond the withdrawal period. A withdrawal period has not been established for use of this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) *Swine*—(a) *Amount*. 3 to 5 milligrams of oxytetracycline per pound of body weight per day. Sows: Administer once 3 milligrams of oxytetracycline per pound of body weight, approximately 8 hours before farrowing or immediately after completion of farrowing.

(b) *Indications for use*. For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*. Sows: As an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli*.

(c) *Limitations*. Administer intramuscularly. If no improvement is noted within 24 hours, consult a veterinarian. Do not inject more than 5 milliliters per site. Discontinue treatment at least 20 days prior to slaughter.

(h)(1) *Specifications*. Each milliliter of sterile solution contains 50 or 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsors*. See No. 054628 in §510.600(c) of this chapter for use of 50 and 100 milligrams per milliliter solution; and Nos. 000859 and 055529 in §510.600(c) for use of 100 milligrams per milliliter solution.

(3) *Conditions of use*—(i) *Amount*. The drug is used in beef cattle, beef calves,

nonlactating dairy cattle, and dairy calves as follows: 3 to 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day; 5 milligrams per pound of body weight per day for treatment of severe forms of the indicated diseases.

(ii) *Indications for use*. The drug is used for treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp.; foot-rot and calf diphtheria caused by *Spherophorus necrophorus*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; wound infections, acute metritis, and traumatic injury caused by staphylococcal and streptococcal organisms.

(iii) *Limitations*. Administer 50-milligram-per-milliliter solution intramuscularly; administer 100-milligram-per-milliliter solution intravenously. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, consult a veterinarian for diagnosis and therapy. When injecting the drug intramuscularly, do not inject more than 10 milliliters per site in adult cattle. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less, do not inject more than 2 milliliters intramuscularly per site. Discontinue treatment at least 22 days before slaughter. Not for use in lactating dairy animals.

(i)(1) *Specifications*. Each milliliter of sterile solution contains 50 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor*. See No. 000859 in §510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount*. The drug is used in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves as follows: Administer 3 to 5 milligrams of the oxytetracycline hydrochloride intramuscularly per pound of body weight per day.

(ii) *Indications for use*. The drug is used for treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp.; foot-rot and diphtheria caused by *Spherophorus necrophorus*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden

tongue caused by *Actinobacillus lignieresii*; wound infections and acute metritis caused by staphylococcal and streptococcal organisms susceptible to oxytetracycline.

(iii) *Limitations.* In severe forms of the indicated diseases, administer the equivalent of 5 milligrams of oxytetracycline hydrochloride per pound of body weight per day. Continue treatment 24 to 48 hours following remission of disease symptoms, not to exceed a total of 4 consecutive days. If no improvement is noted within 24 to 48 hours, consult a veterinarian for diagnosis and therapy. In adult livestock, do not inject more than 10 milliliters at any one site. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less inject only 2 milliliters per site. Discontinue treatment at least 18 days before slaughter. Not for use in lactating dairy cattle.

(j) [Reserved]

(k)(1) *Specifications.* Each milliliter of sterile solution contains either 50 or 100 milligrams of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*—(i) *Amount.* 3 to 5 milligrams per pound of body weight daily, 5 milligrams per pound for anaplasmosis, severe foot rot, and severe forms of other diseases.

(ii) *Indications for use.* Treatment of diseases due to oxytetracycline-susceptible organisms as follows: pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp.; foot rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; acute metritis and wound infections caused by staphylococcal and streptococcal organisms; if labeled for use by or on the order of a licensed veterinarian, it may be used for treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(iii) *Limitations.* Administer by intravenous injection. Treatment should be continued 24 to 48 hours following remission of disease symptoms, but not

to exceed a total of 4 consecutive days. If no improvement occurs within 24 to 48 hours, reevaluate diagnosis and therapy. Discontinue use at least 19 days prior to slaughter. Not for use in lactating dairy cattle.

[40 FR 13858, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.1662a, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 522.1662b Oxytetracycline hydrochloride with lidocaine injection.

(a) *Specifications.* The drug contains 50 or 100 milligrams of oxytetracycline hydrochloride and 2 percent lidocaine in each milliliter of sterile aqueous solution.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for use in the treatment of diseases of dogs caused by pathogens sensitive to oxytetracycline hydrochloride including treatment for the following conditions in dogs caused by susceptible microorganisms: Bacterial infections of the urinary tract caused by *Hemolytic staphylococcus*, *Streptococcus* spp., Bacterial pulmonary infections caused by *Brucella bronchiseptica*, *Streptococcus pyogenes*, *Staphylococcus aureus*, secondary bacterial infections caused by *Micrococcus pyogenes* var. *albus*, *Brucella bronchiseptica*, *Streptococcus* spp.

(2) The drug is administered intramuscularly at a recommended daily dosage to dogs at 5 milligrams per pound of body weight administered in divided doses at 6 to 12 hour intervals. Therapy should be continued for at least 24 hours after all symptoms have subsided.

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

[40 FR 13858, Mar. 27, 1975, as amended at 48 FR 30615, July 5, 1983; 79 FR 16192, Mar. 25, 2014]

§ 522.1664 Oxytetracycline and flunixin.

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base as

§ 522.1680

21 CFR Ch. I (4–1–16 Edition)

amphoteric oxytetracycline and 20 mg flunixin base as flunixin meglumine.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.286 and 556.500 of this chapter.

(d) *Conditions of use cattle*—(1) *Amount.* Administer once as an intramuscular or subcutaneous injection of 1 mL per 22 pounds (lb) body weight (BW) (13.6 mg oxytetracycline and 0.9 mg flunixin per lb BW) where retreatment of calves and yearlings for bacterial pneumonia is impractical due to husbandry conditions, such as cattle on range, or where their repeated restraint is inadvisable.

(2) *Indications for use.* For the treatment of bacterial pneumonia associated with *Pasteurella* spp. and for the control of associated pyrexia in beef and nonlactating dairy cattle.

(3) *Limitations.* Discontinue treatment at least 21 days prior to slaughter of cattle. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. 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.

[76 FR 3489, Jan. 20, 2011, as amended at 79 FR 16192, Mar. 25, 2014]

§ 522.1680 Oxytocin.

(a) *Specifications.* Each milliliter (mL) of solution contains 20 USP units oxytocin.

(b) *Sponsors.* See Nos. , 000859, 054628, 054771 and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Obstetrical.* Administer drug intravenously, intramuscularly, or subcutaneously under aseptic conditions as indicated. The following dosages are recommended and may be repeated as conditions require:

	mL	U.S.P. units
Cats	0.25 to 0.5	5 to 10.
Dogs	0.25 to 1.5	5 to 30.
Ewes, Sows	1.5 to 2.5	30 to 50.
Cows, Horses	5.0	100.

(ii) *Milk letdown.* Intravenous administration is desirable. The following dosage is recommended and may be repeated as conditions require:

	mL	U.S.P. units
Cows	0.5 to 1.0	10 to 20.
Sows	0.25 to 1.0	5 to 20.

(2) *Indications for use.* Oxytocin may be used as a uterine contractor to precipitate and accelerate normal parturition and postpartum evacuation of uterine debris. In surgery it may be used postoperatively following cesarean section to facilitate involution and resistance to the large inflow of blood. It will contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 63097, Nov. 2, 1979; 45 FR 1019, Jan. 4, 1980, as amended at 52 FR 18691, May 19, 1987; 52 FR 25212, July 6, 1987; 52 FR 36023, Sept. 25, 1987; 53 FR 32610, Aug. 26, 1988; 53 FR 40728, Oct. 18, 1988; 54 FR 41442, Oct. 10, 1989; 55 FR 8462, Mar. 8, 1990; 56 FR 14642, Apr. 11, 1991, 56 FR 16002, Apr. 19, 1991; 59 FR 31139, June 17, 1994; 62 FR 35076, June 30, 1997; 62 FR 38906, July 21, 1997; 65 FR 45877, July 26, 2000; 66 FR 22117, May 3, 2001; 68 FR 36913, June 20, 2003; 77 FR 55414, Sept. 10, 2012; 78 FR 17597, Mar. 22, 2013; 78 FR 21060, Apr. 9, 2013; 79 FR 16192, Mar. 25, 2014]

§ 522.1696 Penicillin G procaine injectable dosage forms.

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

(a) *Specifications.* Each milliliter of aqueous suspension contains penicillin G benzathine and penicillin G procaine, each equivalent to 150,000 units of penicillin G.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for the conditions of use in paragraph (d) of this section as follows:

(1) Nos. 054771, 055529, and 061623 for use as in paragraph (d)(1) of this section.

(2) Nos. 000859, 055529, and 061623 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(A), and (d)(2)(iii) of this section.

(3) No. 054771 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use*—(1) *Horses, dogs, and beef cattle*—(i) *Amount*—(A) *Beef cattle.* 2 milliliters per 150 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(B) *Horses.* 2 milliliters per 150 pounds of body weight intramuscularly. Repeat dosage in 48 hours.

(C) *Dogs.* 1 milliliter per 10 to 25 pounds of body weight intramuscularly or subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use.* Treatment of bacterial infections susceptible to penicillin G.

(iii) *Limitations.* Not for use in beef cattle within 30 days of slaughter. 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.

(2) *Beef cattle*—(i) *Amount.* 2 milliliters per 150 pounds of body weight subcutaneously. Repeat dosage in 48 hours.

(ii) *Conditions of use.* (A) Treatment of bacterial pneumonia (*Streptococcus* spp., *Actinomyces pyogenes*, *Staphylococcus aureus*); upper respiratory infections such as rhinitis or pharyngitis (*A. pyogenes*); blackleg (*Clostridium chauvoei*).

(B) As in paragraph (d)(2)(ii)(A) of this section; and prophylaxis of bovine shipping fever in 300- to 500-pound beef calves.

