Food and Drug Administration, HHS

§ 522.468

Colistimethate sodium powder for injection.

(a) Specifications. Each vial contains colistimethate sodium equivalent to 10

(1) Amount. 2 milliliters (equivalent to 500 micrograms of colistimethate).

(b) Indications for use. For terminating unwanted pregnancies from mismatings from 1 week after mating until 4¼ months of gestation.

(i) Single colistimethate sodium injection for terminating unwanted pregnancies from mismatings from 1 week after mating until 4¼ months of gestation. Give cattle a single 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 following the second injection.

(ii) Double colistimethate sodium 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.

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


§ 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.

(b)(1) Specifications. Each milliliter of sterile aqueous solution contains 131.5 micrograms of cloprostenol sodium (equivalent to 125 micrograms of cloprostenol).

(c) Single cloprostenol injection for terminating unwanted pregnancies from mismatings from 1 week after mating until 4¼ months of gestation. 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.

(ii) 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.

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