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

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount.* Administer orally as needed, as a single daily dose based on body weight.

(i) 1 to 2 mg/kilograms (kg) (0.45 to 0.91 mg/pound (lb), for use as in paragraph (d)(2)(i) of this section.

(ii) 3 to 4 mg/kg (1.4 to 1.8 mg/lb) for up to 7 days, for use as in paragraph (d)(2)(ii) of this section.

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

(ii) For the control of postoperative pain and inflammation associated with orthopedic surgery in dogs weighing 4 or more pounds (1.8 kg).

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

[67 FR 68760, Nov. 13, 2002, as amended at 68 FR 18882, Apr. 17, 2003; 72 FR 37437, July 10, 2007; 73 FR 33692, June 13, 2008]

§ 520.540 Dexamethasone oral dosage forms.

§ 520.540a Dexamethasone powder.

(a) *Specifications.* Dexamethasone powder is packaged in packets containing 10 milligrams of dexamethasone.

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

(c) *Conditions of use.* (1) Dexamethasone powder is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug is used as supportive therapy for management or inflammatory conditions such as acute arthritic lameness, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(2) The drug is administered at a dosage level of 5 to 10 milligrams per animal the first day then 5 milligrams per day as required by drench or by sprinkling on a small amount of feed.

(3) 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.

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[40 FR 13838, Mar. 27, 1975; 41 FR 9149, Mar. 3, 1976; 52 FR 7832, Mar. 13, 1987; 70 FR 16934, Apr. 4, 2005]

§ 520.540b Dexamethasone tablets and boluses.

(a)(1) *Specifications.* Each bolus is half-scored and contains 10 milligrams of dexamethasone.

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

(3) *Conditions of use.* (i) Dexamethasone bolus is indicated in cases where cattle and horses require additional steroid therapy following its parenteral administration. The drug may be used as supportive therapy for management of inflammatory conditions such as acute arthritic lamenesses, and for various stress conditions where corticosteroids are required while the animal is being treated for a specific condition.

(ii) Administered orally, 5 to 10 milligrams for the first day, then 5 milligrams per day as required.

(iii) Do not use in viral infections during the viremic stage. With bacterial infections, appropriate antibacterial therapy should be used.

(iv) Do not use in animals with chronic nephritis and hypercorticalism (cushingoid syndrome), except for emergency therapy.

(v) Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection 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.

(vi) Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.