(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; 83 FR 14587, Apr. 5, 2018; 84 FR 8973, Mar. 13, 2019; 84 FR 32992, July 11, 2019; 87 FR 76421, Dec. 14, 2022; 88 FR 16547, Mar. 20, 2023]

§ 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 (ppm) tylvalosin continuously in drinking water for 5 consecutive days.

(2) *Indications for use.* For control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine intended for slaughter and female swine intended for breeding in buildings experiencing an outbreak of PPE; and for control of swine respiratory disease (SRD) associated with *Bordetella bronchiseptica, Glaesserella (Haemophilus) parasuis, Pasteurella multocida, Streptococcus suis,* and *Mycoplasma hyopneumoniae* in groups of swine intended for slaughter and female swine intended for breeding in buildings experiencing an outbreak of SRD.

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

[77 FR 55415, Sept. 10, 2012, as amended at 83 FR 13635, Mar. 30, 2018; 86 FR 57997, Oct. 20, 2021; 89 FR 14410, Feb. 27, 2024]

§ 520.2654 Velagliflozin.

(a) *Specifications.* Each milliliter of solution contains 15 milligrams (mg) velagliflozin.

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

(c) *Conditions of use*—(1) *Amount.* Administer orally 0.45 mg per pound of body weight (1 mg per kilogram) velagliflozin once daily.

(2) *Indications for use.* To improve glycemic control in otherwise healthy cats with diabetes mellitus not previously treated with insulin.

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

[88 FR 84700, Dec. 6, 2023]

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

Sec.

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 058198 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; 86 FR 14819, Mar. 19, 2021]

§ 522.52 Alfaxalone.

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

(b) *Sponsor.* See No. 054771 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; 88 FR 84700, Dec. 6, 2023]

§ 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]

§ 522.88 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 infections 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 200, 250, or 400 milligrams (mg) ampicillin equivalents.

(b) *Sponsors.* See Nos. 000010 and 042791 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.

(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; 82 FR 21690, May 10, 2017; 85 FR 4208, Jan. 24, 2020]

§ 522.90c Ampicillin sodium.

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

(b) See Nos. 042791 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; 86 FR 57997, Oct. 20, 2021]

§ 522.144 Arsenamide.

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

(b) *Sponsor.* See No. 000010 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, as amended at 84 FR 39183, Aug. 9, 2019]

§ 522.147 Atipamezole.

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

(b) *Sponsors.* See Nos. 015914, 052483, 068504, and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 3,750 mcg/m^2 intramuscularly for the reversal of intravenous dexmedetomidine hydrochloride or medetomidine hydrochloride and 5,000 mcg/m^2 intramuscularly for the reversal of intramuscular dexmedetomidine hydrochloride or medetomidine hydrochloride.

(2) *Indications for use.* For the reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride and 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; 84 FR 8973, Mar. 13, 2019; 88 FR 84700, Dec. 6, 2023; 89 FR 42357, May 15, 2024]

§ 522.150 Azaperone.

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

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

(c) *Related tolerances.* See § 556.68 of this chapter.

(d) *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; 81 FR 48702, July 26, 2016; 84 FR 32992, July 11, 2019]

§ 522.158 Bedinvetmab.

(a) *Specifications.* Each single-use vial contains 5, 10, 15, 20, or 30 milligrams (mg) bedinvetmab in an extractable volume of 1 milliliter.

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

(c) *Conditions of use*—(1) *Amount.* Administer 0.23 mg/pound (0.5 mg/kilogram) body weight monthly by subcutaneous injection.

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

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

[88 FR 55564, Aug. 16, 2023]

§ 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 carpel 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).

(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]

§ 522.224 Bupivacaine.

(a) *Specifications*. Each milliliter (mL) of liposomal suspension contains 13.3 milligrams (mg) bupivacaine.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer 5.3 mg/kg (0.4 mL/kg) by infiltration injection into the tissue layers at the time of incisional closure.

(ii) *Indications for use*. For single-dose infiltration into the surgical site to provide local postoperative analgesia for cranial cruciate ligament surgery.

(2) *Cats*—(i) *Amount*. Administer 5.3 mg/kg per forelimb (0.4 mL/kg per forelimb), for a total dose of 10.6 mg/kg/cat, as a 4-point nerve block prior to onychectomy.

(ii) *Indications for use*. For use as a peripheral nerve block to provide regional postoperative analgesia following onychectomy.

[81 FR 67151, Sept. 30, 2016, as amended at 84 FR 8973, Mar. 13, 2019; 85 FR 4208, Jan. 24, 2020]

§ 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.

(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 Butamisole.

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

(b) *Sponsors*. See Nos. 054771 and 058198 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, as amended at 86 FR 14819, Mar. 19, 2021]

§ 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. 043264 for use of the product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(3) Nos. 000061, 017033, 043264, and 059399 for use of the product described in paragraph (a)(3) of this section 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; 87 FR 17945, Mar. 29, 2022; 88 FR 16547, Mar. 20, 2023]

§ 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]

§ 522.304 Carprofen.

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

(b) *Sponsors.* See Nos. 016729, 017033, 054771, 055529, 069043, and 086101 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; 82 FR 43484, Sept. 18, 2017; 88 FR 16547, Mar. 20, 2023; 89 FR 14410, Feb. 27, 2024; 89 FR 85426, Oct. 28, 2024]

§ 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 (lb) (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 preslaughter 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, nonlactating 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. *zooepidemicus*.

(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 suspension contains:

(1) Ceftiofur hydrochloride equivalent to 50 milligrams (mg) of ceftiofur equivalents in the inactive vehicles phospholipan 90H, sorbitan monooleate, and cottonseed oil;

(2) Ceftiofur hydrochloride equivalent to 50 mg ceftiofur equivalents in the inactive vehicles polyoxyethylene sorbitan monooleate (polysorbate 80) in a caprylic/capric triglyceride suspension; or

(3) Ceftiofur hydrochloride equivalent to 50 mg ceftiofur equivalents in the inactive vehicles aluminum monostearate, sorbitan monooleate, and medium chain triglycerides.

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

(1) No. 054771 for products described in paragraphs (a)(1) and (2) of this section; and

(2) No. 055529 for the product described in paragraph (a)(3) of this section.

(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 unapproved 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.* For products described in paragraphs (a)(1) and (3) of this section: Treated swine must not be slaughtered for 4 days following the last treatment. For products described in paragraph (a)(2) of this section: Treated swine must not be slaughtered for 6 days following the last treatment when injection site volumes are greater than 5 mL up to the maximum injection site volume of 15 mL. Treated swine must not be slaughtered for 4 days when injection site volumes are less than or equal to 5 mL.

(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.* (A) For products described in paragraphs (a)(2) and (3) of this section: Treated cattle must not be slaughtered for 3 days following the last treatment. For products described in paragraph (a)(2) of this section: Treated cattle must not be slaughtered for 4 days following the last treatment.

(B) 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; 84 FR 39183, Aug. 9, 2019; 84 FR 53311, Oct. 7, 2019]

§ 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. 017033 and 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, 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; 82 FR 12169, Mar. 1, 2017; 89 FR 95103, Dec. 2, 2024]

§ 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 tonsillitis 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) No. 000061 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(ii) through (viii) and (c)(2) of this section.

(3) No. 068504 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(ii) through (vii), (c)(1)(ix), 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 4½ months of gestation.

(ii) Administer 500 μg by intramuscular injection for unobserved or non-detected estrus in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(iii) Administer 500 μg by intramuscular injection for treatment of pyometra or chronic endometritis in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(iv) Administer 500 μg by intramuscular injection for treatment of mummified fetus in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(v) Administer 500 μg by intramuscular injection for treatment of luteal cysts in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(vi) Administer 500 μg by intramuscular injection for abortion of beef cows, lactating dairy cows, and replacement beef and dairy heifers from 1 week after mating until 5 months of gestation. Not for use in heifers placed in feedlots.

(vii) Administer 500 μg by intramuscular injection as a single injection regimen or double injection regimen with a second injection 11 days after the first injection, for estrus synchronization in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(viii) For use with gonadorelin acetate 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. Gonadorelin acetate as provided in § 522.1077(a)(1) of this chapter.

(ix) For use with gonadorelin to synchronize estrous cycles to allow for FTAI in lactating dairy cows: administer to each cow by intramuscular injection, followed 6 to 8 days later by 500 μg cloprostenol by intramuscular injection, followed 30 to 72 hours later by gonadorelin by intramuscular injection. Gonadorelin as provided in § 522.1077(a)(1) through (3) of this chapter.

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

[79 FR 16185, Mar. 25, 2014, as amended at 85 FR 4208, Jan. 24, 2020; 88 FR 84700, Dec. 6, 2023]

§ 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) *Related tolerances.* See § 556.167 of this chapter.

(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; 84 FR 32992, July 11, 2019]

§ 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. 061133 for use as in paragraphs (c)(1) and (2) of this section.

(2) No. 043264 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, as amended at 84 FR 8973, Mar. 13, 2019; 85 FR 45308, July 28, 2020]

§ 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. 043264 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 millimeters (mm) 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 mm 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; 87 FR 17945, Mar. 29, 2022; 87 FR 58962, Sept. 29, 2022]

§ 522.535 Desoxycorticosterone.

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

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

(1) No. 043264 for use as in paragraphs (c)(1)(i), (c)(2)(i), and (c)(3) of this section.

(2) No. 058198 for use as in paragraphs (c)(1)(ii), (c)(2)(ii), and (c)(3) of this section.

(c) *Conditions of use*—(1) *Amount.* (i) Administer an initial dose of 2.2 mg/kilogram (1 mg/lb) of body weight by subcutaneous injection. Subsequent dosages should be individualized according to label instructions based on patient response to therapy.