(iii) *Limitations.* Not for use within 30 days of slaughter. For Nos. 000859, 055529, and 061623: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

[66 FR 711, Jan. 4, 2001, as amended at 68 FR 34534, June 10, 2003; 70 FR 21947, Apr. 28, 2005; 70 FR 50182, Aug. 26, 2005; 73 FR 16754, Mar. 31, 2008; 75 FR 54017, Sept. 3, 2010; 77 FR 4897, Feb. 1, 2012; 78 FR 17597, Mar. 22, 2013; 79 FR 16192, Mar. 25, 2014]

§ 522.1696b Penicillin G procaine aqueous suspension.

(a) *Specifications.* Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter as follows:

(1) Nos. 000859, 054771, and 055529 for use as in paragraph (d) of this section.

(2) No. 061623 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See § 556.510 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* 10,000 units per pound body weight daily by intramuscular injection at 24-hour intervals. Continue treatment at least 48 hours after symptoms disappear.

(ii) *Indications for use.* Treatment of infections caused by penicillin-sensitive organisms.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle, sheep, swine, and horses*—(i) *Amount.* 3,000 units per pound body weight (1 milliliter per 100 pounds body weight) daily by intramuscular injection.

(A) For Nos. 000859, 054771, 055529, and 061623: Continue treatment at least 48 hours after symptoms disappear.

(B) For No. 055529: Continue treatment at least 1 day after symptoms disappear (usually 2 or 3 days).

(ii) *Indications for use.* Treatment of cattle and sheep for bacterial pneumonia (shipping fever) caused by *Pasteurella multocida*; swine for erysipelas caused by *Erysipelothrix rhusiopathiae*; and horses for strangles caused by *Streptococcus equi*.

(iii) *Limitations.* Not for use in horses intended for food. Milk that has been taken during treatment and for 48 hours after the last treatment must not be used for food.

(A) For Nos. 054771 and 061623: Do not exceed 7 days of treatment in nonlactating dairy and beef cattle, sheep, and swine, or 5 days in lactating cattle. Discontinue treatment for the following number of days before slaughter: Nonruminating cattle (calves)—7; all other cattle—4; sheep—8; and swine—6.

(B) For Nos. 000859 and 055529: Continue treatment at least 1 day after

§522.1696c

symptoms disappear (usually 2 or 3 days).

[66 FR 712, Jan. 4, 2001, as amended at 68 FR 34534, June 10, 2003; 68 FR 42589, July 18, 2003; 69 FR 17586, Apr. 5, 2004; 70 FR 16935, Apr. 4, 2005; 73 FR 14177, Mar. 17, 2008; 75 FR 54017, Sept. 3, 2010; 78 FR 17597, Mar. 22, 2013; 79 FR 16192, Mar. 25, 2014]

§522.1696c Penicillin G procaine in oil.

(a) *Specifications.* Each milliliter contains penicillin G procaine equivalent to 300,000 units of penicillin G.

(b) *Sponsor.* See No. 054771 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Dogs and cats—10,000 units per pound of body weight once daily. Horses—3,000 units per pound of body weight once daily.

(2) *Indications for use.* Treatment of infections of dogs, cats, and horses caused by penicillin-susceptible organisms such as Streptococci, Staphylococci, and Corynebacteria.

(3) *Limitations.* Not for use in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37333, Aug. 18, 1992, as amended at 79 FR 16193, Mar. 25, 2014]

§522.1698 Pentazocine.

(a) *Specifications.* Each milliliter of solution contains pentazocine lactate equivalent to 30 milligrams (mg) of pentazocine base.

(b) *Sponsor.* See No. 054771 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer 0.15 mg pentazocine base per pound of body weight daily by intravenous or intramuscular injection. In cases of severe pain, a second dose is recommended by intramuscular injection 10 to 15 minutes after the initial dose at the same level.

(ii) *Indications for use.* For symptomatic relief of pain due to colic.

(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.

(2) *Dogs*—(i) *Amount.* Administer 0.75 to 1.50 mg of pentazocine base per pound of body weight by intramuscular injection.

21 CFR Ch. I (4–1–16 Edition)

(ii) *Indications for use.* For amelioration of pain accompanying post-operative recovery, fracture, trauma, and spinal disorders.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[42 FR 31450, June 21, 1977, as amended at 42 FR 36995, July 19, 1977; 47 FR 5409, Feb. 5, 1982; 55 FR 23076, June 6, 1990; 79 FR 16193, Mar. 25, 2014]

§522.1704 Pentobarbital.

(a) *Specifications.* Each milliliter of solution contains 64.8 milligrams (mg) of sodium pentobarbital.

(b) *Sponsor.* See No. 000061 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* The drug is administered intravenously “to effect”. For general surgical anesthesia, the usual dose is 11 to 13 mg per pound of body weight. For sedation, the usual dose is approximately 2 mg per pound of body weight. For relieving convulsive seizures caused by strychnine in dogs, the injection should be administered intravenously “to effect”. The drug may be administered intraperitoneally. When given intraperitoneally, it is administered at the same dosage level as for intravenous administration.

(2) *Indications for use.* The drug is indicated for use as a general anesthetic in dogs and cats. Although it may be used as a general surgical anesthetic for horses, it is usually given at a lower dose to cause sedation and hypnosis and may be supplemented with a local anesthetic. It may also be used in dogs for the symptomatic treatment of strychnine poisoning.

(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 16193, Mar. 25, 2014]

§522.1720 Phenylbutazone.

(a) *Specifications*—(1) Each milliliter of solution contains 100 milligrams (mg) of phenylbutazone.

(2) Each milliliter of solution contains 200 mg of phenylbutazone.

(b) *Sponsors.* See sponsor numbers in §510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 054771 for use of product described in paragraph (a)(1) as in paragraph (c) of this section.

(2) Nos. 000061, 000859, 054771, and 061623 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

(3) Nos. 054628 and 058005 for use of product described in paragraph (a)(2) as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer by intravenous injection 10 mg per pound of body weight daily in three divided doses, not to exceed 800 mg daily regardless of weight. Limit intravenous administration to 2 successive days. Oral medication may follow.

(ii) *Indications for use*. It is used for the relief of inflammatory conditions associated with the musculoskeletal system.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount*. Administer by intravenous injection 1 to 2 grams (g) per 1,000 pounds of body weight daily in three divided doses, not to exceed 4 g daily. Limit intravenous administration to not more than 5 successive days.

(ii) *Indications for use*. For the relief of inflammatory conditions associated with the musculoskeletal system.

(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 16193, Mar. 25, 2014]

§ 522.1820 Pituitary luteinizing hormone powder for injection.

(a) *Specifications*. The drug is a lyophilized pituitary extract. Each 6-milliliter vial contains an amount equivalent to 25 milligrams of standard pituitary luteinizing hormone and is reconstituted for use by addition of 5 milliliters of 0.9 percent aqueous sodium chloride solution.

(b) *Sponsor*. No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Cattle and horses: 25 milligrams; swine: 5 milligrams; sheep: 2.5 milligrams; and dogs: 1.0 milligram. Preferably given by intravenous injection, it may be administered subcutaneously. Treatment

may be repeated in 1 to 4 weeks, or as indicated.

(2) *Indications for use*. As an aid in the treatment of breeding disorders related to pituitary hypofunction in cattle, horses, swine, sheep, and dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 79 FR 16193, Mar. 25, 2014]

§ 522.1850 Polysulfated glycosaminoglycan.

(a) *Specifications*. (1) Each 1-milliliter (mL) ampule of solution contains 250 milligrams (mg) polysulfated glycosaminoglycan.

(2) Each mL of solution packaged in 5-mL ampules or 20-, 30-, or 50-mL vials contains 100 mg polysulfated glycosaminoglycan.

(b) *Sponsor*. See No. 010797 in § 510.600(c) of this chapter.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Horses*—(i) *Indications for use*. For the treatment of noninfectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

(ii) *Amount*—(A) *Intra-articular use (carpal)*: 250 mg once a week for 5 weeks.

(B) *Intramuscular use (carpal and hock)*: 500 mg every 4 days for 28 days.

(iii) *Limitations*. Do not use in horses intended for human consumption.

(2) *Dogs*—(i) *Indications for use*. For control of signs associated with noninfectious degenerative and/or traumatic arthritis of canine synovial joints.

(ii) *Amount*. 2 mg per pound of body weight by intramuscular injection twice weekly for up to 4 weeks (maximum of 8 injections).

[72 FR 56896, Oct. 5, 2007, as amended at 74 FR 67816, Dec. 21, 2009]

§ 522.1862 Pralidoxime powder for injection.

(a) *Specifications*. Each vial contains 1 gram (g) of pralidoxime chloride powder for mixing with 20 cubic centimeters of sterile water for injection.

§ 522.1870

Each milliliter of constituted solution contains 50 milligrams (mg) pralidoxime chloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer as soon as possible after exposure to the poison. Before administration of the sterile pralidoxime chloride, atropine is administered intravenously at a dosage rate of 0.05 mg per pound of body weight, followed by administration of an additional 0.15 mg of atropine per pound of body weight administered intramuscularly. Then the appropriate dosage of sterile pralidoxime chloride is administered slowly intravenously. The dosage rate for sterile pralidoxime chloride when administered to horses is 2 g per horse. When administered to dogs and cats, it is 25 mg per pound of body weight. For small dogs and cats, sterile pralidoxime chloride may be administered either intraperitoneally or intramuscularly. A mild degree of atropinization should be maintained for at least 48 hours. Following severe poisoning, a second dose of sterile pralidoxime chloride may be given after 1 hour if muscle weakness has not been relieved.

(2) *Indications for use.* It is used in horses, dogs, and cats as an antidote in the treatment of poisoning due to those pesticides and chemicals of the organophosphate class which have anticholinesterase activity in horses, dogs, and cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16193, Mar. 25, 2014]

§ 522.1870 Praziquantel.

(a) *Specification.* Each milliliter contains 56.8 milligrams of praziquantel.

