

## § 522.380

days. In addition, for bovine respiratory disease, administer 2.2 milligrams per kilogram (1.0 milligram per pound) of body weight every other day on days 1 and 3 (48-hour interval).

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Pasteurella haemolytica*, *P. multocida*, and *Haemophilus somnus* and acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(iii) *Limitations.* For intramuscular or subcutaneous use only. Do not inject more than 15 milliliters at each intramuscular injection site. Do not slaughter treated cattle for 48 hours (2 days) after 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.

[61 FR 29479, June 11, 1996, as amended at 63 FR 53578, Oct. 6, 1998]

## § 522.380 Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution.

(a) [Reserved]

(b)(1) *Specifications.* Chloral hydrate, pentobarbital, and magnesium sulfate sterile aqueous solution contains 42.5 milligrams of chloral hydrate, 8.86 milligrams of pentobarbital, and 21.2 milligrams of magnesium sulfate in each milliliter of sterile aqueous solution containing water, 33.8 percent propylene glycol, and 14.25 percent ethyl alcohol.

(2) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) It is used for general anesthesia and as a sedative-relaxant in cattle and horses.

(ii) For intravenous use only. The drug is administered at a dosage level of 20 to 50 milliliters per 100 pounds of body weight for general anesthesia until the desired effect is produced. Cattle usually require a lower dosage on the basis of body weight. When used as a sedative-relaxant, it is administered at a level of one-fourth to one-half of the anesthetic dosage level.

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(iii) 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 45 FR 16482, Mar. 14, 1980]

## § 522.390 Chloramphenicol injection.

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

(b) *Sponsor.* See Nos. 000069 and 059130 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.* Not for use in animals raised for food production. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992, as amended at 65 FR 45877, July 26, 2000]

## § 522.460 Cloprostenol sodium.

(a)(1) *Specifications.* Each milliliter of the aqueous solution contains 263 micrograms of cloprostenol sodium (equivalent to 250 micrograms of cloprostenol) in a sodium citrate, anhydrous citric acid and sodium chloride buffer containing 0.1 percent w/v chlorocresol B.P. as a bactericide.

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

(3) *Conditions of use.* For intramuscular use in beef and dairy cattle to induce luteolysis.

(i) *Amount.* 2 milliliters (equivalent to 500 micrograms of cloprostenol).

(ii) *Indications.* (a) For scheduling estrus and ovulation to control the time at which cycling cows or heifers can be bred.

(1) Single cloprostenol injection. Treat only animals with a mature corpus luteum. Estrus should occur in 2 to 5 days, and cattle should be inseminated at the usual time relative to the

detection of estrus. If estrus is not observed, treated animals may be inseminated either once at 72 hours post injection or twice at 72 and 96 hours post injection.

(2) Double cloprostenol injection. Give cattle a second injection 11 days after the first injection. Estrus should occur 2 to 5 days after the second injection, and cattle should be inseminated at the usual time relative to the detection of estrus. If estrus is not observed, treated animals may be inseminated either once at about 72 hours post injection or twice at 72 and 96 hours following the second injection.

(b) Single cloprostenol injection for terminating unwanted pregnancies from mismatings from 1 week after mating until 5 months after conception, or for treating unobserved (non-detected) estrus, mummified fetus, and luteal cysts.

(c) Single cloprostenol injection for the treatment of pyometra.

(iii) Do not administer to pregnant animals where the calf is not to be aborted.

(iv) Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Cloprostenol is readily absorbed through the skin and may cause abortion and/or bronchospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(v) 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 131.5 micrograms of cloprostenol sodium (equivalent to 125 micrograms of cloprostenol).

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

(3) *Special considerations*. Labeling shall bear the statements prescribed in paragraphs (a)(3) (iii) and (iv) of this section.

(4) *Conditions of use*—(i) *Amount*. 3 milliliters (equivalent to 375 micrograms of cloprostenol) intramuscularly per animal as a single dose.

(ii) *Indications for use*. To induce abortion in pregnant feedlot heifers

from 1 week after mating until 4½ months of gestation.

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

[47 FR 4678, Feb. 2, 1982, as amended at 48 FR 15619, Apr. 12, 1983; 49 FR 5100, Feb. 10, 1984; 49 FR 29957, July 25, 1984; 65 FR 6892, Feb. 11, 2000]

#### § 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 046573 in § 510.600(c) of this chapter.

(c) [Reserved]

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

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

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

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

(2) [Reserved]

[63 FR 13123, Mar. 18, 1998]

#### § 522.480 Repository corticotropin injection.

(a)(1) *Specifications*. The drug conforms to repository corticotropin injection U.S.P. It contains 40 or 80 U.S.C. (I.U.) units per cubic centimeter.

(2) *Sponsor*. See No. 037990 in § 510.600(c) of this chapter.

(3) *Special considerations*. The drug should be refrigerated. With prolonged use supplement daily diet with potassium chloride at one gram for small animals and from 5 to 10 grams for large animals.

(4) *Conditions of use*. (i) It is used as an intramuscular or subcutaneous injection in cattle and small animals for