use by or on the order of a licensed veterinarian.

[50 FR 43385, Oct. 25, 1985, as amended at 53 FR 23390, June 22, 1988]

§ 520.1341 Megestrol acetate tablets.

(a) *Specifications*. Each tablet contains 5 or 20 milligrams of megestrol acetate.

(b) *Sponsor*. No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*. (1) The drug is used in female dogs for the postponement of estrus and the alleviation of false pregnancy.

(2) It is administered orally, intact, or crushed and mixed with food as follows:

(i) For the postponement of estrus by proestrus treatment, 1 milligram per pound of body weight per day for 8 days.

(ii) For the postponement of estrus by anestrus treatment, 0.25 milligram per pound of body weight per day for 32 days.

(iii) For alleviation of false pregnancy, 1 milligram per pound of body weight per day for 8 days.

(3) Full dosage regimen must be completed to produce the desired effect.

(4) Examination of vaginal smears is recommended to confirm detection of proestrus.

(5) Do not administer for more than two consecutive treatments.

(6) Once therapy is started, the animal should be confined for 3 to 8 days or until cessation of bleeding, since dogs in proestrus accept a male.

(7) Do not use prior to or during first estrus cycle.

(8) Do not use in pregnant animals.

(9) Do not use in the presence of a disease of the reproductive system or with mammary tumors.

(10) Should estrus occur within 30 days after cessation of treatment, mating should be prevented.

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

[40 FR 13838, Mar. 27, 1975, as amended at 52 FR 7832, Mar. 13, 1987]

§ 520.1350 Meloxicam.

(a) *Specifications*. Each milliliter of suspension contains 0.5 or 1.5 milligrams (mg) meloxicam.

(b) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (c) of this section.

(c) *Conditions of use in dogs*—(1) *Amount*. Administer orally as a single dose at 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) on the first day of treatment. For all treatment after day 1, administer 0.045 mg/lb (0.1 mg/kg) body weight once daily.

(2) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis.

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

[68 FR 42968, July 21, 2003, as amended at 69 FR 69523, Nov. 30, 2004]

§ 520.1372 Methimazole.

(a) *Specifications*. Each tablet contains 2.5 or 5 milligrams (mg) methimazole.

(b) *Sponsor*. See No. 043264 in § 510.600 of this chapter.

(c) *Conditions of use in cats*—(1) *Amount*. The starting dose is 2.5 mg every 12 hours. Following 3 weeks of treatment, the dose should be titrated to effect based on individual serum total T4 levels and clinical response.

(2) *Indications for use*. For the treatment of hyperthyroidism.

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

[74 FR 27707, June 11, 2009]

§ 520.1380 Methocarbamol tablets.

(a) *Chemical name*. 3-(O-Methoxyphenoxy)-1,2-propanediol 1-carbamate.

(b) *Specifications*. Each tablet contains 500 milligrams of methocarbamol.

(c) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use*. (1) The drug is administered to dogs and cats as an adjunct to therapy for acute inflammatory and traumatic conditions of the skeletal muscles in order to reduce muscular spasms.

(2) Dosage is based upon severity of symptoms and response noted. The usual initial dose in 60 milligrams per pound of body weight in two or three equally divided doses followed by 30 to 60 milligrams per pound of body weight each following day, usually not to exceed 14 to 21 days.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 67 FR 67521, Nov. 6, 2002]

§ 520.1408 Methylprednisolone tablets.

(a) *Specifications.* Each table contains 1, 2, or 4 milligrams of methylprednisolone.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter for use of 1- and 4-milligram tablets; see No. 000010 for use of 1- and 2-milligram tablets.

(c) *NAS/NRC status.* The conditions of use have been NAS/NRC reviewed and found effective. NADA's for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Special consideration.* (1) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) Systemic therapy with methylprednisolone is contraindicated in animals with arrested tuberculosis, peptic ulcer, acute psychoses, or cushingoid syndrome. The presence of active tuberculosis, diabetes, osteoporosis, chronic psychotic reactions, predisposition to thrombophlebitis, hypertension, congestive heart failure, or renal insufficiency necessitates carefully controlled use of corticosteroids. Some of these conditions occur only rarely in dogs and cats but should be kept in mind.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.

(e) *Conditions of use*—(1) *Amount.* Dogs and cats: 5 to 15 pounds, 2 milligrams; 15 to 40 pounds, 2 to 4 milligrams; 40 to 80 pounds, 4 to 8 milligrams.

(2) *Indications for use.* For use in dogs and cats as an anti-inflammatory agent.

(3) *Limitations.* Administer total daily dose orally in equally divided doses 6 to 10 hours apart until response is noted or 7 days have elapsed. When response is attained, dosage should be gradually reduced until maintenance level is achieved. Hazardous for human use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 52697, Nov. 23, 1982, as amended at 49 FR 20810, May 17, 1984; 50 FR 32844, Aug. 15, 1985; 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 520.1409 Methylprednisolone, aspirin tablets.

(a) *Specifications.* Each tablet contains 0.5 milligram of methylprednisolone and 300 milligrams of aspirin.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *NAS/NRC status.* The conditions of use have been NAS/NRC reviewed and found effective. New animal drug applications for approval of drugs for these conditions of use need not include effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(d) *Special considerations.* (1) Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

(2) Systemic therapy with methylprednisolone is contraindicated in animals with tuberculosis, chronic nephritis, peptic ulcer, or Cushingoid syndrome. The presence of diabetes mellitus, osteoporosis, predisposition to thrombophlebitis, hypertension, congestive heart failure, or renal insufficiency necessitates carefully controlled use of corticosteroids.

(3) Anti-inflammatory action of corticosteroids may mask signs of infection.