(ii) 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.

(2) *Indications for use*—(i) For use as replacement therapy for mineralocorticoid deficiency in dogs with primary hypoadrenocorticism (Addison's Disease).

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

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

[81 FR 22524, Apr. 18, 2016]

§ 522.536 Detomidine.

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

(b) *Sponsor.* See Nos. 015914, 052483, and 059399 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 intraveneous (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, as amended at 86 FR 13184, Mar. 8, 2021; 88 FR 27699, May 3, 2023]

§ 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, 016592, and 061133 for use as in paragraph (a)(3) of this section.

(ii) No. 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 No. 061133 in § 510.600(c) of this chapter.
(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 No. 061133 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. 016592 and 051031 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.govinfo.gov.*

§ 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) Nos. 017033, 068504, 069043, and 086117 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 µg/m^2 of body surface area by intramuscular injection.

(B) For use as a preanesthetic to general anesthesia, administer 125 µg/m^2 of body surface area or 375 µg/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 µg/killogram 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; 86 FR 57997, Oct. 20, 2021; 87 FR 10969, Feb. 28, 2022; 88 FR 27699, May 3, 2023; 88 FR 84701, Dec. 6, 2023]

§ 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 angiocardiography (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; angiocardiography, 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) *Sponsor.* See No. 054771 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; 85 FR 18119, Apr. 1, 2020]

§ 522.690 Dinoprost.

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to:

(1) 5 milligrams (mg) dinoprost; or

(2) 12.5 mg dinoprost.

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

(1) Nos. 054771 and 061133 for use of product described in paragraph (a)(1) as in paragraph (d) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) as in paragraph (d)(1) 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 products described in paragraph (a) of this section as follows:

(i) *Amount.* 25 mg as an intramuscular injection of the 5 mg/mL product or as an intramuscular or subcutaneous injection of the 12.5 mg/mL product.

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

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

(ii) *Indications for use.* (A) For controlling the timing of estrus in estrous cycling mares.

(B) For difficult-to-breed mares (clinically anestrous mares that have a corpus luteum).

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

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

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

(ii) *Indications for use.* For parturition induction in swine.

[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; 81 FR 36789, June 8, 2016; 84 FR 8973, Mar. 13, 2019; 87 FR 17945, Mar. 29, 2022]

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

[79 FR 16187, Mar. 25, 2014]

§ 522.728 Dipyrone.

(a) *Specifications.* Each milliliter of solution contains 500 milligrams (mg) dipyrone.

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

(c) *Conditions of use in horses*—(1) *Amount.* Administer 30 mg per kilogram of body weight (13.6 mg per pound) by intravenous injection, once or twice daily at a 12-hour interval for up to 3 days.

(2) *Indications for use.* For control of pyrexia in horses.

(3) *Limitations.* Do not use in horses intended for human consumption. Do not use in any food-producing animals, including lactating dairy animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[85 FR 18119, Apr. 1, 2020, as amended at 88 FR 14898, Mar. 10, 2023]

§ 522.770 Doramectin.

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

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

(c) *Related tolerances.* See § 556.222 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.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle for human consumption within 35 days of treatment. Not for 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.

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

[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; 84 FR 32992, July 11, 2019; 88 FR 55564, Aug. 16, 2023]

§ 522.772 Doramectin and levamisole.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams (mg) of doramectin and 150 mg levamisole hydrochloride.

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

(c) *Related tolerances.* See §§ 556.222 and 556.350 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Inject subcutaneously in the neck as a single dose at a dosage of 0.2 mg doramectin (0.91 mg/lb) and 6 mg of levamisole hydrochloride per kg (2.72 mg/lb) of body weight.

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms (adults and fourth stage larvae): *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T.*

colubriformis, *T. longispicularis* (adults only), *Oncophora*, *Cooperia pectinata* (adults only), *C. punctata*, *C. surnabada*, *Bunostomum phlebotomum* (adults only), *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum*, *Trichuris* spp. (adults only) and *Nematodirus helvetianus* (adults only); lungworms (adults and fourth stage larvae): *Dictyocaulus viviparus;* eyeworms (adults): *Thelazia* spp.; grubs (parasitic stages): *Hypoderma bovis* and *H. lineatum;* sucking lice: *Haematopinus eurysternus*, *Linognathus vituli*, and *Solenopotes capillatus;* mange mites: *Psoroptes bovis* and *Sarcoptes scabiei* in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age. Not for use in beef bulls intended for breeding over 1 year of age, dairy calves, and veal calves.

(iii) *Limitations.* Cattle must not be slaughtered for human consumption within 15 days following last treatment with this drug product. Not 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 or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[88 FR 14898, Mar. 10, 2023; 89 FR 85426, Oct. 28, 2024]

§ 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) Nos. 016729, 017033, 055529, 058198, 069043, and 086101 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section; and

(2) Nos. 051311, 055529, 058005, 058198, 061133, 069043, and 086101 for use of product described in paragraph (a)(2) as in paragraphs (e)(2) and (3) 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 30 days.

(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 nonlactating 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 7.5 mg/kg of body weight once, by intramuscular or subcutaneous injection behind the ear, 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 7.5 mg/kg of body weight once, by intramuscular or subcutaneous injection behind the ear, 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; 84 FR 8973, Mar. 13, 2019; 84 FR 53311, Oct. 7, 2019; 86 FR 14819, Mar. 19, 2021; 86 FR 61685, Nov. 8, 2021; 87 FR 10969, Feb. 28, 2022; 87 FR 58962, Sept. 29, 2022; 89 FR 14410, Feb. 27, 2024]

§ 522.814 Eprinomectin.

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

(b) *Sponsor.* See No. 000010 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; 84 FR 39184, Aug. 9, 2019]

§ 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. 061133 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[72 FR 69142, Dec. 7, 2007, as amended at 79 FR 16187, Mar. 25, 2014; 84 FR 8973, Mar. 13, 2019; 88 FR 27699, May 3, 2023]

§ 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. 058198 in § 510.600(c) of this chapter.

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

(d) *Conditions of use*—(1) *Beef steer calves 2 months of age and older*—(i) *Amount and indications for use.* (A) An extended-release implant containing 25.7 mg estradiol for increased rate of weight gain for up to 200 days.

(B) An extended-release implant containing 43.9 mg estradiol for increased rate of weight gain for up to 400 days.

(ii) *Limitations.* For subcutaneous ear implantation only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in beef steer calves 2 months of age and older. Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

(2) *Growing beef steers and heifers on pasture (stocker, feeder, and slaughter)*—(i) *Amount and indications for use.* (A) An extended-release implant containing 25.7 mg estradiol for increased rate of weight gain for up to 200 days.

(B) An extended-release implant containing 43.9 mg estradiol for increased rate of weight gain for up to 400 days.

(ii) *Limitations.* For subcutaneous ear implantation only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers on pasture (stocker, feeder, and slaughter). Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

(3) *Growing beef steers and heifers fed in confinement for slaughter*—(i) *Amount and indications for use.* (A) An extended-release implant containing 25.7 mg estradiol for increased rate of weight gain and improved feed efficiency for up to 200 days.

(B) An extended-release implant containing 43.9 mg estradiol for increased rate of weight gain and improved feed efficiency for up to 400 days.

(ii) *Limitations.* For subcutaneous ear implantation only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter. Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for

subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

[69 FR 67818, Nov. 22, 2004, as amended at 77 FR 31723, May 30, 2012; 81 FR 48702, July 26, 2016; 87 FR 10969, Feb. 28, 2022; 88 FR 14898, Mar. 10, 2023; 89 FR 42357, May 15, 2024]

§ 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 000010 in § 510.600(c) of this chapter.

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

(d) *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; 84 FR 39184, Aug. 9, 2019; 84 FR 32992, July 11, 2019]

§ 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]

§ 522.883 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]

§ 522.914 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: 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 bronchiospasms. 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. 000010 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, as amended at 84 FR 39184, Aug. 9, 2019]

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

(3) Nos. 054771, 058005, and 069043 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii) of this section.

(4) 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)(*1*) *Amount.* 20 mg/kg of body weight as an intramuscular injection. A second dose should be administered 48 hours later. Alternatively, 40 mg/kg of body weight as a single subcutaneous injection may be used.

(*2*) *Indications for use.* For treatment of BRD associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*. 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 haemolytica, Pasteurella multocida, and Histophilus somni.*

(C) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. Nos. 000061, 054771, 058005, and 069043: Animals intended for human consumption must not be slaughtered within 38 days of subcutaneous treatment. No. 055529: 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) *Swine.* (i) 300 mg/mL florfenicol in the inactive vehicles n-methyl-2-pyrrolidone, propylene glycol, and polyethylene glycol:

(A) *Amount.* 15 mg/kg of body weight as an intramuscular injection. A second dose should be administered 48 hours later.

(B) *Indications for use.* For the treatment of swine respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella* Choleraesuis, *Streptococcus suis*, *Bordetella bronchiseptica*, and *Glaesserella (Haemophilus) parasuis* in swine except for nursing piglets and swine of reproductive age intended for breeding.

(C) *Limitations.* Swine intended for human consumption must not be slaughtered within 11 days of the last intramuscular treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) [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; 86 FR 14819, Mar. 19, 2021; 87 FR 10969, Feb. 28, 2022; 87 FR 17945, Mar. 29, 2022; 87 FR 76421, Dec. 14, 2022; 89 FR 14410, Feb. 27, 2024; 89 FR 85426, Oct. 28, 2024]

§ 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 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.

[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, carpitis, 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.

(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) *Sponsors.* See Nos. 054771 and 061133 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, carpitis, osselets, and myositis; and allergic states, e.g., hives, urticaria, and insect bites.

