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

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

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

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

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

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

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

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

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

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

§ 522.1014 Gamithromycin.

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

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

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

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

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

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 35 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

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

§ 522.1020 Gelatin.

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

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

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

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

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

[79 FR 16189, Mar. 25, 2014]

§ 522.1044 Gentamicin.

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

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

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

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

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

(4) No. 000859 for use of 100 mg/mL solution in turkeys as in paragraph (d)(2) and in chickens as in paragraph (d)(3) of this section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 522.1066 Glycopyrrolate.

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

(b) *Sponsors.* See Nos. 000859 and 054771 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]

§ 522.1073 Gonadorelin acetate.

(a) *Specifications.* Each milliliter of solution contains 100 micrograms (μg) of gonadorelin as gonadorelin acetate.

(b) *Sponsor.* See No. 068504 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Indications for use and amounts.*

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

(ii) For use with cloprostenol sodium to synchronize estrous cycles to allow for fixed-time artificial insemination 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.

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

[78 FR 17867, Mar. 25, 2013]

§ 522.1075 Gonadorelin diacetate tetrahydrate.

(a) *Specifications.* Each milliliter of solution contains 50 micrograms (μg) of gonadorelin diacetate tetrahydrate.

(b) *Sponsors.* See Nos. 000061, 050604, and 059130 in § 510.600(c) of this chapter.

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

(1) *Amount.* 100 μg per cow as a single intramuscular or intravenous injection.

(2) *Indications for use.* For the treatment of ovarian cysts in dairy cattle.

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

[67 FR 68759, Nov. 13, 2002, as amended at 74 FR 61516, Nov. 25, 2009. Redesignated at 78 FR 17867, Mar. 25, 2013]

§ 522.1077 Gonadorelin hydrochloride.

(a) *Specifications.* Each milliliter of solution contains 50 micrograms (mcg) of gonadorelin (as hydrochloride).

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

(c) *Conditions of use in cattle*—(1) *Indications for use and amounts*—(i) For the treatment of ovarian follicular cysts in cattle, administer 100 mcg gonadorelin by intramuscular injection.

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

(2) *Limitations.* Dinoprost tromethamine as provided by sponsor No. 054771 in § 510.600(c) of this chapter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[78 FR 63872, Oct. 25, 2013]