(c) *Related tolerances.* See § 556.169 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* 6 mg per kilogram of body weight by subcutaneous injection. Treatment should be repeated approximately 48 hours following the first injection.

(2) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia (Pasteurella) haemolytica* and *Pasteurella multocida.*

(3) *Limitations.* Animals intended for human consumption should not be slaughtered within 4 days from the last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

[67 FR 78972, Dec. 27, 2002]

§ 522.533 Deslorelin acetate.

(a) *Specifications.* Each implant contains 2.1 milligrams deslorelin acetate.

(b) *Sponsor.* See 064288 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Horses and ponies*—(i) *Amount.* One implant per mare.

(ii) *Indications for use.* For inducing ovulation within 48 hours in estrous mares with an ovarian follicle greater than 30 millimiters in diameter. Follicular size should be determined by rectal palpation and/or ultrasonography prior to treatment.

(iii) *Limitations.* Administer subcutaneously in the neck. Not for use in horses or ponies intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 44383, Aug. 19, 1998]

§ 522.535 Desoxycorticosterone pivalate.

(a) *Specifications.* Each milliliter of sterile aqueous suspension contains 25 milligrams of desoxycorticosterone pivalate.

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

(c) [Reserved]

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(ii) *Indications for use.* For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

(iii) *Limitations.* For intramuscular use only. Do not use in pregnant dogs, dogs suffering from congestive heart disease, severe renal disease, or edema. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[63 FR 13122, Mar. 18, 1998]

§ 522.536 Detomidine hydrochloride injection.

(a) *Specification.* Each milliliter of sterile aqueous solution contains 10 milligrams of detomidine hydrochloride.

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

(c) *Conditions of use*—(1) *Amount.* For sedation, analgesia, or sedation and analgesia: 20 or 40 micrograms per kilogram (0.2 or 0.4 milliliter per 100 kilogram or 220 pounds) by body weight, depending on depth and duration required.

(2) *Indication for use.* As a sedative and analgesic to facilitate minor surgical and diagnostic procedures in mature horses and yearlings.

(3) *Limitations.* For sedation administer intraveneously (IV) or intramuscularly (IM); for analgesia by IV; for both sedation and analgesia by IV. Do not use in horses with pre-existing atrioventricular or sinoauricular block, with severe coronary insufficiency, cerebrovascular disease, respiratory disease, or chronic renal failure. Do not use in breeding animals. Not for use in horses intended for food. Federal law restricts this drug to use

by or on the order of a licensed veterinarian.

[54 FR 50365, Dec. 6, 1989; 54 FR 51551, Dec. 15, 1989]

§ 522.540 Dexamethasone injection.

(a)(1) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) dexamethasone.

(2) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(i) Nos. 000061, 059130, and 061623 for use as in paragraph (a)(3) of this section.

(ii) No. 058005 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) *Conditions of use*—(i) *Amount.* The drug is administered intravenously or intramuscularly and dosage may be repeated if necessary, as follows:

(A) *Dogs.* 0.25 to 1 mg.

(B) *Cats.* 0.125 to 0.5 mg.

(C) *Horses.* 2.5 to 5 mg.

(D) *Cattle.* 5 to 20 mg, depending on the severity of the condition.

(ii) *Indications for use.* The drug is indicated:

(A) For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses;

(B) As an anti-inflammatory agent in dogs and cats.

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

(b)(1) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains either 2.0 milligrams of dexamethasone or 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3.0 milligrams dexamethasone).

(2) *Sponsor.* See number in § 510.600(c) of this chapter as follows:

(i) No. 061623 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(ii) No. 000402 for use of 2.0 milligrams dexamethasone or 4.0 milligrams dexamethasone sodium phosphate injections.

(3) *Conditions of use.* (i) The drug is used in dogs for the treatment of inflammatory conditions, as supportive therapy in canine posterior paresis, as supportive therapy before or after surgery to enhance recovery of poor surgical risks, and as supportive therapy in nonspecific dermatosis. [1]

(ii) The drug is administered intravenously at 0.25 to 1 milligram initially. The dose may be repeated for 3 to 5 days or until a response is noted. If continued treatment is required, oral therapy may be substituted. When therapy is withdrawn after prolonged use, the daily dose should be reduced gradually over several days. [1]

(iii) 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.

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

(c)(1) *Specifications.* The drug is a sterile aqueous solution. Each milliliter contains 2.0 milligrams of dexamethasone or 4.0 milligrams of dexamethasone sodium phosphate (equivalent to 3.0 milligrams of dexamethasone).

(2) *Sponsor.* See Nos. 000402 and 061623 in § 510.600(c) of this chapter.

(3) *Conditions of use.* (i) The drug is used as a rapid adrenal glucocorticoid and/or anti-inflammatory agent in horses. [1]

(ii) The drug is administered intravenously at a dosage of 2.5 to 5.0 milligrams. If permanent corticosteroid effect is required, oral therapy may be substituted. When therapy is withdrawn after prolonged use, the daily dose should be reduced gradually over several days. [1]

(iii) 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.

[1] These conditions are NAS/NRC-reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.