(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) *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, as amended at 88 FR 55564, Aug. 16, 2023]

§ 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 061133 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. 016592, 058198, and 069043 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.* Approved only for intravenous administration in cattle. Intramuscular administration has resulted in violative residues in the edible tissues of cattle sent to slaughter. 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) [Reserved]

(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; 82 FR 43484, Sept. 18, 2017; 86 FR 57997, Oct. 20, 2021; 89 FR 85426, Oct. 28, 2024]

§ 522.995 Fluprostenol.

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

(b) *Sponsor.* See No. 058198 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, as amended at 86 FR 14820, Mar. 19, 2021]

§ 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.

(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*—(i) *Single pack.* 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 constituted, each milliliter of solution contains 35 IU FSH.

(ii) *Dual pack.* Each package contains 2 vials. Each vial contains 700 international units (IU) porcine-pituitary-derived FSH equivalent to 400 milligrams NIH–FSH–P1, as a dry powder. Constitute with 20 mL bacteriostatic sodium chloride injection, using strict aseptic technique. When constituted, each milliliter of 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; 82 FR 21690, May 10, 2017; 82 FR 43484, Sept. 18, 2017]

§ 522.1008 Frunevetmab.

(a) *Specifications.* Each milliliter (mL) of solution contains 7 milligrams (mg) frunevetmab.

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

(c) *Conditions of use*—(1) *Cats*—(i) *Amount.* Administer once a month by subcutaneous injection the full contents of one or two 1-mL vials to achieve a minimum dosage of 0.45 mg/lb (1 mg/kg) body weight.

(ii) *Indications for use.* For the control of pain associated with osteoarthritis in cats.

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

(2) [Reserved]

[87 FR 58962, Sept. 29, 2022]

§ 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. 061133 as described in paragraph (a)(2) of this section for use as in paragraph (d)(2)(ii) of this section.

(3) No. 058198 as described in paragraph (a)(2) of this section 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 (/lb) 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; 84 FR 8973, Mar. 13, 2019; 86 FR 14820, Mar. 19, 2021]

§ 522.1014 Gamithromycin.

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

(b) *Sponsor.* See No. 000010 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; 84 FR 39184, Aug. 9, 2019]

§ 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. 069043 for use of 50 mg/mL solution in dogs as in paragraph (d)(5) of this section.

(4) Nos. 016592 and 061133 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.* Administer subcutaneously in the neck 1 mg of gentamicin per 0.2 mL dose, using the 50- or 100-mg/mL product diluted with sterile saline to a concentration of 5 mg/mL.

(ii) *Indications for use.* As an aid in the prevention of early mortality in 1- to 3-day old turkey poults due to *Arizona paracolon* infections susceptible to gentamicin.

(iii) *Limitations.* Injected poults must not be slaughtered for food for at least 9 weeks after treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Chickens*—(i) *Amount.* Administer subcutaneously in the neck 0.2 mg of gentamicin per 0.2 mL dose, using the 50- or 100-mg/mL product diluted with sterile saline to a concentration of 1.0 mg/mL.

(ii) *Indications for use.* For prevention of early mortality in day-old chickens caused by *Escherichia coli*, *Salmonella*

typhimurium, and *Pseudomonas aeruginosa* susceptible to gentamicin.

(iii) *Limitations.* Injected chicks must not be slaughtered for food for at least 5 weeks after treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Swine*—(i) *Amount.* Administer 5 mg of gentamicin as a single intramuscular dose using the 5 mg/mL solution.

(ii) *Indications for use.* For treatment of porcine colibacillosis in piglets up to 3 days old caused by strains of *Escherichia 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(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; 81 FR 22524, Apr. 18, 2016; 83 FR 48946, Sept. 28, 2018; 84 FR 8973, Mar. 13, 2019; 88 FR 16547, Mar. 20, 2023]

§ 522.1055 Gleptoferron.

(a) *Specifications.* Each milliliter (mL) contains the equivalent of 200 milligrams of elemental iron as gleptoferron, a complex of ferric hydroxide and dextran glucoheptonic acid.

(b) *Sponsors.* See No. 013744 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Indications for use and amounts.* (i) Prevention of anemia due to iron deficiency: Administer 1 mL (200 mg iron) per pig by intramuscular injection on or before 3 days of age.

(ii) Treatment of anemia due to iron deficiency: Administer 1 mL (200 mg iron) per pig by intramuscular injection as soon as signs of deficiency appear.

(2) [Reserved]

[81 FR 59134, Aug. 29, 2016, as amended at 82 FR 11508, Feb. 24, 2017; 82 FR 21690, May 10, 2017]

§ 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 (equivalent to 43 μg gonadorelin); 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 (e)(1)(i) and (iii) of this section.

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

(3) Nos. 000010 and 061133 for use of the 50-μg/mL product described in paragraph (a)(3) of this section as in paragraphs (e)(1)(i) and (v) of this section.

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

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

(d) *Special considerations.* (1) Concurrent luteolytic drug use is approved as follows:

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

(ii) Cloprostenol injection for use as in paragraph (e)(1)(iv) of this section as provided by No. 068504 in § 510.600(c) of this chapter.

(iii) Cloprostenol injection for use as in paragraph (e)(1)(v) of this section as provided by Nos. 000010 in § 510.600(c) of this chapter.

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

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

(e) *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 (No. 000061), or 100 μg gonadorelin diacetate tetrahydrate (Nos. 000010 and 061133), or 100 μg gonadorelin (as gonadorelin acetate; No. 068504) by intramuscular or intravenous injection.

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

(iii) For use with cloprostenol sodium to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in beef cows and 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.

(iv) For use with cloprostenol sodium 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.

(v) For use with cloprostenol sodium 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 diacetate tetrahydrate 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 diacetate tetrahydrate by intramuscular injection.

(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) [Reserved]

[83 FR 64740, Dec. 18, 2018, as amended at 84 FR 8973, Mar. 13, 2019; 84 FR 39184, Aug. 9, 2019; 84 FR 32992, July 11, 2019; 86 FR 13184, Mar. 8, 2021; 86 FR 14820, Mar. 19, 2021; 87 FR 17946, Mar. 29, 2022; 88 FR 27699, May 3, 2023]

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

(d) *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 (noncycling) 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; 84 FR 32992, July 11, 2019]

§ 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) No. 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; 83 FR 13635, Mar. 30, 2018]

§ 522.1083 Gonadotropin releasing factor analog-diphtheria toxoid conjugate.

(a) *Specifications.* Each milliliter (mL) 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.* Each intact male pig or gilt should receive two 2-mL (0.4 mg) doses by subcutaneous injection. Administer the first dose no earlier than 9 weeks of age. Administer the second dose at least 4 weeks after the first dose.

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

(ii) *Gilts intended for slaughter:* For the temporary suppression of estrus.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. For reduction of boar taint, intact male 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; 85 FR 45308, July 28, 2020]

§ 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. 037990 and 058198 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16189, Mar. 25, 2014, as amended at 86 FR 14820, Mar. 19, 2021]

§ 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 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.

(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 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.

(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. 000010 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; 84 FR 39184, Aug. 9, 2019]

§ 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 or subcutaneous 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, as amended at 87 FR 10969, Feb. 28, 2022]

§ 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) 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.

(2) No. 000010 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(i)(B), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(B), (c)(2)(ii), and (c)(2)(iii) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*—(A) *Porcine zinc insulin zinc.* 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.

(B) *Protamine zinc recombinant human insulin.* Administer a starting dose of 0.2 to 0.5 IU/pound of body weight (0.5 to 1.0 IU/kg) once daily. When transitioning from another insulin product, this form of insulin should be started once daily, regardless of the frequency of prior insulin use. The dose should be given concurrently with or right after a meal. Reevaluate the dog at appropriate intervals and adjust the dose based on both clinical signs and laboratory test results 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; 84 FR 39184, Aug. 9, 2019]

§ 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 young piglets by sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 016592 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 013744 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) No. 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. 016592 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. 016592, 042552, and 058005 for use product described in paragraph (a)(2) of this section as follows:

(i) For prevention of 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 anemia due to iron deficiency, intramuscularly inject

200 mg of elemental iron at the first sign of anemia.

[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; 81 FR 22524, Apr. 18, 2016; 81 FR 59134, Aug. 29, 2016; 82 FR 11508, Feb. 24, 2017; 83 FR 48946, Sept. 28, 2018; 86 FR 14820, Mar. 19, 2021; 89 FR 85427, Oct. 28, 2024]

§ 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) [Reserved]

(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) Nos. 000010, 016592, 055529, 058005, and 061133 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2) through (e)(5) of this section; and

(2) No. 000010 for use of the product described in paragraph (a)(3) of this section as in paragraphs (e)(3) and (e)(6) of this section.

(c) *Related tolerances.* See § 556.344 of this chapter.

(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) [Reserved]

(2) *Cattle*—(i) *Amount.* 200 micrograms per kilogram (µg/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 µg/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, *Hyostrongylus 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 µg/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 µg/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 µg/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; 81 FR 59134, Aug. 29, 2016; 84 FR 8974, Mar. 13, 2019; 84 FR 32992, July 11, 2019; 84 FR 39184, Aug. 9, 2019; 88 FR 27699, May 3, 2023]

§ 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. 000010, 055529, 058005, 061133, and 061651 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*); cattle grubs (parasitic stages) (*Hypoderma bovis*, *H. lineatum*); sucking lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mange mites (cattle scab) (*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.* Do not treat cattle within 21 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 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; 84 FR 39184, Aug. 9, 2019; 86 FR 14820, Mar. 19, 2021; 86 FR 57997, Oct. 20, 2021]

EDITORIAL NOTE: At 81 FR 22524, Apr. 18, 2016, § 522.1193 was amended; however, the amendment could not be incorporated due to inaccurate amendatory instruction.

