Food and Drug Administration, HHS

§ 522.1289 Lufenuron.

(a) Specifications. Each milliliter of suspension contains 10 milligrams (mg) of lufenuron.

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

(c) Conditions of use in cats—(1) Amount. 10 mg per kilogram (4.5 mg per pound) of body weight every 6 months, by subcutaneous injection.

(2) Indications for use. For control of flea populations in cats 6 weeks of age and older.

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

[79 FR 16191, Mar. 25, 2014]

§ 522.1290 Luprostiol.

(a) Specifications. Each milliliter of solution contains 7.5 milligrams (mg) of 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.


§ 522.1315 Maropitant.

(a) Specifications. Each milliliter of solution contains 10 milligrams (mg) maropitant as maropitant citrate.

(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Dogs—(i) Amount. Administer 1.0 mg per kilogram (mg/kg) of body weight by subcutaneous injection once daily for up to 5 consecutive days.

(ii) Indications for use. For the prevention and treatment of acute vomiting.

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

(2) Cats—(i) Amount. Administer 1.0 mg/kg of body weight by subcutaneous injection once daily for up to 5 consecutive days.

(ii) Indications for use. For the treatment of vomiting.

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


§ 522.1335 Medetomidine.

(a) Specifications. Each milliliter of solution contains 1.0 milligrams of medetomidine hydrochloride.

(b) Sponsor. See 052483 in § 510.600(c) of this chapter.

(c) Conditions of use—(1) Amount. 750 micrograms intravenously (IV) or 1,000 micrograms intramuscularly per square meter of body surface. The IV route is more efficacious for dental care.

(2) Indications for use. As a sedative and analgesic in dogs over 12 weeks of age to facilitate clinical examinations,