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

[41 FR 28265, July 9, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.540, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 522.542 Dexamethasone-21-isonicotinate suspension.

(a) *Specifications.* Each milliliter of sterile suspension contains 1 milligram of dexamethasone-21-isonicotinate.

(b) *Sponsor.* No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used in the treatment of various inflammatory conditions associated with the musculoskeletal system in dogs, cats, and horses.

(2) It is recommended for intramuscular administration as follows: Dogs—0.25 to 1 milligram; cats—0.125 to 0.5 milligram; horses—5 to 20 milligrams. Dosage may be repeated.

(3) Clinical and experimental data have demonstrated that corticosteriods 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 following by dystocia, fetal death, retained placenta, and metritis.

(4) Not for use in horses intended for food.

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

[42 FR 37543, July 22, 1977, as amended at 47 FR 14703, Apr. 6, 1982]

§ 522.558 Dexmedetomidine.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligram (mg) of dexmedetomidine hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Indications for use and amount.* (A) For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures, administer 375 micrograms (µg) per square meter (/m^2) of body surface area by intravenous injection or 500 µg/m^2 of body surface area by intramuscular injection.

(B) For use as a preanesthetic to general anesthesia, administer 125 µg/m^2 of body surface area or 375 µg/m^2 of body surface area by intramuscular injection.

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

(2) *Cats*—(i) *Amount.* 40 µg/killogram by intramuscular injection.

(ii) *Indications for use.* For use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures, and minor dental procedures; and as a preanesthetic to general anesthesia.

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

[72 FR 263, Jan. 4, 2007, as amended at 72 FR 19797, Apr. 20, 2007; 72 FR 51365, Sept. 7, 2007; 75 FR 60308, Sept. 30, 2010]

§ 522.563 Diatrizoate meglumine and diatrizoate sodium injection.

(a) *Specifications.* Diatrizoate meglumine and diatrizoate sodium injection contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium, in sterile aqueous solution.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is indicated for use in dogs and cats for visualization in excretion urography, including renal angiography, uretography, cystography, and urethrography; aortography; angiocardiography, peripheral arteriography, and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography. It is also useful as an aid in delineating peritoneal hernias and fistulous tracts.

(2) For excretion urography administer 0.5 to 1.0 milliliter per pound of body weight to a maximum of 30 milliliters intravenously. For cystography remove urine, administer 5 to 25 milliliters directly into the bladder via catheter. For urethrography administer 1.0 to 5 milliliters via catheter

into the urethra to provide desired contrasts delineation. For angiocardiography (including aortography) rapidly inject 5 to 10 milliliters directly into the heart via catheter or intraventricular puncture. For cerebral angiography rapid injection of 3 to 10 milliliters via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography rapidly inject 3 to 10 milliliters intravascularly into the vascular bed to be delineated. For lymphography slowly inject 1.0 to 10 milliliters directly into the lymph vessel to be delineated. For arthrography slowly inject 1.0 to 5 milliliters directly into the joint to be delineated. For discography slowly inject 0.5 to 1.0 milliliter directly into the disc to be delineated. For sialography slowly inject 0.5 to 1.0 milliliter into the duct to be delineated. For delineation of fistulous tracts slowly inject quantity necessary to fill the tract. For delineation of peritoneal hernias inject 0.5 to 1.0 milliliter per pound of body weight directly into the peritoneal cavity.

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

[44 FR 12993, Mar. 9, 1979, as amended at 50 FR 41489, Oct. 11, 1985]

§ 522.650 Dihydrostreptomycin sulfate injection.

(a) *Specifications*. Each milliliter contains dihydrostreptomycin sulfate equivalent to 500 milligrams of dihydrostreptomycin.

(b) *Sponsor*. See Nos. 000069 and 055529 in § 510.600(c) of this chapter.

(c) *National Academy of Sciences/National Research Council (NAS/NRC) status*. The conditions of use were NAS/NRC reviewed and found 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.

(d) *Conditions of use*—(1) *Amount*. 5 milligrams per pound of body weight every 12 hours.

(2) *Indications for use*. Treatment of leptospirosis in dogs and horses due to *Leptospira canicola*, *L. icterohemorrhagiae*, and *L. pomona;* in cattle due to *L. pomona;* and in swine due to *L. pomona;* and *L. grippotyphosa*.

(3) *Limitations*. Administer by deep intramuscular injection only. Treatment should be continued for 3 to 5 days or until the urine is free of leptospira for at least 72 hours as measured by darkfield microscopic examination. Treatment with subtherapeutic dosages, excessive duration of therapy, or inappropriate use of this antibiotic may lead to the emergence of streptomycin or dihydrostreptomycin resistant organisms. Discontinue use 30 days before slaughter for food. Not for use in animals producing milk because use of the drug will contaminate the milk. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37331, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 522.690 Dinoprost solution.

(a) *Specifications*. Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to 5 milligrams (mg) dinoprost.

(b) *Sponsors*. See Nos. 000009 and 059130 in § 510.600(c) of this chapter.

(c) *Special considerations*. (1) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and bronchiospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 1 mg per 100 pounds of body weight as a single intramuscular injection.

(ii) *Indications*. For its luteolytic effect to control timing of estrus in estrus cycling mares and in clinically anestrous mares that have a corpus luteum.

(iii) *Limitations*. Not for use in horses intended for food.

(2) *Cattle*—(i) *Beef cattle and nonlactating dairy heifers*—(A) *Amount*. 25 mg as an intramuscular injection either once or twice at a 10- to 12-day interval.

(B) *Indications*. For its luteolytic effect to control timing of estrus and