§ 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. 00010, 017033, 054771, 058198, 059399, and 069043 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; 83 FR 48946, Sept. 28, 2018; 86 FR 14820, Mar. 19, 2021; 88 FR 27699, May 3, 2023; 88 FR 55564, Aug. 16, 2023]

§ 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.

(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) ketoprofen.

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

(1) No. 054771 for use as in paragraphs (d)(1) and (d)(2) of this section.

(2) No. 061133 for use as in paragraph (d)(1) of this section.

(c) *Related tolerances.* See § 556.345 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* Administer by intravenous injection 1.0 mg per pound (/lb) of body weight once daily for up to 5 days.

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

(2) *Cattle*—(i) *Amount.* Administer by subcutaneous injection 3 mg per kilogram (1.36 mg/lb) of body weight once daily for up to 3 days.

(ii) *Indications for use.* For the control of pyrexia associated with bovine respiratory disease (BRD) in beef heifers, beef steers, beef calves 2 months of age

and older, beef bulls, replacement dairy heifers, and dairy bulls.

(iii) *Limitations.* Not for use in reproducing animals over 1 year of age. Cattle must not be slaughtered for human consumption within 48 hours following last treatment with this drug product. Not for use in female dairy cattle 1 year 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 or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[86 FR 61685, Nov. 8, 2021]

§ 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 016592 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) *Related tolerances.* See § 556.350 of this chapter.

(d) *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*).

(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 retreatment 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; 83 FR 48946, Sept. 28, 2018; 84 FR 32992, July 11, 2019]

§ 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. 016592 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. 061133 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. For No 054771: 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 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; 81 FR 59134, Aug. 29, 2016; 84 FR 8974, Mar. 13, 2019; 88 FR 16548, Mar. 20, 2023]

§ 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 Luprostiol.

(a) *Specifications.* Each milliliter of solution contains 7.5 milligrams (mg) luprostiol.

(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 pregnancies. Luprostiol is readily absorbed through the skin and can cause abortion and/or bronchiospasms. 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 or intravenous 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 or intravenous 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; 81 FR 22524, Apr. 18, 2016]

§ 522.1335 Medetomidine.

(a) *Specifications.* Each milliliter of solution contains 1.0 milligrams of medetomidine hydrochloride.

(b) *Sponsor.* See Nos. 015914 and 052483 in § 510.600(c) of this chapter.

(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; 82 FR 58556, Dec. 13, 2017]

§ 522.1338 Medetomidine and vatinoxan.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligrams (mg) medetomidine hydrochloride and 10 mg vatinoxan hydrochloride.

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

(c) *Conditions of use*—(1) *Amount.* Administer by intramuscular injection a dose based on body surface area (BSA). Calculate the dose using 1 mg medetomidine per square meter ($/m^2$) BSA or use the dosing table provided in labeling.

(2) *Indications for use.* For use as a sedative and analgesic in dogs to facilitate clinical examination, clinical procedures, and minor surgical procedures.

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

[87 FR 58962, Sept. 29, 2022, as amended at 87 FR 76421, Dec. 14, 2022]

§ 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 Nos. 000010 and 086073 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer only by deep intramuscular injection in the lumbar muscles (L_3–L_5).

(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 L_5) to mature 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; 82 FR 21690, May 10, 2017; 84 FR 39184, Aug. 9, 2019]

§ 522.1367 Meloxicam.

(a) *Specifications.* Each milliliter of solution contains 5.0 milligrams (mg) meloxicam.

(b) *Sponsors.* See Nos. 000010, 016729, 017033, 055529, and 086101 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 § 520.1367(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; 85 FR 18119, Apr. 1, 2020; 88 FR 14898, Mar. 10, 2023]

§ 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 15 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; 88 FR 14898, Mar. 10, 2023]

§ 522.1380 Methocarbamol.

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

(b) *Sponsor.* See No. 051031 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, as amended at 82 FR 11508, Feb. 24, 2017]

§ 522.1410 Methylprednisolone.

(a) *Specifications.* Each milliliter of suspension contains 20 or 40 milligrams (mg) of methylprednisolone acetate.

(b) *Sponsors.* See Nos. 054771 and 069043 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; 83 FR 48946, Sept. 28, 2018]

§ 522.1450 Moxidectin solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 10 milligrams (mg) moxidectin.

(b) *Sponsors.* See Nos. 055529, 058198, and 061133 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 cattle—(1) Amount.* Administer by subcutaneous injection 1 mL for each 110 pounds (lb) (50 kilograms (kg)) body weight to provide 0.2 mg moxidectin/2.2 lb (0.2 mg/kg) body weight.

(2) *Indications for use.* Beef and nonlactating dairy cattle: For treatment and control of Gastrointestinal roundworms: *Ostertagia ostertagi* (adults, fourth-stage larvae, and inhibited larvae), *Haemonchus placei* (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); Cattle grubs: *Hypoderma bovis* and *Hypoderma lineatum;* Mites: *Psoroptes ovis* (*Psoroptes communis* var. *bovis*); Lice: *Linognathus vituli* and *Solenopotes capillatus.* For protection from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 42 days after treatment, with *Haemonchus placei* for 35 days after treatment, and with *Ostertagia ostertagi* and *Trichostrongylus axei* for 14 days after treatment.

(3) *Limitations.* Cattle must not be slaughtered for human consumption within 21 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 for preruminating 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; 82 FR 21690, May 10, 2017; 86 FR 14820, Mar. 19, 2021; 88 FR 27699, May 3, 2023; 89 FR 95103, Dec. 2, 2024]

§ 522.1451 Moxidectin microspheres for injection.

(a) *Specifications.* The drug product consists of two separate vials. One vial contains 10 percent moxidectin microspheres and the second vial contains a vehicle for constitution of the moxidectin microspheres.

(1) Each milliliter (mL) of constituted suspension contains 3.4 milligrams (mg) moxidectin.

(2) Each mL of constituted suspension contains 10 mg moxidectin.

(b) *Sponsor.* See No. 54771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* (i) Using the suspension described in paragraph (a)(1) of this section, administer 0.05 mL of the constituted suspension per kilogram (kg) of body weight (0.023 mL per pound (lb)) as a single subcutaneous injection to provide 0.17 mg/kg body weight (0.0773 mg/lb).

(ii) Using the suspension described in paragraph (a)(2) of this section, administer 0.05 mL of the constituted suspension/kg of body weight (0.023 mL/lb) as a single subcutaneous injection to provide 0.5 mg/kg body weight (0.23 mg/lb).

(2) *Indications for use*—(i) *Suspension described in paragraph (a)(1) of this section.* For prevention of heartworm disease caused by *Dirofilaria immitis* in

dogs 6 months of age and older; and for treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

(ii) *Suspension described in paragraph (a)(2) of this section.* For prevention of heartworm disease caused by *Dirofilaria immitis* for 12 months in dogs 12 months of age and older; and for treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

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

[85 FR 4208, Jan. 24, 2020]

§ 522.1452 Nalorphine.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams of nalorphine hydrochloride.

(b) *Sponsor.* See No. 000010 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; 84 FR 39184, Aug. 9, 2019]

§ 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 (/) 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]

§ 522.1660 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, 016592, 054771, 055529, 061133, and 069254 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.500 of this chapter; and for No. 061133, see also § 500.1410 of this chapter.

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

(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.

(ii) *Limitations.* Administer intramuscularly. Do not inject more than 5 mL per site in adult swine. Discontinue treatment at least 28 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[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.govinfo.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.*

(ii) *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. For No. 055529: Federal law restricts this

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

(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.

(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. For No. 055529: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[68 FR 54805, Sept. 19, 2003. Redesignated and amended at 69 FR 31879, June 8, 2004; 73 FR 14926, Mar. 20, 2008; 88 FR 16548, Mar. 20, 2023]

§ 522.1662 Oxytetracycline.

(a) For related tolerances see § 556.500 of this chapter.

(b)(1) *Specifications.* Each milliliter (mL) of solution contains 50 milligrams (mg) oxytetracycline hydrochloride.

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

(3) *Conditions of use*—(i) *Amount.* Administer 3 to 5 mg per pound of body weight (mg/lb) per day by intramuscular injection. Leptospirosis, severe foot-rot, and severe forms of the indicated diseases should be treated with 5 mg/lb per day. Treatment should be continued for 24 to 48 hours following remission of clinical signs of disease, not to exceed 4 consecutive days. Not more than 10 mL should be injected per injection site in adult cattle, and only 2 mL per injection site in calves weighing 100 pounds or less.

(ii) *Indications for use.* Beef cattle, beef calves, nonlactating dairy cattle, and dairy calves; for treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex (*Pasteurella* spp., *Haemophilus* spp., *Klebsiella* spp.), bacterial enteritis (scours) (*Escherichia coli*), foot-rot (*Spherophorus necrophorus*), diphtheria (*Spherophorus necrophorus*), wooden tongue (*Actinobacillus lignieresii*), leptospirosis (*Leptospira pomona*), and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations.* Discontinue treatment at least 20 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter (mL) of solution contains 50 or 100 milligrams (mg) oxytetracycline hydrochloride.

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

(3) *Conditions of use*—(i) *Beef cattle and nonlactating dairy cattle*—(A) *Amount.* Administer 3 to 5 mg per pound of body weight (mg/lb) per day; 5 mg/lb per day for the treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases. For 50-mg/mL solution, administer intramuscularly or intravenously; for 100-mg/mL solution, administer intramuscularly only. Treatment should be continued for 24 to 48 hours following remission of clinical signs of disease, not to exceed 4 consecutive days.

(B) *Indications for use.* For 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,* anaplasmosis caused by *Anaplasma marginale;* and wound infections and

acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp.