(b) *Sponsors.* See Nos. 000859 and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* For dogs 5 pounds and under, 0.3 milliliter (17.0 milligrams); for 6 to 10 pounds, 0.5 milliliter (28.4 milligrams); for 11 to 25 pounds, 1.0 milliliter (56.8 milligrams); if over 25 Pounds, 0.2 milliliter (11.4 milligrams) per 5 pounds body weight to a maximum of 3 milliliters (170.4 milligrams).

21 CFR Ch. I (4–1–16 Edition)

(ii) *Indications for use.* For removal of canine cestodes *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*, and removal and control of canine cestode *Echinococcus multilocularis*.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount.* For cats under 5 pounds, 0.2 milliliter (11.4 milligrams); 5 to 10 pounds, 0.4 milliliter (22.7 milligrams); 11 pounds and over, 0.6 milliliter (34.1 milligrams) maximum.

(ii) *Indications for use.* For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis*.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 10464, Feb. 3, 1981, as amended at 47 FR 6617, Feb. 16, 1982; 58 FR 42853, Aug. 12, 1993; 67 FR 79853, Dec. 31, 2002; 78 FR 17868, Mar. 25, 2013]

§ 522.1881 Prednisolone acetate.

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams (mg) of prednisolone acetate.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* The drug is administered to horses intra-articularly at a dosage level of 50 to 100 mg. The dose may be repeated when necessary. The drug is administered to dogs and cats intramuscularly at a dosage level of 10 to 50 mg. The dosage may be repeated when necessary. If the condition is of a chronic nature, an oral corticosteroid may be given as a maintenance dosage. The drug may be given intra-articularly to dogs and cats at a dosage level of 5 to 25 mg. The dose may be repeated when necessary after 7 days for two or three doses.

(2) *Indications for use.* The drug is indicated in the treatment of dogs, cats, and horses for conditions requiring an anti-inflammatory agent. The drug is indicated for the treatment of acute musculoskeletal inflammations such as bursitis, carpalitis, and spondylitis. The drug is indicated as supportive therapy in nonspecific dermatosis such as summer eczema and atopy. The drug may be used as supportive therapy pre- and postoperatively and for various stress

conditions when corticosteroids are required while the animal is being treated for a specific condition.

(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 16194, Mar. 25, 2014]

§ 522.1883 Prednisolone sodium phosphate.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) prednisolone sodium phosphate (equivalent to 14.88 mg of prednisolone).

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Administer intravenously in a dosage of 2½ to 5 mg per pound of body weight, initially for shock and shock-like states, followed by equal maintenance doses at 1-, 3-, 6-, or 10-hour intervals as determined by the condition of the animal.

(2) *Indications for use.* Administer when a rapid adrenal glucocorticoid and/or anti-inflammatory effect is necessary.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 59881, Oct. 20, 2003]

§ 522.1884 Prednisolone sodium succinate.

(a) *Specifications.* Each milliliter of prednisolone sodium succinate injection contains: Prednisolone sodium succinate equivalent in activity to 10, 20, or 50 milligrams (mg) of prednisolone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for products containing 10, 20, and 50 mg equivalent prednisolone activity per milliliter for use in horses, dogs, and cats as provided in paragraphs (c)(1)(i), (ii), and (iii) of this section.

(c) *Conditions of use—(1) Amount and indications for use—(i) Horses.* Administer 50 to 100 mg as an initial dose by intravenous injection over a period of one-half to 1 minute, or by intramuscular injection, and may be repeated in inflammatory, allergic, or other stress conditions at intervals of 12, 24, or 48 hours, depending upon the

size of the animal, the severity of the condition and the response to treatment.

(ii) *Dogs.* Administer by intravenous injection at a range of 2.5 to 5 mg per pound of body weight as an initial dose followed by maintenance doses at 1, 3, 6, or 10 hour intervals, as determined by the condition of the animal, for treatment of shock.

(iii) *Dogs and cats.* Administer by intramuscular injection for treatment of inflammatory, allergic, and less severe stress conditions, where immediate effect is not required, at 1 to 5 mg ranging upward to 30 to 50 mg in large breeds of dogs. Dosage may be repeated in 12 to 24 hours and continued for 3 to 5 days if necessary. If permanent corticosteroid effect is required, oral therapy with prednisolone tablets may be substituted.

(2) *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 16194, Mar. 25, 2014]

§ 522.1885 Prednisolone tertiary butylacetate.

(a) *Specifications.* Each milliliter of suspension contains 20 milligrams (mg) of prednisolone tertiary butylacetate.

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

(c) *Conditions of use—(1) Amount—(i) Horses:* Administer by intramuscular injection 100 to 300 mg or by intrasynovial injection at a dosage level of 50 to 100 mg. Retreatment of horses in 24 to 48 hours may be necessary, depending on the general condition of the animal and the severity and duration of the disease.

(ii) *Dogs and cats:* Administer by intramuscular injection 1 mg per 5 pounds of body weight or intrasynovially at a dosage level of 10 to 20 mg.

(2) *Indications for use.* It is used as an anti-inflammatory agent in horses, dogs, and cats.

(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 16194, Mar. 25, 2014]

§ 522.1890

21 CFR Ch. I (4–1–16 Edition)

§ 522.1890 Sterile prednisone suspension.

(a) *Specifications.* Each milliliter of suspension contains 10 to 40 milligrams (mg) of prednisone.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Horses.* Administer 100 to 400 mg by intramuscular injection, repeating if necessary.

(ii) *Dogs and cats.* Administer 0.25 to 1.0 mg per pound of body weight by intramuscular injection for 3 to 5 days or until a response is noted. Treatment may be continued with an orally administered dose.

(2) *Indications for use.* It is used for conditions requiring an anti-inflammatory agent.

(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 16194, Mar. 25, 2014]

§ 522.1920 Prochlorperazine and isopropamide.

(a) *Specifications.* Each milliliter of solution contains prochlorperazine edisylate equivalent to 4 milligrams (mg) prochlorperazine and isopropamide iodide equivalent to 0.28 mg of isopropamide.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* (i) Dosage is administered by subcutaneous injection twice daily as follows:

Weight of animal in pounds	Dosage in milliliters
Up to 4	0.25
5 to 14	0.5–1
15 to 30	2–3
30 to 45	3–4
45 to 60	4–5
Over 60	6

(ii) Following the last injection, administer prochlorperazine and isopropamide sustained release capsules as indicated.

(2) *Indications for use.* For use in dogs and cats in which gastrointestinal disturbances are associated with emotional stress.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16194, Mar. 25, 2014]

§ 522.1940 Progesterone and estradiol benzoate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 054771 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), (c)(2)(iii), and (c)(3) of this section.

(2) No. 000986 for use as in paragraphs (c)(1) and (c)(2) of this section.

(b) *Related tolerances.* See §§ 556.240 and 556.540 of this chapter.

(c) *Conditions of use in cattle.* It is used for implantation as follows:

(1) *Suckling beef calves*—(i) *Amount*—(A) 100 milligrams (mg) progesterone and 10 mg estradiol benzoate (one implant consisting of 4 pellets, each pellet containing 25 mg progesterone and 2.5 mg estradiol benzoate) per implant dose.

(B) 100 mg progesterone and 10 mg estradiol benzoate (one implant consisting of 5 pellets, each of 4 pellets containing 25 mg progesterone and 2.5 mg estradiol benzoate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* For use in suckling beef calves (at least 45 days of age) up to 400 pounds (lb) of body weight. For subcutaneous ear implantation, one dose per animal. Do not use in bull calves intended for reproduction. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Steers*—(i) *Amount*—(A) 200 mg progesterone and 20 mg estradiol benzoate (one implant consisting of 8 pellets, each pellet containing 25 mg progesterone and 2.5 mg estradiol benzoate) per implant dose.

(B) 200 mg progesterone and 20 mg estradiol benzoate (one implant consisting of 9 pellets, each of 8 pellets containing 25 mg progesterone and 2.5

mg estradiol benzoate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* For animals weighing 400 lb or more; for subcutaneous ear implantation, one dose per animal. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Steers fed in confinement for slaughter*—(i) *Amount.* Reimplant 200 mg progesterone and 20 mg estradiol benzoate on approximately day 70 following an initial implant of 100 mg progesterone and 10 mg estradiol benzoate or 200 mg progesterone and 20 mg estradiol benzoate.

(ii) *Indications for use.* For additional improvement in rate of weight gain.

(iii) *Limitations.* For subcutaneous ear implantation. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 70055, Dec. 2, 2004, as amended at 77 FR 31723, May 30, 2012; 79 FR 16194, Mar. 25, 2014]

§ 522.1962 Promazine.

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) promazine hydrochloride.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 054771 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii)(A), (c)(1)(iii), and (c)(2) of this section.

(2) No. 061623 for use as in paragraphs (c)(1)(i)(B), (c)(1)(ii)(B), and (c)(1)(iii) of this section.

(c) *Conditions of use*—(1) *Horses*—(i) *Amount*—(A) 0.2 to 0.5 milligrams per pounds (mg/lb) body weight intramuscularly or intravenously every 4 to 6 hours.

(B) 0.2 to 0.5 mg/lb body weight intravenously as required.

(ii) *Indications for use*—(A) For use as a tranquilizer, preanesthetic, or for minor operative procedures in conjunc-

tion with local anesthesia; and as adjunctive therapy for tetanus.

(B) For use as a tranquilizer and preanesthetic.

(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.

(2) *Dogs and cats*—(i) *Amount.* 1 to 2 mg/lb body weight intramuscularly or intravenously every 4 to 6 hours.

(ii) *Indications for use.* For use as a tranquilizer, preanesthetic, for minor operative procedures in conjunction with local anesthesia, as adjunctive therapy for tetanus, and as an antiemetic prior to worming; or to prevent motion sickness in dogs.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 18962, Mar. 27, 1981, as amended at 68 FR 59881, Oct. 20, 2003; 70 FR 50183, Aug. 26, 2005; 79 FR 16194, Mar. 25, 2014]

§ 522.2002 Propiopromazine.

