

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

**§ 522.518**

stimulation of the adrenal cortex where there is a general deficiency of corticotropin (ACTH). It is also a therapeutic agent for primary bovine ketosis.

(ii) It is administered to cattle initially at 200 to 600 units followed by a dose daily or every other day of 200 to 300 units and to small animals at one unit per pound of body weight to be repeated as indicated.

(iii) For use only by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* The drug conforms to repository corticotropin injection U.S.P. It contains 40 or 80 U.S.P. units per milliliter.

(2) *Sponsor.* See No. 000864 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) For intramuscular injection in dogs as a diagnostic aid to test for adrenal dysfunction. For intramuscular or subcutaneous injection in dogs and cats for stimulation of the adrenal cortex where there is a general deficiency of ACTH.

(ii) For diagnostic use: Administer at one unit per pound of body weight intramuscularly. For therapeutic use: Administer at one unit per pound of body weight intramuscularly or subcutaneously, initially, to be repeated as indicated.

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

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status.* The therapeutic indication for use has been reviewed by NAS/NRC and found to be effective. Applications for this use need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 13858, Mar. 27, 1985, as amended at 50 FR 40966, Oct. 8, 1985; 53 FR 45760, Nov. 14, 1988]

**§ 522.518 Cupric glycinate injection.**

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

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

(c) *Conditions of use—(1) Amount.* 200 milligrams (1 mL) for calves 300 pounds

**21 CFR Ch. I (4–1–01 Edition)**

and under; 400 milligrams (2 mL) for calves over 300 pounds and adult cattle.

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

(3) *Limitations.* For subcutaneous use only; repeat dose in 3 months in young calves, in 6 months in cattle; discontinue use 30 days before treated animals are slaughtered for food use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

**§ 522.533 Deslorelin acetate.**

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

(b) *Sponsor.* See 064288 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Horses and ponies—(i) Amount.* One implant per mare.

(ii) *Indications for use.* For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimeters in diameter. Follicular size should be determined by rectal palpation and/or ultrasonography prior to treatment.

(iii) *Limitations.* Administer subcutaneously in the neck. Not for use in horses or ponies intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 44383, Aug. 19, 1998]

**§ 522.535 Desoxycorticosterone pivalate.**

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

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

(c) [Reserved]

(d) *Conditions of use—(1) Dogs—(i) Amount.* Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per