(C) *Limitations.* Exceeding the highest recommended dose of 5 mg/lb, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 mL 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Swine*—(A) *Amount.* Administer 3 to 5 mg/lb per day by intramuscular injection. Sows: Administer 3 mg/lb by intramuscular injection 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.* Do not inject more than 5 mL per injection site. Do not use for more than 4 consecutive days. Discontinue treatment at least 26 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d)(1) *Specifications.* Each milliliter of solution contains 100 mg of oxytetracycline hydrochloride.

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

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*—(i) *Amount.* Administer 3 to 5 mg of oxytetracycline per pound of body weight per day by intramuscular injection, not to exceed a total of 4 consecutive days. Administer 5 mg/lb of body weight per day for treatment of anaplasmosis, severe foot-rot, or severe cases of other indicated diseases, not to exceed a total of 4 consecutive days.

(ii) *Indications for use.* For 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. For treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis*.

(iii) *Limitations.* 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. Discontinue treatment at least 15 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)(1) *Specifications.* Each milliliter of solution contains 50 mg of oxytetracycline hydrochloride.

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

(3) *Conditions of use in beef cattle and nonlactating dairy cattle.* It is used as follows:

(i) *Amount.* Administer by intravenous or intramuscular injection at 3 to 5 mg/lb of body weight per day, not exceed a total of 4 consecutive days.

(ii) *Indications for use.* For 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; and treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis.*

(iii) *Limitations.* 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. Discontinue treatment at least 22 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Conditions of use in swine.* It is used in swine as follows:

(i) *Amount.* Administer by intramuscular injection at 3 to 5 mg/lb of body weight per day to swine, not to exceed a total of 4 consecutive days. Administered to sows at 3 mg/lb of body weight approximately 8 hours before farrowing or immediately after farrowing.

(ii) *Indications for use.* 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.*

(iii) *Limitations.* Discontinue treatment at least 22 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(5) *Poultry (broilers, turkeys, and breeding chickens).* It is used as follows:

(i) *Amount.* Administer subcutaneously to chickens and turkeys according to age as directed on labeling.

(ii) *Indications for use.* 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.*

(iii) *Limitations.* Do not administer to laying hens unless the eggs are used for hatching only. Discontinue treatment at least 5 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(f)(1) *Specifications.* Each milliliter of solution contains 100 mg of oxytetracycline hydrochloride.

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

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*—(i) *Amount.* Administer 3 to 5 mg of oxytetracycline per pound of body weight per day by intramuscular injection, not to exceed a total of 4 consecutive days. Administer 5 mg/lb of body weight per day for treatment of anaplasmosis, severe foot-rot, or severe cases of other indicated diseases, not to exceed a total of 4 consecutive days.

(ii) *Indications for use.* For 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. For treatment of anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis.*

(iii) *Limitations.* 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. Discontinue treatment at least 15 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(g)(1) *Specifications.* Each milliliter (mL) of solution contains 100 milligrams (mg) oxytetracycline hydrochloride.

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

(3) *Conditions of use.* 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.* Administer 3 to 5 mg/lb body weight per day by intramuscular, intravenous, or subcutaneous injection. In severe forms of the indicated diseases, administer 5 mg/lb body weight per day. Continue treatment 24 to 48 hours following remission of clinical signs of disease, not to exceed 4 consecutive days.

(B) *Indications for use.* For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., *Haemophilus* spp., or *Klebsiella* spp.

(C) *Limitations.* Do not inject more than 10 mL per intramuscular injection site in adult cattle, and no more than 1 mL 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Swine*—(A) *Amount.* Administer 3 to 5 mg/lb body weight per day by intramuscular injection. Sows: Administer 3 mg/lb body weight once, by intramuscular injection, 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.* Do not inject more than 5 mL per site. Discontinue treatment at least 20 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(h)(1) *Specifications.* Each milliliter (mL) of solution contains 50 or 100 milligrams (mg) oxytetracycline hydrochloride.

(2) *Sponsors.* See No. 069043 in § 510.600(c) of this chapter for use of 50- and 100-mg/mL solution and Nos. 016592 and 055529 in § 510.600(c) of this chapter for use of 100-mg/mL solution.

(3) *Conditions of use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves*—(i) *Amount.* Administer 3 to 5 mg/lb body weight per day by intramuscular injection; 5 mg/lb body weight per day for treatment of severe forms of the indicated diseases.

(ii) *Indications for use.* For treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp., foot-rot and calf diphtheria caused by *Fusobacterium necrophorum,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresii;* and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations.* Do not inject more than 10 mL 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 mL per site. Discontinue treatment at least 22 days before slaughter. Not for use in lactating dairy animals. 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.

(i)(1) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle, beef calves, nonlactating dairy cattle, and dairy calves*—(i) *Amount.* Administer 3 to 5 mg/lb body weight per day by intramuscular injection not to exceed a total of 4 consecutive days.

(ii) *Indications for use.* 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.* 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. Discontinue treatment at least 18 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(j)(1) *Specifications.* Each milliliter (mL) of solution contains either 50 or 100 milligrams (mg) of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*—(i) *Amount.*

Administer 3 to 5 mg/lb body weight daily by intravenous injection. Administer 5 mg/lb for anaplasmosis, severe foot rot, and severe forms of other diseases. Treatment should be continued 24 to 48 hours following remission of clinical signs of disease, but not to exceed 4 consecutive days.

(ii) *Indications for use.* For 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*, anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis;* and acute metritis and wound infections caused by staphylococcal and streptococcal organisms.

(iii) *Limitations.* Not for use in lactating dairy cattle. Discontinue use at least 19 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975. Redesignated at 88 FR 14898, Mar. 10, 2023]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §522.1662, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 522.1663 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. Redesignated at 88 FR 14898, Mar. 10, 2023]

§ 522.1664 Oxytetracycline and flunixin.

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base as 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. 054771 and 061133 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]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.1680, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov.*

§ 522.1684 Pegbovigrastim.

(a) *Specifications.* Each pre-filled, single-dose syringe contains 15 milligrams of pegbovigrastim.

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

(c) *Conditions of use in cattle*—(1) *Amount.* Administer the first dose (syringe) by subcutaneous injection 7 days prior to the cow's or heifer's anticipated calving date. If necessary, the first dose may be administered within a range of 4 to 10 days prior to the anticipated calving date to accommodate management schedules. Administer the second dose (syringe) by subcutaneous injection within 24 hours after calving.

(2) *Indications for use.* For the reduction in the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers.

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

[81 FR 36789, June 8, 2016, as amended at 81 FR 48702, July 26, 2016]

§ 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 and 061133 for use as in paragraph (d)(1) of this section.

(2) Nos. 016592 and 061133 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) *Indications for 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) *Indications for 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 No. 016592: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. For No. 016592: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[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; 81 FR 22524, Apr. 18, 2016; 84 FR 8974, Mar. 13, 2019; 85 FR 18120, Apr. 1, 2020; 88 FR 16548, Mar. 20, 2023]

§ 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. 016592 and 054771 for use as in paragraph (d) of this section.

(2) Nos. 055529 and 061133 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.

(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.

(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 061133: 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. 016592 and 055529: treatment should not exceed 4 consecutive days. A withdrawal period has not been established for this product in pre-ruminating calves. Discontinue treatment for the following number of days before slaughter: cattle—14; sheep—9; and swine—7.

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

[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; 81 FR 22524, Apr. 18, 2016; 84 FR 8974, Mar. 13, 2019; 85 FR 18120, Apr. 1, 2020; 88 FR 14899, Mar. 10, 2023; 88 FR 16548, Mar. 20, 2023; 88 FR 27700, May 3, 2023; 89 FR 85427, Oct. 28, 2024]

§ 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.

(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. Redesignated at 86 FR 61685, Nov. 8, 2021, and further redesignated at 88 FR 14899, Mar. 10, 2023]

§ 522.1700 Pentobarbital and phenytoin.

(a) *Specifications.* Each milliliter (mL) of solution contains 390 milligrams (mg) pentobarbital sodium and 50 mg phenytoin sodium.

(b) *Sponsors.* See Nos. 000061, 051311, 054925, and 086119 in § 510.600(c) of this chapter.

(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) *Amount.* Administer 1 mL per 10 pounds of body weight as a single, bolus intravenous or intracardiac injection.

(2) *Indications for use.* For humane, painless, and rapid euthanasia.

(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.

[85 FR 18120, Apr. 1, 2020, as amended at 85 FR 45308, July 28, 2020. Redesignated at 86 FR 61685, Nov. 8, 2021; 88 FR 84701, Dec. 6, 2023]

§ 522.1703 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. Redesignated at 86 FR 61685, Nov. 8, 2021]

§ 522.1704 Pentosan polysulfate sodium.

(a) *Specifications*. Each milliliter of solution contains 250 milligrams (mg) of pentosan polysulfate sodium.

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

(c) *Conditions of use*—(1) *Amount*. Administer 3 mg per kilogram of body weight (1.4 mg per pound) by intramuscular injection once weekly for 4 weeks for a total of four doses.

(2) *Indications for use*. For the control of clinical signs associated with osteoarthritis in horses.

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

[88 FR 16548, Mar. 20, 2023, as amended at 88 FR 84701, Dec. 6, 2023]

§ 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, 054771, 058198, and 061133 for use of product described in paragraph (a)(2) of this section as in paragraph (c) of this section.

(3) Nos. 058005 and 069043 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, as amended at 83 FR 48946, Sept. 28, 2018; 84 FR 8974, Mar. 13, 2019; 86 FR 14820, Mar. 19, 2021]

§ 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]

§ 522.1860 Pradofloxacin.

(a) *Specifications*. Each milliliter (mL) of solution contains 200 milligrams (mg) pradofloxacin.