(a) *Specifications.* Each milliliter of solution contains 5 or 10 milligrams (mg) propiopromazine hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amounts and indications for use.* Administer 0.05 to 0.5 mg per pound of body weight by intravenous or intramuscular injection for tranquilization. Administer 0.25 mg per pound of body weight by intravenous injection as a preanesthetic.

(2) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16195, Mar. 25, 2014]

§ 522.2005 Propofol.

(a) *Specifications.* Each milliliter of emulsion contains 10 milligrams (mg) propofol.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 000859 for use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.

(2) No. 054771 for use as in paragraph (c) of this section.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer by intravenous injection according to label directions.

§ 522.2012

The use of preanesthetic medication reduces propofol dose requirements.

(2) *Indications for use*—(i) As a single injection to provide general anesthesia for short procedures; for induction and maintenance of general anesthesia using incremental doses to effect; for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 20269, Apr. 19, 2010, as amended at 75 FR 38700, July 6, 2010; 78 FR 17868, Mar. 25, 2013; 79 FR 16195, Mar. 25, 2014; 80 FR 18776, Apr. 8, 2015]

§ 522.2012 Prostalene.

(a) *Specifications*. Each milliliter of solution contains 1 milligram of prostalene.

(b) *Sponsor*. No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 5 micrograms per kilogram of body weight as a single subcutaneous injection.

(2) *Indications for use*. For the control of estrus in mares.

(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 16195, Mar. 25, 2014]

§ 522.2063 Pyrilamine.

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

(b) *Sponsors*. See sponsor numbers in § 510.600(c) of this chapter for uses in paragraph (c) of this section.

(1) No. 000061 for use as in paragraph (c)(1)(i), (2), and (3) of this section.

(2) No. 061623 for use as in paragraph (c)(1)(ii), (2), and (3) of this section.

(c) *Conditions of use*—(1) *Amount*—(i) Horses, 40 to 60 mg per 100 pounds (lbs) body weight; foals, 20 mg/100 lbs body weight. Administer by intramuscular, subcutaneous, or intravenous injection. Dosage may be repeated every 6 to 12 hours whenever necessary.

21 CFR Ch. I (4–1–16 Edition)

(ii) Horses, 40 to 60 mg/100 lbs body weight; foals, 20 mg/100 lbs body weight. Administer by slow intravenous injection. Dosage may be repeated every 6 to 12 hours if necessary.

(2) *Indications for use*. It is intended for treating horses in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(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 16195, Mar. 25, 2014]

§ 522.2075 Robenacoxib.

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

(b) *Sponsor*. See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount*. Administer 0.91 mg per pound (2 mg/kilogram) by subcutaneous injection, once daily, for a maximum of 3 days.

(2) *Indications for use*. For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats at least 4 months of age for a maximum of 3 days.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[80 FR 61297, Oct. 13, 2015]

§ 522.2076 Romifidine.

(a) *Specifications*. Each milliliter of solution contains 10 milligrams (mg) romifidine hydrochloride.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. 40 to 120 micrograms per kilogram of body weight (mcg/kg BW) intravenously for sedation and analgesia; 100 mcg/kg BW intravenously as a preanesthetic.

(2) *Indications for use*. For use as a sedative and analgesic to facilitate handling, clinical examinations, clinical procedures, and minor surgical procedures in adult horses; and for use as a preanesthetic prior to the induction of general anesthesia in adult horses.

(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.

[69 FR 47363, Aug. 5, 2004, as amended at 79 FR 16195, Mar. 25, 2014]

§ 522.2100 Selenium and vitamin E.

(a)(1) *Specifications.* Each milliliter of emulsion contains 5.48 milligrams (mg) sodium selenite (equivalent to 2.5 mg selenium) and 50 mg of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use in horses—(i) Amount.* Administer 1 milliliter (mL) per (✓) 100 pounds (lbs) of body weight by intravenous injection or by deep intramuscular injection in divided doses in two or more sites in the gluteal or cervical muscles. Administration may be repeated at 5 to 10 day intervals.

(ii) *Indications for use.* For the prevention and treatment of selenium-tocopherol deficiency syndrome in horses.

(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.

(b)(1) *Specifications.* Each milliliter contains 2.19 mg of sodium selenite (equivalent to 1 mg of selenium), 50 mg of vitamin E (68 I.U.) (as d-alpha tocopheryl acetate).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use in dogs—(i) Amount.* Administer by subcutaneous or intramuscular injection in divided doses in two or more sites at 1 mL/20 lbs of body weight with a minimum dosage of ¼ mL and a maximum dosage of 5 mL. The dose is repeated at 3-day intervals until a satisfactory therapeutic response is observed. A maintenance regimen is then initiated which consists of 1 mL per 40 lbs of body weight with a minimum dosage of ¼ mL which is repeated every 3 days or 7 days, or longer, as required to maintain continued improvement or an asymptomatic condition; or the drug may be used in capsule form for oral maintenance therapy.

(ii) *Indications for use.* As an aid in alleviating and controlling inflamma-

tion, pain, and lameness associated with certain arthropathies in dogs.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter contains 2.19 milligrams of selenite sodium (equivalent to 1 milligram selenium), 50 milligrams vitamin E (68 U.S.P. units).

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* Calves: 2.5 to 3.75 milliliters per 100 pounds of body weight. Lambs 2 weeks of age or older: 1 milliliter per 40 pounds, minimum 1 milliliter. Ewes: 2.5 milliliters per 100 pounds. Sows: 1 milliliter per 40 pounds. Weanling pigs: 1 milliliter per 40 pounds, minimum 1 milliliter.

(ii) *Indications for use.* Calves, lambs, and ewes: prevention and treatment of white muscle disease (selenium-tocopherol deficiency syndrome). Sows and weanling pigs: an aid in the prevention and treatment of selenium-tocopherol deficiency.

(iii) *Limitations.* For subcutaneous or intramuscular use. Not for use in newborn pigs. Do not use in pregnant ewes. Calves: Discontinue use 30 days before treated calves are slaughtered for human consumption. Lambs, ewes, sows, or pigs: Discontinue use 14 days before treated lambs, ewes, sows, or pigs are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications.* Each milliliter contains 10.95 milligrams selenite sodium (equivalent to 5 milligrams selenium), 50 milligrams vitamin E (68 U.S.P. units).

(2) *Sponsors.* See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* Breeding beef cows: 1 milliliter per 200 pounds of body weight during the middle third of gestation, and 30 days before calving. Weanling calves: 1 milliliter per 200 pounds of body weight.

(ii) *Indications for use.* Weanling calves and breeding beef cows: For the prevention and treatment of selenium-tocopherol deficiency syndrome.

(iii) *Limitations.* For subcutaneous or intramuscular use. Discontinue use 30

§ 522.2112

21 CFR Ch. I (4-1-16 Edition)

days before treated cattle are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter contains 0.55 milligram selenite sodium (equivalent to 0.25 milligram selenium), 50 milligrams (68 U.S.P. units) vitamin E.

(2) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(3) *Conditions of use—(i) Dosage.* New-born lambs: 1 milliliter. Lambs 2 weeks of age or older: 4 milliliters. Baby pigs: 1 milliliter (or treat the sow during the last week of pregnancy).

(ii) *Indications for use.* Lambs: for prevention and treatment of white muscle disease (selenium-tocopherol deficiency syndrome). Baby pigs: an aid in the prevention and treatment of selenium-tocopherol deficiency.

(iii) *Limitations.* For subcutaneous or intramuscular use only. Discontinue use 14 days before treated animals are slaughtered for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987; 57 FR 21209, May 19, 1992; 58 FR 57556, Oct. 26, 1993; 60 FR 57833, Nov. 22, 1995; 64 FR 27916, May 24, 1999; 79 FR 16195, Mar. 25, 2014]

§ 522.2112 Sometribove zinc suspension.

(a) *Specifications.* Each single-dose syringe contains 500 milligrams (mg) sometribove zinc in a prolonged-release suspension.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Inject 500 mg every 14 days starting during the 9th or 10th week (57 to 70 days) after calving and continue until the end of lactation.

(2) *Indications for use.* To increase production of marketable milk in healthy lactating dairy cows.

(3) *Limitations.* Use in lactating dairy cows only. Safety to replacement bulls born to treated dairy cows has not been established. Inject subcutaneously. Avoid injections within 2 weeks of expected slaughter to minimize injection site blemishes on carcass. There is no milk discard or preslaughter with-

drawal period. Use may reduce pregnancy rates and increase days open. Treated cows are at an increased risk for mastitis and higher milk somatic cell counts. Use care to differentiate increased body temperature due to use of this product from an increased body temperature that may occur due to illness. Cows treated with this product may have more enlarged hocks and disorders of the foot region. Use may reduce hemoglobin and hematocrit values during treatment. Human warning: Avoid prolonged or repeated contact with eyes and skin.

[58 FR 59947, Nov. 12, 1993, as amended at 67 FR 18085, Apr. 15, 2002; 68 FR 62006, Oct. 31, 2003; 74 FR 53164, Oct. 16, 2009]

§ 522.2120 Spectinomycin dihydrochloride injection.

(a) *Specifications.* The spectinomycin dihydrochloride pentahydrate used in manufacturing the drug is the antibiotic substance produced by the growth of *Streptomyces flavopersicus* (var. Abbott) or the same antibiotic substance produced by any other means. Each milliliter of the drug contains the following amount of spectinomycin activity from spectinomycin dihydrochloride pentahydrate:

(1) 5 milligrams when used as provided in paragraph (d)(1) of this section.

(2) [Reserved]

(3) 100 milligrams when used as provided in paragraphs (d) (2), (3), and (4) of this section.

