## Food and Drug Administration, HHS

- (c) Related tolerances. See §556.286 of this chapter.
- (d) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (e) Conditions of use—(1) Horses—(i) Amount. 0.5 mg per pound (/lb) of body weight per day, intravenously or intramuscularly, for up to 5 days.
- (ii) Indications for use. For alleviation of inflammation and pain associated with musculoskeletal disorders, and alleviation of visceral pain associated with colic.
- (iii) *Limitations*. Do not use in horses intended for human consumption.
- (2) Cattle—(i) Amounts and indications for use—(A) Administer 1.1 to 2.2 mg/kilogram (kg) (0.5 to 1.0 mg/lb) of body weight per day intravenously, as a single dose or divided into two doses administered at 12-hour intervals, for up to 3 days for control of pyrexia associated with bovine respiratory disease and endotoxemia or for control of inflammation in endotoxemia.
- (B) Administer 2.2 mg/kg (1.0 mg/lb) of body weight once intravenously for control of pyrexia associated with acute bovine mastitis.
- (ii) Limitations. Cattle must not be slaughtered for human consumption within 4 days of last treatment. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. Do not use in dry dairy cows. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal.
- (B) For control of pyrexia associated with acute bovine mastitis.
- (iii) Limitations. Do not slaughter for food use within 4 days of last treatment. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. For Nos. 000061, 055529, 059130, and 061623: Do not use in dry dairy cows. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. For No. 057561: Not for use in lactating or dry dairy cows.
- (3) Swine—(i) Amount. Administer 2.2 mg/kg (1.0 mg/lb) of body weight as a single intramuscular injection.

- (ii) *Indications for use*. For the control of pyrexia associated with swine respiratory disease.
- (iii) *Limitations*. Swine must not be slaughtered for human consumption within 12 days of last treatment.

[42 FR 39103, Aug. 2, 1977, as amended at 52 FR 7832, Mar. 13, 1987; 60 FR 54942, Oct. 27, 1995; 62 FR 22888, Apr. 28, 1997; 63 FR 38749, July 20, 1998; 67 FR 9400, Mar. 1, 2002; 68 FR 70701, Dec. 19, 2003; 69 FR 53618, Sept. 2, 2004; 69 FR 60308, Oct. 8, 2004; 70 FR 48868, Aug. 22, 2005; 70 FR 70998, Nov. 25, 2005; 71 FR 15564, Mar. 29, 2006; 71 FR 16222, Mar. 31, 2006; 73 FR 2809, Jan. 16, 2008; 73 FR 28037, May 15, 2008; 74 FR 6994, Feb. 12, 2009; 74 FR 34236, July 15, 2009; 75 FR 13225, Mar. 19, 2010; 75 FR 76260, Dec. 8, 2010; 79 FR 16189, Mar. 25, 2014]

## §522.995 Fluprostenol.

- (a) Specifications. Each milliliter of solution contains fluprostenol sodium equivalent to 50 micrograms ( $\mu g$ ) of fluprostenol.
- (b) Sponsor. See No. 000859 in  $\S 510.600(c)$  of this chapter.
- (c) Conditions of use in horses—(1) Amount. Administer 0.55 µg fluprostenol per kilogram of body weight by intramuscular injection.
- (2) Indications for use. For use in mares for its luteolytic effect to control the timing of estrus in estrous cycling and in clinically anestrous mares that have a corpus luteum.
- (3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16189, Mar. 25, 2014]

## § 522.1002 Follicle stimulating hormone.

- (a)(1) Specifications. Each package contains 2 vials. One vial contains dry, powdered, porcine pituitary gland equivalent to 75 units (NIH-FSH-S1) of follicle stimulating hormone. The other vial contains 10 milliliters of aqueous diluent.
- (2) *Sponsor*. See No. 052923 in §510.600(c) of this chapter.
- (3) Conditions of use. (i) Dosage. 12.5 units of follicle stimulating hormone twice a day for 3 days (a total of 75 units). To effect regression of the corpus luteum, prostaglandin should be given with the 5th dose.