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

(c) *Related tolerances*. See § 556.530 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount*. Administer a single dose of 10 mg/kg (2.3 mL/100 lb) body weight by subcutaneous injection.

(ii) *Indications for use*. Cattle intended for slaughter (beef calves 2 months of age and older, growing beef steers, growing beef heifers, and beef bulls intended for slaughter), and in cattle intended for breeding less than 1 year of age (replacement beef and dairy heifers less than 1 year of age and beef and dairy bulls less than 1 year of age): for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*.

(iii) *Limitations*. Cattle intended for human consumption must not be slaughtered within 4 days of treatment. Not for use in female dairy cattle 1 year of age and older, including dry dairy cows; use in these cattle may cause drug residues in milk and/or in calves born to these cows. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. 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.

(2) *Swine*—(i) *Amount*. Administer a single dose of 7.5 mg/kg (1.7 mL/100 lb) body weight by intramuscular injection.

(ii) *Indications for use*. Weaned swine intended for slaughter (nursery, growing, and finishing swine, boars intended for slaughter, barrows, gilts intended for slaughter, and sows intended for slaughter): for the treatment of swine respiratory disease associated with *Bordetella bronchiseptica*, *Glaesserella*

(Haemophilus) parasuis, Pasteurella multocida, Streptococcus suis, and *Mycoplasma hyopneumoniae.*

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 2 days of treatment. 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.

[89 FR 85427, Oct. 28, 2024]

§ 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. 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) *Specifications.* Each milliliter (mL) of solution contains 56.8 milligrams of praziquantel.

(b) *Sponsors.* See Nos. 058198 and 061133 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer by subcutaneous or intramuscular injection for dogs and puppies 5 pounds (lb) and under, 0.3 mL; for 6 to 10 lb, 0.5 mL; for 11 to 25 lb, 1.0 mL; if over 25 lb, 0.2 mL/5 lb body weight to a maximum of 3 mL.

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

(2) *Cats*—(i) *Amount.* Administer by subcutaneous or intramuscular injection for cats and kittens under 5 lb, 0.2 mL; 5 to 10 lb, 0.4 mL; 11 lb and over, 0.6 mL maximum.

(ii) *Indications for use.* For removal of feline cestodes *Dipylidium caninum* and *Taenia taeniaeformis.*

(iii) *Limitations.* Federal law restricts the 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; 81 FR 67151, Sept. 30, 2016; 84 FR 8974, Mar. 13, 2019; 86 FR 14820, Mar. 19, 2021]

§ 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, carpitis, 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. 061133 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, as amended at 84 FR 8974, Mar. 13, 2019]

§ 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]

§ 522.1890 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) *Specifications*—(1) *Each implant consists of progesterone and estradiol benzoate.* (i) 100 mg progesterone and 10 mg estradiol benzoate (one implant consisting of four pellets, each containing 25 mg progesterone and 2.5 mg estradiol benzoate).

(ii) 200 mg progesterone and 20 mg estradiol benzoate (one implant consisting of eight pellets, each containing 25 mg progesterone and 2.5 mg estradiol benzoate).

(2) *Each implant consists of progesterone and estradiol benzoate and tylosin tartrate.* (i) 100 mg progesterone, 10 mg estradiol benzoate, and 29 mg tylosin tartrate (one implant consisting of four pellets, each containing 25 mg progesterone and 2.5 mg estradiol benzoate, and one pellet containing 29 mg tylosin tartrate).

(ii) 200 mg progesterone, 20 mg estradiol benzoate, and 29 mg tylosin tartrate (one implant consisting of eight pellets, each containing 25 mg progesterone and 2.5 mg estradiol benzoate, and one pellet containing 29 mg tylosin tartrate).

(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 (e)(1)(i)(A), (e)(1)(ii), (e)(2)(i)(A), (B), (C), and (e)(2)(ii) of this section.

(2) No. 058198 for use as in paragraphs (e)(1)(i)(A), (e)(1)(i)(B), (e)(1)(ii), and (e)(3) of this section.

(c) *Related tolerances.* See §§ 556.240 and 556.540 of this chapter.

(d) *Special considerations.* Labeling of implants described in paragraphs (a)(2)(i) and (a)(2)(ii) for use in paragraphs (e)(1)(i)(B), (e)(1)(ii), (e)(3)(i), and (e)(3)(ii) of this section shall 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 calves 45 days of age and older and weighing up to 400 lbs*—(i) *Amounts and indications for use.* (A) An implant containing 100 mg progesterone and 10 mg estradiol benzoate as described in paragraph (a)(1)(i) of this section for increased rate of weight gain.

(B) An implant containing 100 mg progesterone, 10 mg estradiol benzoate, and 29 mg tylosin tartrate as described in paragraph (a)(2)(i) of this section for increased rate of weight gain.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Other than when used as described in (e)(2)(i)(B) of this section, the implant as described in paragraph (a)(1)(i) of this section is not approved for repeated implantation (reimplantation). The implant as described in paragraph (a)(2)(i) of this

section is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant. Do not use in beef calves less than 45 days of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

(2) *Growing beef steers fed in confinement for slaughter*—(i) *Amounts and indications for use.* (A) An implant containing 200 mg progesterone and 20 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain and improved feed efficiency.

(B) An implant containing 200 mg progesterone and 20 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain in a reimplantation program where an implant as described in paragraph (a)(1)(i) of this section is the first implant and an implant as described in paragraph (a)(1)(ii) of this section is administered approximately 70 days later.

(C) An implant containing 200 mg progesterone and 20 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain in a reimplantation program where an implant as described in paragraph (a)(1)(ii) of this section is the first implant and an implant as described in paragraph (a)(1)(ii) of this section is administered approximately 70 days later.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Other than when used as described in paragraphs (e)(2)(i)(B) or (C) of this section, the implant described in paragraph (a)(1)(ii) of this section is not approved for repeated implantation (reimplantation) with any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter as safety and effectiveness have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

(3) *Growing beef steers weighing 400 lbs or more*—(i) *Amounts and indications for use.* An implant containing 200 mg progesterone, 20 mg estradiol benzoate, and 29 mg tylosin tartrate as described in paragraph (a)(2)(ii) of this section for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* The implant as described in paragraph (a)(2)(ii) of this section is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

[89 FR 42358, May 15, 2024]

§ 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. 061133 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 conjunction 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; 84 FR 8974, Mar. 13, 2019]

§ 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)(1) No. 086064 for use as in paragraphs (c)(1), (c)(2)(i), (c)(3), (d)(1), (d)(2)(i), and (d)(3) of this section.

(2) No. 054771 for use as in paragraphs (c)(1), (c)(2)(ii), (c)(3), (d)(1), (d)(2)(ii), and (d)(3) of this section.

(3) Nos. 054771 and 068504 for use as in paragraphs (c)(1), (c)(2)(iii), and (c)(3) of this section.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer by intravenous injection according to label directions. 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; and for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) For induction of general anesthesia; for maintenance of anesthesia for up to 20 minutes; and for induction of general anesthesia followed by maintenance with an inhalant anesthetic.

(iii) For induction and maintenance of general anesthesia; and for induction of general 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.

(d) *Conditions of use in cats*—(1) *Amount.* Administer by intravenous injection according to label directions. 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; and for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) For induction and maintenance of general anesthesia; and for induction of general 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; 81 FR 36789, June 8, 2016; 90 FR 6800, Jan. 21, 2025]

§ 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. 061133 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.

(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, as amended at 84 FR 8974, Mar. 13, 2019]

§ 522.2065 Rabacfosadine.

(a) *Specifications.* Each vial of powder contains 16.4 milligrams (mg) rabacfosadine. Each milliliter of constituted solution contains 8.2 mg rabacfosadine.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer rabacfosadine at 1 mg/kilogram body weight as a 30-minute intravenous infusion, once every 3 weeks, for up to 5 doses.

(2) *Indications for use.* For the treatment of lymphoma in dogs.

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

[87 FR 10969, Feb. 28, 2022]

§ 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*—(1) *Dogs*—(i) *Amount.* Administer 0.91 mg per pound (2 mg/kilogram (kg)) by subcutaneous injection, once daily, for a maximum of 3 days. After the initial subcutaneous dose, subsequent doses can be given by subcutaneous injection or as the oral tablet in dogs weighing at least 5.5 pounds (2.5 kg) and at least 4 months of age, for a maximum of 3 total doses over 3 days, not to exceed 1 dose per day. See § 520.2075(c)(1) of this chapter.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with soft tissue surgery in dogs at least 4 months of age for a maximum of 3 days.

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

(2) *Cats*—(i) *Amount.* Administer 0.91 mg per pound (2 mg/kg) by subcutaneous injection, once daily, for a maximum of 3 days.

(ii) *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.

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

[80 FR 61297, Oct. 13, 2015, as amended at 82 FR 12170, Mar. 1, 2017]

§ 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]

§ 522.2092 Secobarbital and dibucaine.

(a) *Specifications.* Each milliliter (mL) of solution contains 400 milligram (mg) secobarbital sodium and 25 mg dibucaine hydrochloride.

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

(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) *Amount.* Administer 1 mL per 10 pounds of body weight as a single, bolus intravenous injection.

(2) *Indications for use.* For humane, painless, and rapid euthanasia.

(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.

[85 FR 18120, Apr. 1, 2020]

§ 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 inflammation, 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 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.* Newborn 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. 086106 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 withdrawal 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; 81 FR 48702, July 26, 2016; 85 FR 4208, Jan. 24, 2020]

§ 522.2120 Spectinomycin hydrochloride.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) spectinomycin hydrochloride (as spectinomycin dihydrochloride pentahydrate).