(b) *Sponsor.* In § 510.600 of this chapter, see No. 000859 for conditions of use as in paragraph (d) of this section, and see No. 054771 for conditions of use as in paragraph (d)(2) and (d)(4) of this section.

(c) *Special considerations.* The quantity of spectinomycin referred to in this section refers to the equivalent weight of base activity for the drug.

(d) *Conditions of use.* It is administered as spectinomycin dihydrochloride pentahydrate as follows:

(1) Subcutaneously in the treatment of 1-to-3-day-old turkey poults at the rate of 1 to 2 milligrams per poult as an aid in the prevention of mortality associated with Arizona group infection.

(2) Subcutaneously in the treatment of 1-to-3-day old:

(i) Turkey poults at the rate of 5 milligrams per poult as an aid in the control of chronic respiratory disease (CRD) associated with *E. coli*.

(ii) Baby chicks at the rate of 2.5 to 5 milligrams per chick as an aid in the control of mortality and to lessen severity of infections caused by *M. synoviae*, *S. typhimurium*, *S. infantis*, and *E. coli*.

(3) Intramuscularly in the treatment of dogs:

(i) At a dosage level of 2.5 milligrams to 5.0 milligrams per pound of body weight twice daily. Treatment may be continued for 4 days. For treatment of infections caused by gram-negative and gram-positive organisms susceptible to spectinomycin.

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

(4) Administer single injection of 0.1 milliliter (10 milligrams) subcutaneously in nape of neck of 1- to 3-day-old turkey poults as an aid in control of airsacculitis associated with *M. meleagridis* sensitive to spectinomycin.

[40 FR 13858, Mar. 27, 1975, as amended at 43 FR 9273, Mar. 7, 1978; 46 FR 18964, Mar. 27, 1981; 47 FR 14149, Apr. 2, 1982; 61 FR 5507, Feb. 13, 1996; 61 FR 31028, June 19, 1996; 65 FR 45877, July 26, 2000; 66 FR 22118, May 3, 2001; 79 FR 16195, Mar. 25, 2014]

§ 522.2121 Spectinomycin sulfate.

(a) *Specifications*. Each milliliter of solution contains spectinomycin sulfate tetrahydrate equivalent to 100 milligrams (mg) spectinomycin.

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.600 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. 10 to 15 mg per kilogram of body weight at 24-hour intervals for 3 to 5 consecutive days.

(2) *Indications for use*. For the treatment of bovine respiratory disease (pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*.

(3) *Limitations*. Do not slaughter within 11 days of last treatment. Do not use in female dairy cattle 20 months of age

or older. Use in this class of cattle may cause residues in milk. A withdrawal period has not been established for this product 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.

[72 FR 31178, June 6, 2007, as amended at 79 FR 16195, Mar. 25, 2014]

§ 522.2150 Stanazolol.

(a) *Specifications*. Each milliliter of suspension contains 50 milligrams (mg) of stanozolol.

(b) *Sponsor*. No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs and cats*. For cats and small breeds of dogs: 25 mg. For larger dogs: 50 mg. Administer by deep intramuscular injection in the thigh at weekly intervals, for several weeks.

(ii) *Horses*. Administer 25 mg per 100 pounds of body weight by deep intramuscular injection in the gluteal region at weekly intervals, for not more than 4 weeks.

(2) *Indications for use*. For use as an anabolic steroid treatment.

(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 16195, Mar. 25, 2014]

§ 522.2200 Sulfachlorpyridazine.

(a) *Specifications*. Each milliliter of solution contains sodium sulfachlorpyridazine equivalent to 200 milligrams (mg) sulfachlorpyridazine.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.630 of this chapter.

(d) *Conditions of use in calves*. It is used as follows:

(1) *Amount*. Administer 30 to 45 mg per pound (lb) of body weight in divided doses by twice daily injection for 1 to 5 days.

(2) *Indications for use*. For the treatment of diarrhea caused or complicated by *Escherichia coli* (colibacillosis).

(3) *Limitations*. Treated calves must not be slaughtered for food during treatment or for 5 days after the last treatment. A withdrawal period has

§ 522.2220

21 CFR Ch. I (4–1–16 Edition)

not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[75 FR 10167, Mar. 5, 2010]

§ 522.2220 Sulfadimethoxine.

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

(1) 100 milligrams (mg) of sulfadimethoxine sodium.

(2) 400 mg of sulfadimethoxine sodium.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 054628 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(2) No. 054771 for use of the product described in paragraph (a)(2) as in paragraphs (d)(2), (3), and (4) of this section.

(3) Nos. 000859, 057561, and 061623 for use of the product described in paragraph (a)(2) as in paragraph (d)(4) of this section.

(c) *Related tolerances.* See § 556.640 of this chapter.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer by subcutaneous, intramuscular, or intravenous injection at an initial dose of 25 mg per pound of body weight followed by 12.5 mg per pound of body weight every 24 hours thereafter. Continue treatment until the animal is free from symptoms for 48 hours.

(ii) *Indications for use.* For use in the treatment of sulfadimethoxine-susceptible bacterial infections in dogs.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs and cats*—(i) *Amount.* Administer by intravenous or subcutaneous injection at an initial dose of 55 mg per kilogram of body weight followed by 27.5 mg per kilogram of body weight every 24 hours.

(ii) *Indications for use.* For the treatment of respiratory, genitourinary tract, enteric, and soft tissue infections when caused by *Streptococci*, *Staphylococci*, *Escherichia*, *Salmonella*, *Klebsiella*, *Proteus*, or *Shigella* organisms sensitive to sulfadimethoxine, and in the treatment of canine bacterial enteritis associated with coccidiosis and canine Salmonellosis.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Horses*—(i) *Amount.* Administer by intravenous injection at an initial dose of 55 mg per kilogram of body weight followed by 27.5 mg per kilogram of body weight every 24 hours until the patient is asymptomatic for 48 hours.

(ii) *Indications for use.* For the treatment of respiratory disease caused by *Streptococcus equi* (strangles).

(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.

(4) *Cattle*—(i) *Amount.* Administer an initial dose of 25 mg per pound of body weight by intravenous injection followed by 12.5 mg per pound of body weight every 24 hours until the animal is asymptomatic for 48 hours.

(ii) *Indications for use.* For the treatment of bovine respiratory disease complex (shipping fever complex) and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(iii) *Limitations.* Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Do not administer within 5 days of slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[79 FR 16196, Mar. 25, 2014]

§ 522.2240 Sulfaethoxyppyridazine.

(a) *Specifications.* The drug is an aqueous solution of sulfaethoxyppyridazine.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.650 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Administer 2.5 grams per 100 pounds of body weight per day by intravenous injection for not more than 4 days; or first treatment may be followed by 3 days of treatment with sulfaethoxyppyridazine in drinking water or tablets in accordance with

§§ 520.2240a(e) and 520.2240b(e) of this chapter.

(2) *Indications for use.* For treatment of respiratory infection (pneumonia, shipping fever), foot rot, calf scours; as adjunctive therapy in septicemia accompanying mastitis and metritis.

(3) *Limitations.* Do not treat within 16 days of slaughter. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16196, Mar. 25, 2014]

§ 522.2260 Sulfamethazine.

(a) *Specifications.* Each milliliter (mL) of solution contains 250 milligrams (mg) sulfamethazine sodium.

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Initially administer 20 mL for each 50 pounds (lb) of body weight (100 mg/lb) by intravenous injection, followed by 20 mL per 100 lb of body weight (50 mg/lb) by intravenous injection, daily thereafter. Treatment should not exceed a total of 5 consecutive days.

(2) *Indications for use.* For cattle for treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis and acute metritis (*Streptococcus* spp.) when caused by one or more pathogenic organisms sensitive to sulfamethazine.

(3) *Limitations.* Withdraw medication from cattle 10 days prior to slaughter. Do not use in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 62055, Dec. 22, 1981, as amended at 67 FR 78355, Dec. 24, 2002; 75 FR 10167, Mar. 5, 2010; 76 FR 53051, Aug. 25, 2011; 81 FR 17608, Mar. 30, 2016]

§ 522.2340 Sulfomyxin.

(a) *Specifications.* Sulfomyxin for injection is sterile. It is derived from the antibiotic substance produced by the growth of *Bacillus polymyxa* or is the same substance produced by any other means.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations.* The quantities of antibiotic in paragraph (e) of this section refer to the activity of the appropriate standard.

(d) *Related tolerances.* See § 556.700 of this chapter.

(e) *Conditions of use.* (1) It is used or intended for use in chickens and turkeys as an aid in the treatment of disease caused or complicated by *E. coli*, such as colibacillosis and complicated chronic respiratory disease.

(2) It is administered by subcutaneous injection as follows:

Age of birds in days	Antibiotic activity	
	Chickens (units)	Turkeys (units)
1 to 14	12,500	12,500
15 to 28	25,000	25,000
29 to 63	50,000	50,000
Over 63	50,000	100,000

(3) A second injection may be given 3 days later if symptoms persist.

(4) Not for use in laying hens; do not treat chickens within 5 days of slaughter; do not treat turkeys within 7 days of slaughter.

[40 FR 13858, Mar. 27, 1975, as amended at 79 FR 16196, Mar. 25, 2014]

§ 522.2404 Thialbarbitone sodium for injection.

(a) *Specifications.* Thialbarbitone sodium for injection when reconstituted with sterile distilled water provides 94 milligrams of thialbarbitone sodium per milliliter of solution.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered as a general anesthetic in surgical procedures on dogs, cats, swine, sheep, cattle, and horses. The drug is used for procedures of relatively short duration. However, the period of anesthesia can be lengthened by slower initial injection and supplemental administration during surgery.

