## Food and Drug Administration, HHS

the labeling requirements of §201.105 of this chapter.

- (d) Related tolerances. See §556.360 of this chapter.
- (e) Conditions of use. It is used for animals as follows:
- (1) Dogs and cats—(i) Amount. 5 mg per pound (/lb) of body weight twice daily or 10 mg/lb body weight once daily by intramuscular injection; 5 to 10 mg/lb body weight one or two times daily by slow intravenous injection.
- (ii) Indications for use. Infections caused by Gram-positive organisms, particularly streptococci and staphylococci.
- (iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (2) Swine—(i) Amount. 5 mg/lb body weight once daily by intramuscular injection for 3 to 7 days.
- (ii) *Indications for use*. Treatment of infectious arthritis and mycoplasma pneumonia.
- (iii) *Limitations*. Do not treat within 48 hours of slaughter.

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 31351, Aug. 2, 1985; 67 FR 34388, May 14, 2002; 68 FR 51705, Aug. 28, 2003; 69 FR 11507, Mar. 11, 2004; 69 FR 47361, Aug. 5, 2004; 71 FR 51996, Sept. 1, 2006]

## §522.1289 Lufenuron suspension.

- (a) *Specifications*. Each milliliter of sterile aqueous suspension contains 10 milligrams of lufenuron.
- (b) Sponsor. See No. 058198 in  $\S510.600$ (c) of this chapter.
  - (c) [Reserved]
- (d) Conditions of use—(1) Cats—(i) Amount. 10 milligrams per kilogram (4.5 milligrams per pound) of body weight every 6 months, subcutaneously.
- (ii) Indications for use. For use in cats 6 weeks of age and older, for control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.
- (iii) *Limitations*. For subcutaneous use in cats only. The safety of this product in reproducing animals has not been established. Do not use in dogs. Federal law restricts this drug to use

by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 29552, June 1, 1998]

## § 522.1290 Luprostiol.

- (a) Specifications. Each milliliter of solution contains 7.5 milligrams (mg) luprostiol.
- (b) Sponsor. See No. 051311 in \$510.600(c) of this chapter.
- (c) Special considerations. Labeling shall bear the following statements: Warning: Women of childbearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Luprostiol is readily absorbed through the skin and can cause abortion and/or bronchiospasms. Direct contact with the skin should therefore be avoided. Accidental spillage on the skin should be washed off immediately with soap and water.
- (d) Conditions of use in horses—(1) Amount. 7.5 mg by intramuscular injection.
- (2) Indications for use. For estrus control and termination of pregnancy in mares.
- (3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use in horses intended for human consumption

[55 FR 1185, Jan. 12, 1990, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995; 61 FR 66582, Dec. 18, 1996; 74 FR 25146, May 27, 2009]

## § 522.1315 Maropitant.

- (a) *Specifications*. Each milliliter of solution contains 10 milligrams (mg) maropitant as maropitant citrate.
- (b) Sponsor. See No. 000069 in §510.600(c) of this chapter.
- (c) Conditions of use in dogs—(1) Amount. Administer 1.0 mg per kilogram body weight by subcutaneous injection once daily for up to 5 consecutive days.
- (2) Indications for use. For the prevention and treatment of acute vomiting.