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

(1) Nos. 016592 and 054771 for use as in paragraph (d)(1) of this section; and

(2) No. 058198 for use as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See § 556.600 of this chapter.

(d) *Conditions of use.* It is administered as follows:

(1) *Turkeys (1- to 3-day-old poults) and chickens (newly hatched chicks)*—(i) *Amounts and indications for use.* (A) Administer 5 mg per poult subcutaneously as an aid in the control of chronic respiratory disease (CRD) associated with *Escherichia coli* in 1- to 3-day-old turkey poults.

(B) Administer 10 mg per poult as a single subcutaneous injection in the nape of the neck as an aid in the control of airsacculitis associated with *Mycoplasma meleagridis* sensitive to spectinomycin in 1- to 3-day-old turkey poults.

(C) Administer 2.5 to 5 mg per chick as an aid in the control of mortality and to lessen severity of infections caused by *M. synoviae*, *Salmonella typhimurium*, *S. infantis*, and *E. coli*.

(ii) *Limitations.* For use only in 1- to 3-day-old turkey poults and newly hatched chicks. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* Administer 2.5 to 5.0 mg per pound of body weight by intramuscular injection twice daily. Treatment may be continued for 4 days.

(ii) *Indications for use.* For treatment of infections caused by gram-negative and gram-positive organisms susceptible to spectinomycin.

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

[86 FR 14820, Mar. 19, 2021, as amended at 88 FR 27700, May 3, 2023]

§ 522.2121 Spectinomycin sulfate.

(a) *Specifications.* Each milliliter of solution contains spectinomycin sulfate tetrahydrate equivalent to 100 milligrams (mg) spectinomycin.

(b) *Sponsor.* See Nos. 054771 and 061133 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; 88 FR 14899, Mar. 10, 2023]

§ 522.2150 Stanozolol.

(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]

§ 522.2220 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. 069043 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. 016592 and 061133 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16196, Mar. 25, 2014, as amended at 81 FR 22524, Apr. 18, 2016; 83 FR 48946, Sept. 28, 2018; 84 FR 8974, Mar. 13, 2019; 88 FR 14900, Mar. 10, 2023]

§ 522.2240 Sulfaethoxypyridazine.

(a) *Specifications.* The drug is an aqueous solution of sulfaethoxypyridazine.

(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 sulfaethoxypyridazine 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. 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; 88 FR 14900, Mar. 10, 2023]

§ 522.2343 Testosterone propionate and estradiol benzoate.

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

(1) No. 054771 for use as in paragraph (d)(1) of this section.

(2) No. 058198 for use as in paragraph (d)(2) of this section.

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

(c) *Special considerations.* Labeling of the implants described in paragraph (d)(2) of this section shall bear the following: ''Federal law restricts this

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

(d) *Conditions of use*—(1) *Growing beef heifers fed in confinement for slaughter*—(i) *Amounts and indications for use.* An implant containing 200 mg testosterone propionate and 20 mg estradiol benzoate (one implant consisting of eight pellets, each containing 25 mg testosterone propionate and 2.5 mg estradiol benzoate) for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

(2) *Growing beef heifers weighing 400 lbs or more*—(i) *Amounts and indications for use.* An implant containing 200 mg testosterone propionate, 20 mg estradiol benzoate, and 29 mg tylosin tartrate (one implant consisting of eight pellets, each containing 25 mg testosterone propionate and 2.5 mg estradiol benzoate, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

[89 FR 42358, May 15, 2024]

§ 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.

(2) It is administered intravenously. The drug is injected slowly to dogs, cats, cattle, sheep, and swine. For horses, it is recommended that a preanesthetic 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. 054771 and 069043 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 anethesia, 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16196, Mar. 25, 2014, as amended at 83 FR 48946, Sept. 28, 2018]

§ 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. 061133 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 ⅔ 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, as amended at 84 FR 8974, Mar. 13, 2019]

§ 522.2450 Tigilanol.

(a) *Specifications.* Each milliliter (mL) of solution contains 1 milligram tigilanol tiglate.

(b) *Sponsor.* See No. 086132 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer as an intratumoral injection at a dose of 0.5 mL per cubic centimeter of tumor volume.

(2) *Indications for use.* For the treatment of non-metastatic cutaneous mast cell tumors and non-metastatic subcutaneous mast cell tumors located at or distal to the elbow or the hock in dogs.

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

[86 FR 17064, Apr. 1, 2021]

§ 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 bodyweight 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 nonlactating 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.

(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. 017033, 051311, and 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Expressed as milligrams of the drug combination:

(A) An initial intramuscular dosage of 3 to 4.5 milligrams per pound (mg/lb) of body weight for diagnostic purposes; 4.5 to 6 mg/lb 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/lb of body weight. The maximum total safe dose is 13.6 mg/lb of body weight.

(B) Administer intravenously at 1 to 2 mg/lb (2.2 to 4.4 mg/kg) body weight to effect for induction of anesthesia followed by maintenance with an inhalant anesthetic.

(ii) *Indications for use.* (A) Intramuscular administration in dogs for restraint and minor procedures of short duration (30 minutes average) requiring mild to moderate analgesia.

(B) Intravenous administration in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic.

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

(2) *Cats*—(i) *Amount.* An initial intramuscular dosage of 4.4 to 5.4 mg/lb of body weight is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 mg/lb 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/lb 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/lb of body weight.

(ii) *Indications for use.* For restraint or for anesthesia combined with muscle relaxation.

(iii) *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 83 FR 14587, Apr. 5, 2018; 86 FR 17064, Apr. 1, 2021; 87 FR 10969, Feb. 28, 2022; 88 FR 16548, Mar. 20, 2023; 89 FR 95103, Dec. 2, 2024]

§ 522.2471 Tilmicosin.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) tilmicosin base as tilmicosin phosphate.

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

(c) *Related tolerances.* See § 556.735 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 10 to 20 milligrams per kilograms (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.* Animals intended for human consumption must not be slaughtered within 42 days of last

treatment. Do not use in lactating dairy cattle 20 months of age or older. Use of tilmicosin in this class of cattle may cause milk residues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(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.* Not for use in lactating ewes producing milk for human consumption. Animals intended for human consumption must not be slaughtered within 42 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[67 FR 72367, Dec. 5, 2002, as amended at 75 FR 9334, Mar. 2, 2010; 81 FR 48703, July 26, 2016; 88 FR 16548, Mar. 20, 2023]

§ 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. 061133 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. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 18159, Apr. 1, 2014, as amended at 82 FR 21691, May 10, 2017; 84 FR 8974, Mar. 13, 2019]

§ 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. 000061 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii) and (iii), (d)(2)(i)(A), and (d)(2)(ii) and (iii) of this section.

(2) No. 058198 for use as in paragraph (d) of this section.

(b) *Related tolerances.* See § 556.739 of this chapter.

(c) *Special considerations.* Labeling of implants described in paragraph (d)(1)(i)(B) and (d)(2)(i)(B) of this section shall bear the following: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''.

(d) *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; 81 FR 48703, July 26, 2016; 88 FR 55566, Aug. 16, 2023]

§ 522.2477 Trenbolone acetate and estradiol.

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

(1) No. 058198 for use in paragraphs (d)(1)(i)(B), (d)(1)(ii), (d)(2)(i)(B), (d)(2)(i)(D), (d)(2)(ii), (d)(3)(i)(B), (d)(3)(i)(D), (d)(3)(ii), (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) of this section.

(2) No. 000061 for use in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(ii), (d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(E), (d)(2)(ii), (d)(3)(i)(A), (d)(3)(i)(C), (d)(3)(i)(E), (d)(3)(ii), (d)(4)(i)(A), and (d)(4)(ii) of this section.

(3) No. 054771 for use in paragraphs (d)(2)(i)(A), (C), (d)(2)(ii), (d)(4)(i)(A), and (d)(4)(ii) of this section.

(b) *Related tolerances.* See §§ 556.240 and 556.739 of this chapter.

(c) *Special considerations.* Labeling of implants described in paragraphs (d)(1)(i)(B), (d)(2)(i)(B), (d)(2)(i)(D), (d)(3)(i)(B), (d)(3)(i)(D), and (d)(4)(i)(B) of this section shall bear the following: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(d) *Conditions of use*—(1) *Growing beef steers and heifers fed in confinement for slaughter*—(i) *Amounts and indications.* (A) An implant containing 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets each containing 20 mg trenbolone acetate and 2 mg estradiol) for increased rate of weight gain and improved feed efficiency.

(B) An implant containing 200 mg trenbolone acetate, 20 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of 10 pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(C) An extended- and delayed-release implant containing 200 mg trenbolone acetate and 20 mg estradiol (1 implant consisting of 10 coated pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol) for increased rate of weight gain and improved feed efficiency during 70 to 200 days after implantation.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

(2) *Growing beef steers fed in confinement for slaughter*—(i) *Amounts and indications.* (A) An implant containing 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of four pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol) for increased rate of weight gain and improved feed efficiency.

(B) An implant containing 80 mg trenbolone acetate, 16 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of four pellets, each containing 20 mg trenbolone acetate and 4

mg estradiol, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(C) An implant containing 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of six pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol) for increased rate of weight gain and improved feed efficiency.

(D) An implant containing 120 mg trenbolone acetate, 24 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of six pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(E) An extended-release implant containing 200 mg trenbolone acetate and 40 mg estradiol (one implant consisting of six coated pellets and four uncoated pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol) for increased rate of weight gain and improved feed efficiency for up to 200 days after implantation.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers fed in confinement for slaughter. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

(3) *Growing beef heifers fed in confinement for slaughter*—(i) *Amounts and indications.* (A) An implant containing 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of four pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol) for increased rate of weight gain.

(B) An implant containing 80 mg trenbolone acetate, 8 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of four pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(C) An implant containing 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of seven pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol) for increased rate of weight gain and improved feed efficiency.