§ 522.2424

(2) It is administered intravenously. The drug is injected slowly to dogs, cats, cattle, sheep, and swine. For horses, it is recommended that a pre-anesthetic sedation be administered to the horse 30 minutes before the drug is administered. The drug is then injected rapidly and completely. The drug is used at the following dosage levels:

Species	Weight of animal in pounds	Dosage in milligrams per pound
Dog	Over 50	14.1
Do	30-50	18.8
Do	10-30	23.5
Do	Under 10	28.2
Cat	31.3-37.6
Horse	6.3-7.8
Cattle and swine	6.7-9.4
Calves and sheep	9.4-11.8

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

[40 FR 13858, Mar. 27, 1975, as amended at 79 FR 16196, Mar. 25, 2014]

§ 522.2424 Thiamylal.

(a) *Specifications.* The drug is a sterile powder. It is reconstituted with sterile distilled water, water for injection, or sodium chloride injection, to a desired concentration of 0.5 to 4 percent sodium thiamylal.

(b) *Sponsors.* See Nos. 054628 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Administer by intravenous injection to effect. The average single dose is:

(i) *Dogs and cats:* 8 milligrams (mg) per pound of body weight (when used with a preanesthetic, generally one-half the normal dose).

(ii) *Swine:* 40 mg per 5 pounds (lbs) of body weight.

(iii) *Horses:* Light anesthesia, 1 gram per 500 lbs to 1,100 lbs of body weight; deep anesthesia, 1 gram per 300 lbs of body weight (40 mg/12 lbs of body weight).

(iv) *Cattle:* Short duration, 20 mg/5 lbs of body weight; longer duration, 40 mg/7 lbs of body weight.

(2) *Indications for use.* It is used as an ultra-short-acting anesthetic in dogs, cats, swine, horses, and cattle.

(3) *Limitations.* Do not use in horses intended for human consumption. Fed-

21 CFR Ch. I (4-1-16 Edition)

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

[79 FR 16196, Mar. 25, 2014]

§ 522.2444 Thiopental injectable dosage forms.

§ 522.2444a Thiopental powder for injection.

(a) *Specifications.* The drug contains sodium thiopental powder for constitution with sterile water for injection.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—(1) Amount.* Administer by intravenous injection as follows:

(i) 6 to 9 milligrams (mg) per pound of body weight for brief anesthesia (6 to 10 minutes).

(ii) 10 to 12 mg per pound of body weight for anesthesia of 15 to 25 minutes duration.

(2) *Indications for use.* It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical and other procedures. It is also used to induce anesthesia in dogs and cats which then have surgical anesthesia maintained by use of a volatile anesthetic.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16196, Mar. 25, 2014]

§ 522.2444b Thiopental and pentobarbital powder for injection.

(a) *Specifications.* Each gram of powder contains 750 milligrams (mg) of sodium thiopental and 250 mg of sodium pentobarbital powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* For total anesthesia, it is given at approximately 10 to 12 mg per pound of body weight over a period of 3.5 to 5 minutes. When preanesthetic medication is used, wait at least an hour before administering thiopental and sodium pentobarbital for injection, and the dosage necessary for anesthesia is reduced. Usually ½ to ¾ the normal amount is adequate.

(2) *Indications for use.* It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical procedures.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16197, Mar. 25, 2014]

§ 522.2460 Tildipirosin.

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

(1) 180 milligrams (mg) tildipirosin.

(2) [Reserved]

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.733 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer 4 mg/kg of body-weight one time by subcutaneous injection in the neck.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*.

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 21 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product 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]

[77 FR 39391, July 3, 2012]

§ 522.2470 Tiletamine and zolazepam for injection.

(a) *Specifications.* The drug is a sterile powder. Each milliliter of constituted solution contains tiletamine hydrochloride equivalent to 50 milligrams (mg) of tiletamine base and zolazepam hydrochloride equivalent to 50 mg of zolazepam base.

(b) *Sponsors.* See Nos. 026637 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Expressed as milligrams of the drug combination:

(i) *Healthy dogs:* An initial intramuscular dosage of 3 to 4.5 mg per pound of body weight for diagnostic purposes; 4.5 to 6 mg per pound of body weight for minor procedures of short duration such as repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the total dose given should not exceed 12 mg per pound of body weight. The maximum total safe dose is 13.6 milligrams per pound of body weight.

(ii) *Healthy cats:* An initial intramuscular dosage of 4.4 to 5.4 mg per pound of body weight for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 mg per pound of body weight for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations, and other procedures of short duration. Initial dosages of 6.5 to 7.2 mg per pound of body weight are recommended for ovariohysterectomy and onychectomy. When supplemental doses are required, such individual supplemental doses should be given in increments that are less than the initial dose, and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 mg per pound of body weight.

(2) *Indications for use.* For restraint or for anesthesia combined with muscle relaxation in cats and in dogs for restraint and minor procedures of short duration (30 minutes) requiring mild to moderate analgesia.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16197, Mar. 25, 2014, as amended at 80 FR 34279, June 16, 2015]

§ 522.2471 Tilmicosin.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) tilmicosin base as tilmicosin phosphate.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

§ 522.2473

(c) *Related tolerances.* See § 556.735 of this chapter.

(d) *Special considerations.* (1) Not for human use. Use of this antibiotic in humans may prove fatal. Do not use in automatically powered syringes.

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

(e) *Conditions of use—(1) Cattle—(i) Amount.* 10 to 20 milligrams per kilogram (mg/kg) of body weight as a single subcutaneous injection.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*.

(iii) *Limitations.* Do not use in female dairy cattle 20 months of age or older. Use of this antibiotic in this class of cattle may cause milk residues. Do not slaughter within 42 days of last treatment.

(2) *Sheep—(i) Amount.* 10 mg/kg body weight as a single subcutaneous injection.

(ii) *Indications for use.* For the treatment of ovine respiratory disease (ORD) associated with *Mannheimia (P.) haemolytica*.

(iii) *Limitations.* Do not slaughter within 28 days of last treatment.

[67 FR 72367, Dec. 5, 2002, as amended at 75 FR 9334, Mar. 2, 2010]

§ 522.2473 Tiludronate.

(a) *Specifications.* Each vial of powder contains 500 milligrams (mg) tiludronate disodium. Each milliliter of constituted solution contains 20 mg tiludronate disodium.

(b) *Sponsor.* See No. 013744 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer a single dose of 1 mg per kilogram (0.45 mg/pound) of body weight by intravenous infusion.

(2) *Indication for use.* For the control of clinical signs associated with navicular syndrome.

(3) *Limitations.* Do not use in horses intended for human consumption. Fed-

21 CFR Ch. I (4–1–16 Edition)

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

[79 FR 18159, Apr. 1, 2014]

§ 522.2474 Tolazoline.

(a) *Specifications.* Each milliliter of solution contains tolazoline hydrochloride equivalent to 100 milligrams (mg) of base activity.

(b) *Sponsor.* See No. 059399 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer slowly by intravenous injection 4 mg per kilogram of body weight or 1.8 mg per pound (4 milliliters (mL) per 100 kilograms or 4 mL per 220 pounds).

(2) *Indications for use.* For use in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine.

(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 16197, Mar. 25, 2014, as amended at 79 FR 74020, Dec. 15, 2014; 80 FR 13230, Mar. 13, 2015]

§ 522.2476 Trenbolone acetate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 021641 for use as in paragraph (c) of this section.

(2) No. 000061 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

(b) *Related tolerances.* See § 556.739 of this chapter.

(c) *Conditions of use—(1) Steers fed in confinement for slaughter—(i) Amount.* Use 126 days prior to slaughter; should be reimplanted once after 63 days.

(A) 140 milligrams (mg) trenbolone acetate (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 140 mg trenbolone acetate (one implant consisting of 8 pellets, each of 7 pellets containing 20 milligrams trenbolone acetate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Heifers fed in confinement for slaughter—(i) Amount.* Use last 63 days prior to slaughter.

(A) 200 mg trenbolone acetate (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 200 mg of trenbolone acetate (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg of trenbolone acetate, and 1 pellet containing 29 mg of tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[66 FR 47961, Sept. 17, 2001, as amended at 69 FR 70056, Dec. 2, 2004; 74 FR 61517, Nov. 25, 2009]

EDITORIAL NOTE: At 77 FR 31723, May 30, 2012, § 522.2476 was amended in paragraph (b)(1) by removing “021641” and in its place adding “000986”; however, the amendment could not be incorporated because (b)(1) didn't exist.

§ 522.2477 Trenbolone acetate and estradiol.

(a) [Reserved]

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 000986 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(i)(E), (d)(1)(i)(F), (d)(1)(ii), (d)(1)(iii), (d)(2), and (d)(3) of this section.

(2) No. 000061 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D),

(d)(1)(i)(G), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(D), (d)(2)(ii), (d)(2)(iii), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii) of this section.

(3) No. 054771 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii) of this section.

(d) *Conditions of use—(1) Steers fed in confinement for slaughter—(i) Amount.* (A) 120 milligrams (mg) trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(C) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose.

(D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(E) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(F) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(G) 200 milligram (mg) trenbolone acetate and 40 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do

not use in calves to be processed for veal.

(2) *Heifers fed in confinement for slaughter*—(i) *Amount*. (A) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(A) of this section.

(B) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 8 pellets, each of 7 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose for use as in paragraphs (d)(2)(ii)(A) of this section.

(C) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

(D) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(A) of this section.

(E) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

(F) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use*. (A) For increased rate of weight gain and improved feed efficiency.

(B) For increased rate of weight gain.

(iii) *Limitations*. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Pasture cattle (slaughter, stocker, and feeder steers and heifers)*—(i) *Amount*. (A) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 2 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 3 pellets, each of 2 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use*. For increased rate of weight gain.

(iii) *Limitations*. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[60 FR 4376, Jan. 23, 1995]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §522.2477, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Specifications*—(1) Each implant consists of:

(i) 8 pellets, each pellet containing 25 milligrams (mg) trenbolone acetate and 3.5 mg estradiol benzoate.

