§ 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 Nos. 000061 and 068504 in §510.600(c) of this chapter.

(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.

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

(d) **Conditions of use.** (1) **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.

(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.

§ 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.