(D) An implant containing 140 mg trenbolone acetate, 14 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of seven pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(E) An extended-release implant containing 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of six coated pellets and four uncoated pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol) for increased rate of weight gain and improved feed efficiency for up to 200 days after implantation.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef heifers fed in confinement for slaughter. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

(4) *Growing beef steers and heifers on pasture (stocker, feeder, and slaughter)*—(i) *Amounts and indications for use.* (A) An implant containing 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of two pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol) for increased rate of weight gain.

(B) An implant containing 40 mg trenbolone acetate, 8 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of two pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers on pasture (stocker, feeder, and slaughter). Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

[89 FR 42359, May 15, 2024]

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Specifications.* (1) Each implant consists of:

(i) 50 milligrams (mg) trenbolone acetate and 7 mg estradiol benzoate (one implant consisting of two pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(ii) 100 milligrams (mg) trenbolone acetate and 14 mg estradiol benzoate (one implant consisting of four pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(iii) 200 mg trenbolone acetate and 28 mg estradiol benzoate (one implant consisting of eight pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(2) Each extended-release implant consists of:

(i) 150 mg trenbolone acetate and 21 mg estradiol benzoate (one implant consisting of six pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(ii) 200 mg trenbolone acetate and 28 mg estradiol benzoate (one implant consisting of eight pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

(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) *Growing beef steers and heifers fed in confinement for slaughter*—(i) *Amounts and indications for use.*

(A) An implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain in growing beef steers fed in confinement for slaughter and for increased rate of weight gain and improved feed efficiency in growing beef heifers fed in confinement for slaughter. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(ii) of this section is the first implant and an implant as described in paragraph (a)(1)(ii) or (iii) or (a)(2)(ii) of this section is administered 60 to 120 days later.

(B) An implant containing 200 mg trenbolone acetate and 28 mg estradiol benzoate as described in paragraph (a)(1)(iii) of this section for increased rate of weight gain and improved feed efficiency in growing beef steers fed in confinement for slaughter and for increased rate of weight gain in growing beef heifers fed in confinement for slaughter. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(ii) of this section is the first implant and an implant as described in paragraph (a)(1)(iii) of this section is administered 60 to 120 days later.

(C) An extended-release implant containing 150 mg trenbolone acetate and 21 mg estradiol benzoate as described in paragraph (a)(2)(i) of this section for increased rate of weight gain for up to 200 days.

(D) An extended-release implant containing 200 mg trenbolone acetate and 28 mg estradiol benzoate as described in paragraph (a)(2)(ii) of this section for increased rate of weight gain and improved feed efficiency for up to 200 days. For increased rate of weight gain for up to 200 days in a reimplantation program where an implant as described in paragraph (a)(1)(ii) of this section is the first implant and an implant as described in paragraph (a)(2)(ii) of this section is administered 60 to 120 days later.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Other than as described on the labeling, this implant is not approved for repeated implantation (reimplantation) with any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter as safety and effectiveness have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. The extended-release implant described in paragraph (a)(2)(i) of this section, used as described in paragraph (d)(1)(i)(C) of this section, is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant.

(2) *Growing beef steers and heifers on pasture (stocker, feeder, and slaughter)*—(i) *Amounts and indications for use.* (A) An implant containing 50 mg trenbolone acetate and 7 mg estradiol benzoate as described in paragraph (a)(1)(i) of this section for increased rate of weight gain.

(B) An implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain.

(C) An extended-release implant containing 150 mg trenbolone acetate and 21 mg estradiol benzoate as described in paragraph (a)(2)(i) of this section for increased rate of weight gain for up to 200 days.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers on pasture (stocker, feeder, and slaughter). Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

(3) *Growing beef steers and heifers in a dry lot*—(i) *Amount and indications for use.* (A) An implant containing 50 mg trenbolone acetate and 7 mg estradiol benzoate as described in paragraph (a)(1)(i) of this section for increased rate of weight gain in growing beef steers and heifers in a dry lot.

(B) An implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain in growing beef steers and heifers in a dry lot.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers in a dry lot. Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

[88 FR 14900, Mar. 10, 2023; 89 FR 85427, Oct. 28, 2024, as amended at 90 FR 6801, Jan. 21, 2025]

§ 522.2483 Triamcinolone.

(a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams (mg) triamcinolone acetonide.

(b) *Sponsors.* See Nos. 000010 and 069043 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; 83 FR 48946, Sept. 28, 2018]

§ 522.2582 Trifluprom azine.

(a) *Specifications.* Each milliliter of solution contains 20 milligrams (mg) of trifluprom azine 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. 016592 and 051031 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.* Milk taken during treatment and for 24 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 4 days following the last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. 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; 81 FR 22524, Apr. 18, 2016; 82 FR 11508, Feb. 24, 2017; 87 FR 58962, Sept. 29, 2022]

§ 522.2630 Tulathromycin.

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

(1) 100 milligrams (mg) tulathromycin

(2) 25 mg tulathromycin

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

(1) Nos. 000061, 013744, 051311, 054771, 055529, 058198, 061133, 068504, and 069043 for use of product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii)(A), and (d)(2) of this section.

(2) Nos. 013744, 051311, 054771, 058198, 068504, and 069043 for use of product described in paragraph (a)(2) as in paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.

(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. This drug 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. 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; 81 FR 67151, Sept. 30, 2016; 86 FR 57997, Oct. 20, 2021; 87 FR 58962, Sept. 29, 2022; 88 FR 16548, Mar. 20, 2023; 88 FR 27700, May 3, 2023; 89 FR 95103, Dec. 2, 2024; 90 FR 6801, Jan. 21, 2025]

§ 522.2632 Tulathromycin and ketoprofen.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) tulathromycin and 120 milligrams (mg) ketoprofen.

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

(c) *Related tolerances.* See §§ 556.345 and 556.745 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer as a single subcutaneous injection 2.5 mg tulathromycin and 3 mg ketoprofen per kilogram (1.1 mL/100 lb) of body weight.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis*, and control of pyrexia associated with BRD in beef steers, beef heifers, beef calves 2 months of age and older, beef bulls, dairy bulls, and replacement dairy heifers.

(iii) *Limitations.* Not for use in reproducing animals over 1 year of age. Cattle must not be slaughtered for human consumption within 18 days following last treatment with this drug product. Not for use in female dairy cattle 1 year 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 or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[86 FR 61685, Nov. 8, 2021]

§ 522.2640 Tylosin.

(a) *Specifications.* Each milliliter (mL) of solution contains 50 or 200 milligrams (mg) of tylosin activity (as tylosin base).

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

(1) Nos. 016592 and 058198 for use of 50- or 200-mg/mL solutions as in paragraph (e) of this section.

(2) No. 061133 for use of a 200-mg/mL solution as in paragraphs (e)(1) and (2) of this section.

(c) *Related tolerances.* See § 556.746 of this chapter.

(d) *Special considerations.* Labeling must bear the warning statements: ''Do not administer to horses or other equines. Injection of tylosin in equines has been fatal.''

(e) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* Administer 8 mg per pound (mg/lb) of body weight by intramuscular injection once daily for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear.

(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 *A. pyogenes.*

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 21 days of the last use of this drug product. 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. This product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Swine*—(i) *Amount.* Administer 4 mg/lb of body weight by intramuscular injection twice daily for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. If tylosin medicated drinking water is used as a 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.

(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.* Swine intended for human consumption must not be slaughtered within 14 days of the last use of this drug product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Dogs and cats*—(i) *Amount.* Administer 3 to 5 mg/lb of body weight by intramuscular injection at 12- to 24-hour intervals.

(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.

[81 FR 67151, Sept. 30, 2016, as amended at 84 FR 8974, Mar. 13, 2019; 84 FR 32992, July 11, 2019; 88 FR 14900, Mar. 10, 2023; 88 FR 16549, Mar. 20, 2023; 88 FR 84701, Dec. 6, 2023]

§ 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. 069043 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(2) Nos. 000010 and 061133 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. 043264 and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section; 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.

(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; 83 FR 48946, Sept. 28, 2018; 84 FR 8974, Mar. 13, 2019; 87 FR 17946, Mar. 29, 2022]

§ 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.* A s 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) Weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers: For increased rate of weight gain and improved feed conversion.

(B) Suckling calves: For increased rate of weight gain.

(iii) *Limitations.* Implant pellets subcutaneously only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant within a single production phase as safety and effectiveness have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated. A withdrawal period has not been established for this product in preruminating calves. Do not use in replacement beef heifers after weaning or in bulls, dairy cows, or replacement dairy heifers.

(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; 88 FR 55566, Aug. 16, 2023]

§ 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. 011788 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; 87 FR 76422, Dec. 14, 2022]

§ 522.2694 Zinc, copper, manganese, and selenium.

(a) *Specifications.* Each milliliter (mL) of solution contains 60 milligrams (mg) zinc as zinc oxide, 15 mg copper as copper carbonate, 10 mg manganese as manganese carbonate, and 5 mg selenium as sodium selenite.

(b) *Sponsor.* See No. 066679 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer a single dose by subcutaneous injection to cattle up to 1 year of age, 1 mL/100 lb bodyweight; to cattle from 1 to 2 years of age, 1 mL/150 lb bodyweight, and to cattle over 2 years of age, 1 mL/200 lb bodyweight.

(2) *Indications for use.* As a supplemental source of zinc, copper, manganese, and selenium in cattle.

(3) *Limitations.* Cattle must not be slaughtered for human food consumption within 14 days of the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[89 FR 85428, Oct. 28, 2024]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

Sec.

FLUOCINOLONE TOPICAL AND OTIC DOSAGE FORMS