(ii) 4 pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(2) Each extended release implant consists of:

(i) 8 pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(ii) 6 pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(b) *Sponsor*. See No. 054771 in §510.600(c) of this chapter.

(c) *Related tolerances*. See §§556.240 and 556.739 of this chapter.

(d) *Conditions of use*—(1) *Steers fed in confinement for slaughter*. (i) For an implant as described in paragraph (a)(1)(i) of this section:

(A) *Amount*. 200 mg trenbolone acetate and 28 mg estradiol benzoate.

(B) *Indications for use*. For increased rate of weight gain and improved feed efficiency.

(C) *Limitations*. Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) For an implant as described in paragraph (a)(1)(ii) of this section:

(A) *Amount*. 100 mg trenbolone acetate and 14 mg estradiol benzoate.

(B) *Indications for use*. For increased rate of weight gain.

(C) *Limitations*. Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(iii) For an implant as described in paragraph (a)(2)(i) of this section:

(A) *Amount*. 200 mg trenbolone acetate and 28 mg estradiol benzoate in an extended release implant.

(B) *Indications for use*. For increased rate of weight gain and improved feed efficiency for up to 200 days.

(C) *Limitations*. Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Heifers fed in confinement for slaughter*—(i) For an implant as described in paragraph (a)(1)(i) of this section:

(A) *Amount*. 200 mg trenbolone acetate and 28 mg estradiol benzoate.

(B) *Indications for use*. For increased rate of weight gain.

(C) *Limitations*. Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating

calves. Do not use in calves to be processed for veal.

(ii) For an implant as described in paragraph (a)(1)(ii) of this section:

(A) *Amount*. 100 mg trenbolone acetate and 14 mg estradiol benzoate.

(B) *Indications for use*. For increased rate of weight gain and improved feed efficiency.

(C) *Limitations*. Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(iii) For an implant as described in paragraph (a)(2)(i) of this section:

(A) *Amount*. 200 mg trenbolone acetate and 28 mg estradiol benzoate in an extended release implant.

(B) *Indications for use*. For increased rate of weight gain and improved feed efficiency for up to 200 days.

(C) *Limitations*. Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Pasture steers and heifers (slaughter, stocker, and feeder)*—(i) For an implant as described in paragraph (a)(2)(ii) of this section:

(A) *Amount*. 150 mg trenbolone acetate and 21 mg estradiol benzoate in an extended release implant.

(B) *Indications for use*. For increased rate of weight gain for up to 200 days.

(C) *Limitations*. Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) [Reserved]

[67 FR 78972, Dec. 27, 2002, as amended at 69 FR 67818, Nov. 22, 2004; 79 FR 16197, Mar. 25, 2014; 79 FR 64116, Oct. 28, 2014]

§ 522.2483 Triamcinolone.

(a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams (mg) triamcinolone acetonide.

(b) *Sponsors.* See Nos. 000010 and 054628 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*—(A) *Intramuscular or subcutaneous.* For inflammatory, arthritic, or allergic disorders, administer 0.05 to 0.1 mg per pound (lb) of body weight as a single injection. For dermatologic disorders, administer 0.1 mg per pound (lb) of body weight as a single injection. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted.

(B) *Intralesional.* Administer 1.2 to 1.8 mg, divided in several injections around the lesion, spaced 0.5 to 2.5 centimeters apart, depending on lesion size. At any one site, the dose injected should not exceed 0.6 mg. and should be well into the cutis to prevent rupture of the epidermis. When treating animals with multiple lesions, do not exceed a total dose of 6 mg.

(C) *Intra-articular and intrasynovial.* Administer 1 to 3 mg as a single injection, depending on the size of the joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 3 mg.

(ii) *Indications for use.* For the treatment of inflammation and related disorders, and the management and treatment of acute arthritis and allergic and dermatologic disorders.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount*—(A) *Intramuscular or subcutaneous.* Administer 0.01 to 0.02 mg/lb of body weight as a single injection. Usual dose is 12 to 20 mg.

(B) *Intra-articular and intrasynovial.* Administer 6 to 18 mg as a single injection, depending on the size of the joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 18 mg.

(ii) *Indications for use.* For the treatment of inflammation and related disorders.

(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.

[75 FR 10167, Mar. 5, 2010, as amended at 78 FR 21060, Apr. 9, 2013; 80 FR 34279, June 16, 2015]

§ 522.2582 Triflupromazine.

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

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Dogs.* Administer by intravenous injection at a dosage of 0.5 to 1 mg per pound of body weight daily, or by intramuscular injection at a dosage of 1 to 2 mg per pound of body weight daily.

(ii) *Cats.* Administer by intramuscular injection at a dosage of 2 to 4 mg per pound of body weight daily.

(iii) *Horses.* Administer by intravenous or intramuscular injection at a dosage of 10 to 15 mg per 100 pounds of body weight daily to a maximum dose of 100 mg.

(2) *Indications for use.* For use in dogs, cats, and horses to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.

(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 16197, Mar. 25, 2014]

§ 522.2610 Trimethoprim and sulfadiazine.

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

(1) 40 milligrams (mg) trimethoprim suspended in a solution containing 200 mg sulfadiazine; or

(2) 80 mg trimethoprim suspended in a solution containing 400 mg sulfadiazine (as the sodium salt).

(b) *Sponsors*. See Nos. 000061 and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 1 mL of the product described in paragraph (a)(1) of this section (40 mg trimethoprim and 200 mg sulfadiazine) per 20 pounds (9 kilograms) of body weight per day by subcutaneous injection.

(ii) *Indications for use*. For the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to *Streptococcus zooepidemicus*.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount*. 2 mL of the product described in paragraph (a)(2) of this section (160 mg trimethoprim and 800 mg sulfadiazine) per 100 pounds (45 kilograms) of body weight per day by intravenous injection as single, daily dose for 5 to 7 days. The daily dose may also be halved and given morning and evening.

(ii) *Indications for use*. For use where systemic antibacterial action against sensitive organisms is required during treatment of acute strangles, respiratory tract infections, acute urogenital infections, and wound infections and abscesses.

(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.

[71 FR 30803, May 31, 2006, as amended at 79 FR 16197, Mar. 25, 2014]

§ 522.2615 Tripelennamine.

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

(b) *Sponsors*. See Nos. 000859 and 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.741 of this chapter.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount*. Administer 0.5 mg per pound of body weight by intramuscular injection.

(ii) *Indications for use*. For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount*. Administer 0.5 mg per pound of body weight by intramuscular injection.

(ii) *Indications for use*. For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(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.

(3) *Cattle*—(i) *Amount*. Administer 0.5 mg per pound of body weight by intravenous or intramuscular injection.

(ii) *Indications for use*. For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(iii) *Limitations*. Treated cattle must not be slaughtered for food during treatment and for 4 days following the last treatment. Milk that has been taken during treatment and for 24 hours (two milkings) after the last treatment must not be used for food. A withdrawal period has not been established for this product 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.

[51 FR 44450, Dec. 10, 1986, as amended at 61 FR 29480, June 11, 1996; 62 FR 4164, Jan. 29, 1997; 78 FR 17597, Mar. 22, 2013; 79 FR 16198, Mar. 25, 2014]

§ 522.2630 Tulathromycin.

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

(1) 100 milligrams (mg) tulathromycin

(2) 25 mg tulathromycin

(b) *Sponsor*. See No. 054771 in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) Product described as in paragraph (a)(1) of this section for use as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii)(A), and (d)(2) of this section.

(2) Product described as in paragraph (a)(2) of this section for use as in paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.

§ 522.2640

21 CFR Ch. I (4–1–16 Edition)

(c) *Related tolerances.* See § 556.745 of this chapter.

(d) *Conditions of use—(1) Cattle—(i) Amount.* 2.5 mg per kilogram (/kg) body weight as a single subcutaneous injection in the neck.

(ii) *Indications for use—(A) Beef and non-lactating dairy cattle.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*. For the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.

(B) *Suckling calves, dairy calves, and veal calves.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.

(iii) *Limitations.* (A) Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) Calves intended for human consumption must not be slaughtered within 22 days from the last treatment. Not for use in ruminating cattle. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine—(i) Amount.* 2.5 mg/kg body weight as a single intramuscular injection in the neck.

(ii) *Indications for use.* For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *P. multocida*, *Bordetella bronchiseptica*, *Haemophilus parasuis*, and *Mycoplasma hyopneumoniae*; and for the control of SRD associated with *A. pleuropneumoniae*, *P. multocida*, and *M. hyopneumoniae* in groups of pigs where SRD has been diagnosed.

(iii) *Limitations.* Swine intended for human consumption must not be

slaughtered within 5 days from the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[70 FR 39918, July 12, 2005, as amended at 71 FR 57416, Sept. 29, 2006; 72 FR 54540, Sept. 26, 2007; 73 FR 6018, Feb. 1, 2008; 73 FR 58872, Oct. 8, 2008; 74 FR 53165, Oct. 16, 2009; 78 FR 63872, Oct. 25, 2013; 79 FR 74020, Dec. 15, 2014; 80 FR 13230, Mar. 13, 2015]

§ 522.2640 Tylosin.

(a) *Specifications.* Each milliliter of solution contains 50 or 200 milligrams of tylosin activity (as tylosin base).

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000986 for use in paragraphs (d)(1), (2), and (3) of this section.

(2) No. 000010 for use as in paragraphs (d)(1) and (2) of this section.

(c) *Related tolerances.* See § 556.740 of this chapter.

(d) *Conditions of use—(1) Beef cattle and nonlactating dairy cattle—(i) Amount.* 8 milligrams per pound of body weight once daily.

(ii) *Indications for use.* Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Arcanobacterium pyogenes*; foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *Arcanobacterium pyogenes*.

(iii) *Limitations.* Administer intramuscularly for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear. Use a 50-milligram-per-milliliter solution for calves weighing less than 200 pounds. Do not inject more than 10 milliliters per site. Do not administer within 21 days of slaughter. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Swine—(i) Amount.* 4 milligrams per pound of body weight twice daily.

(ii) *Indications for use.* Treatment of swine arthritis caused by *Mycoplasma*

hyosynoviae; swine pneumonia caused by *Pasteurella* spp.; swine erysipelas caused by *Erysipelothrix rhusiopathiae*; swine dysentery associated with *Treponema hyodysenteriae* when followed by appropriate medication in the drinking water and/or feed.

(iii) *Limitations.* Administer intramuscularly for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 5 milliliters per site. Do not administer within 14 days of slaughter. If tylosin medicated drinking water is used as followup treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.

(3) *Dogs and cats*—(i) *Amount.* Administer 3 to 5 milligrams per pound of body weight by intramuscular injection at 12- to 24-hour intervals. Use 50 milligram per milliliter solution only.

(ii) *Indications for use*—(a) *Dogs.* Treatment of upper respiratory infections such as bronchitis, tracheobronchitis, tracheitis, laryngitis, tonsillitis, and pneumonia caused by *Staphylococci* spp., hemolytic *Streptococci* spp., and *Pasteurella multocida*.

(b) *Cats.* Treatment of upper respiratory infections when caused by *Staphylococci* spp. and hemolytic *Streptococci* spp. and for feline pneumonitis when caused by tylosin susceptible organisms.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 48643, Oct. 2, 1981, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 49841, Dec. 5, 1985; 50 FR 50292, Dec. 10, 1985; 53 FR 40728, Oct. 18, 1988; 59 FR 14365, Mar. 28, 1994; 62 FR 35077, June 30, 1997; 68 FR 24879, May 9, 2003; 70 FR 16935, Apr. 4, 2005. Redesignated and amended at 74 FR 11644, Mar. 19, 2009; 79 FR 16198, Mar. 25, 2014]

§ 522.2662 Xylazine.

(a) *Specifications.* Each milliliter (mL) of solution contains xylazine hydrochloride equivalent to:

- (1) 20 milligrams (mg) xylazine.
- (2) 100 mg xylazine.
- (3) 300 mg xylazine.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 054628 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(2) Nos. 000010 and 061623 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(3) Nos. 000859 and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1); and product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

(4) No. 059399 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section; product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section; and product described in paragraph (a)(3) of this section as in paragraphs (d)(3)(i), (d)(3)(ii)(B), and (d)(3)(iii) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Dogs and cats*—(i) *Amount.* 0.5 mg/pound (lb) intravenously or 1.0 mg/lb subcutaneously.

(ii) *Indications for use.* To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(2) *Horses*—(i) *Amount.* 0.5 mg/lb intravenously or 1.0 mg/lb intramuscularly.

(ii) *Indications for use.* To produce sedation, as an analgesic, and as a preanesthetic to local or general anesthesia.

(iii) *Limitations.* Do not use in horses intended for human consumption.

(3) *Elk and deer*—(i) *Amount.* Administer intramuscularly, by hand syringe, or by syringe dart, in the heavy muscles of the croup or shoulder as follows:

(A) Elk (*Cervus canadensis*): 0.25 to 0.5 mg/lb.

(B) Mule deer (*Odocoileus hemionus*), sika deer (*Cervus nippon*), and white-tailed deer (*Odocoileus virginianus*): 1 to 2 mg/lb.

§ 522.2670

21 CFR Ch. I (4–1–16 Edition)

(C) Fallow deer (*Dama dama*): 2 to 4 mg/lb.

(ii) *Indications for use.* (A) To produce sedation, as an analgesic, and as a preanesthetic to local anesthesia.

(B) To produce sedation, accompanied by a shorter period of analgesia. May be used to calm and facilitate handling of fractious animals for diagnostic procedures, for minor surgical procedures, for therapeutic medication for sedation and relief of pain following injury or surgery, and as a preanesthetic to local anesthetic. At the recommended dosages, can be used in conjunction with local anesthetics, such as procaine or lidocaine.

(iii) *Limitations.* Do not use in domestic food-producing animals. Do not use in Cervidae less than 15 days before or during the hunting season.

[68 FR 26206, May 15, 2003, as amended at 75 FR 10167, Mar. 5, 2010, 78 FR 21060, Apr. 9, 2013; 79 FR 16198, Mar. 25, 2014; 79 FR 21127, Apr. 15, 2014; 79 FR 74020, Dec. 15, 2014; 80 FR 13230, Mar. 13, 2015]

§ 522.2670 Yohimbine.

(a) *Specifications.* Each milliliter (mL) of solution contains 2 or 5 milligrams (mg) of yohimbine (as hydrochloride).

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (c) of this section.

(1) No. 059399 for use of in 2 mg/mL solution as in paragraph (c)(1) of this section.

(2) No. 053923 for use of in 5 mg/mL solution as in paragraph (c)(2) of this section.

(c) *Conditions of use—(1) Dogs—(i) Amount.* Administer 0.05 mg per pound (0.11 mg per kilogram) of body weight by intravenous injection.

(ii) *Indications for use.* To reverse the effects of xylazine in dogs.

(iii) *Limitations.* Not for use in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Deer and elk—(i) Amount.* Administer 0.2 to 0.3 mg per kilogram of body weight by intravenous injection.

(ii) *Indications for use.* As an antagonist to xylazine sedation in free ranging or confined members of the family Cervidae (deer and elk).

(iii) *Limitations.* Do not use in domestic food-producing animals. Do not use for 30 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 74020, Dec. 15, 2014, as amended at 80 FR 13230, Mar. 13, 2015]

§ 522.2680 Zeranol.

(a) *Specifications.* Each pellet contains 12, 18, or 20 milligrams (mg) zeranol.

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

(c) *Related tolerances.* See § 556.760 of this chapter.

(d) *Conditions of use—(1) Beef cattle—(i) Amount.* 36 mg zeranol (one implant consisting of 3 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use—(A)* For increased rate of weight gain and improved feed conversion in weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers.

(B) For increased rate of weight gain in suckling calves.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in bulls intended for reproduction or in dairy animals. Do not use before 1 month of age or after weaning in heifers intended for reproduction. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Feedlot lambs—(i) Amount.* 12 mg zeranol (one implant consisting of 1 pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed conversion.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in breeding animals. Do not implant animals within 40 days of slaughter. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Steers fed in confinement for slaughter*—(i) *Amount*. 72 mg zeranol (one implant consisting of 6 pellets, each pellet containing 12 mg zeranol) per implant dose.

(ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations*. Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(4) *Pasture cattle (slaughter, stocker, feeder steers, and heifers)*—(i) *Amount*. 138 mg zeranol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg zeranol and a seventh pellet containing 18 mg zeranol) per implant dose.

(ii) *Indications for use*. For increased rate of weight gain.

(iii) *Limitations*. Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[59 FR 19639, Apr. 25, 1994; 60 FR 26360, May 17, 1995, as amended at 62 FR 61625, Nov. 19, 1997; 64 FR 46840, Aug. 27, 1999; 67 FR 6867, Feb. 14, 2002; 70 FR 6764, Feb. 9, 2005]

§ 522.2690 Zinc gluconate.

(a) *Specifications*. Each milliliter of solution contains 13.1 milligrams zinc as zinc gluconate neutralized to pH 7.0 with L-arginine.

(b) *Sponsor*. See No. 076175 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. The volume injected into each testicle is based on testicular width as determined by measuring each testicle at its widest point using a metric scale (millimeter) caliper.

(2) *Indications for use*. Intratesticular injection for chemical sterilization of 3- to 10-month-old male dogs.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 26995, May 19, 2003, as amended at 76 FR 79064, Dec. 21, 2011]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

Sec.

- 524.86 Amitraz.
 524.154 Bacitracin, neomycin, and polymyxin B ophthalmic ointment.
 524.155 Bacitracin, neomycin, polymyxin B, and hydrocortisone ophthalmic ointment.
 524.390 Chloramphenicol ophthalmic ointment.
 524.402 Chlorhexidine.
 524.450 Clotrimazole.
 524.463 Copper naphthenate.
 524.575 Cyclosporine ophthalmic ointment.
 524.590 Diclofenac.
 524.660 Dimethyl sulfoxide.
 524.770 Doramectin.
 524.775 Emodepside and praziquantel.
 524.802 Enrofloxacin and silver sulfadiazine otic emulsion.
 524.814 Eprinomectin.
 524.900 Famphur.
 524.920 Fenthion.
 524.916 Fentanyl.
 524.955 Florfenicol, terbinafine, and betamethasone acetate otic gel.
 524.957 Florfenicol, terbinafine, and mometasone otic solution.
 524.960 Flumethasone, neomycin, and polymyxin B ophthalmic solution.
 524.981 [Reserved]
 524.981a Fluocinolone cream.
 524.981b Fluocinolone solution.
 524.981c Fluocinolone and neomycin cream.
 524.981d Fluocinolone and dimethyl sulfoxide solution.
 524.981e Fluocinolone and dimethyl sulfoxide otic solution.
 524.1005 Furazolidone powder.
 524.1044 Gentamicin ophthalmic and topical dosage forms.
 524.1044a Gentamicin ophthalmic solution.
 524.1044b Gentamicin and betamethasone otic solution.
 524.1044c Gentamicin ophthalmic ointment.
 524.1044d Gentamicin and betamethasone ointment.
 524.1044e Gentamicin spray.
 524.1044f Gentamicin and betamethasone spray.
 524.1044g Gentamicin, betamethasone, and clotrimazole ointment.
 524.1044h Gentamicin, mometasone, and clotrimazole otic suspension.
 524.1044i Gentamicin and betamethasone ophthalmic solution.
 524.1132 Hydrocortisone, miconazole, and gentamicin otic suspension.
 524.1140 Imidacloprid and ivermectin.
 524.1146 Imidacloprid and moxidectin.
 524.1193 Ivermectin topical solution.
 524.1195 Ivermectin otic suspension.