

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

(3) *Clinical and experimental data.* It has been 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) *Restrictions.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 41 FR 27316, July 2, 1976; 52 FR 7832, Mar. 13, 1987]

#### § 522.204 Boldenone undecylenate injection.

(a) *Specifications.* Each milliliter contains 25 or 50 milligrams of boldenone undecylenate in a sesame oil base.

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

(c) *Conditions of use.* (1) It is intended for use as an aid in treating debilitated horses following disease or overwork and overexertion when an improvement in weight, hair coat, or general physical condition is desired. The drug is given only as adjunctive therapy to other specific and supportive therapy for diseases, surgical cases, and traumatic injuries. Optimal results can be expected only when good management and feeding practices are followed.

(2) It is administered intramuscularly at a dosage level of 0.5 milligram per pound of body weight. Treatment may be repeated at 3-week intervals.

(3) For use in horses only. Do not administer to horses intended for use as food. The effectiveness of the drug in stallions and pregnant mares has not been established, nor has the drug been shown not to be teratogenic in pregnant mares; therefore, this drug should not be used in stallions and pregnant mares.

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

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 41489, Oct. 11, 1985]

#### § 522.234 Butamisol hydrochloride.

(a) *Specifications.* The drug contains 11 milligrams of butamisol per milliliter in a solution consisting of 70 percent propylene glycol, 4 percent benzyl alcohol and distilled water.

(b) *Sponsor.* See Nos. 000859 and 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is administered by subcutaneous injection to dogs for the treatment of infections with whipworms (*Trichuris vulpis*), and the hookworm (*Ancylostoma caninum*).

(2) The drug is administered subcutaneously at the rate of 0.1 milliliter per pound of body weight. In problem cases, retreatment for whipworms may be necessary in approximately 3 months. For hookworms, a second injection should be given 21 days after the initial treatment.

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

[43 FR 15625, Apr. 14, 1978. Redesignated at 43 FR 60883, Dec. 29, 1978, and amended at 45 FR 29789, May 6, 1980; 51 FR 19329, May 29, 1986; 67 FR 63055, Oct. 10, 2002]

#### § 522.246 Butorphanol tartrate injection.

(a) *Specifications.* Each milliliter of aqueous solution contains either 0.5, 2 or 10 milligrams of butorphanol (as butorphanol tartrate).

(b) *Sponsors.* Approval to firms identified in § 510.600(c) of this chapter for use as indicated:

(1) See No. 057926 for use as in paragraph (c)(2) of this section.

(2) See No. 000856 for use as in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 0.025 milligram of butorphanol base activity per pound of body weight (equivalent to 0.5 milliliter per 10 pounds), using 0.5 milligram per milliliter solution.

(ii) *Indications for use.* For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

(iii) *Limitations.* For subcutaneous injection in dogs only. Repeat at intervals of 6 to 12 hours as required. If necessary, increase dose to maximum of 0.05 milligram per pound of body weight. Treatment should not normally be required for longer than 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Horses*—(i) *Amount.* 0.05 milligram of butorphanol base activity per pound of body weight (0.1 milligram/kilogram) using 10 milligrams per milliliter solution.

(ii) *Indications for use.* For the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

(iii) *Limitations.* For intravenous use in horses only. Dose may be repeated within 3 to 4 hours. Treatment should not exceed 48 hours. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cats*—(i) *Amount.* 0.2 milligram of butorphanol base activity per pound of body weight (0.4 milligram/kilogram), using 2 milligrams per milliliter solution.

(ii) *Indications for use.* For the relief of pain in cats caused by major or minor trauma, or pain associated with surgical procedures.

(iii) *Limitations.* For subcutaneous injection in cats only. Dose may be repeated up to 4 times per day. Do not treat for more than 2 days. Safety for use in pregnant female cats, breeding male cats or kittens less than 4 months of age has not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[45 FR 29276, May 2, 1980, as amended at 50 FR 24508, June 11, 1985; 53 FR 27851, July 25, 1988; 59 FR 41665, Aug. 15, 1994; 63 FR 66432, Dec. 2, 1998]

#### §522.311 Carfentanil citrate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 3 milligrams of carfentanil citrate.

(b) *Sponsor.* See No. 053923 in §510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* 5 to 20 micrograms per kilogram (.005 to .020 milligram per kilogram) of body weight.

(2) *Indications for use.* For immobilizing free ranging and confined members of the family Cervidae (deer, elk, and moose).

(3) *Limitations.* Inject into large muscle of neck, shoulder, back, or hindquarter. Avoid intrathoracic, intra-abdominal, or subcutaneous injection. To reverse effect, use 7 milligrams of diprenorphine for each milligram of carefentanil citrate, given intravenously or one-half intravenously and one-half intramuscularly or subcutaneously. Do not use in domestic animals intended for food. Do not use 30 days before or during hunting season. Do not use in animals that display clinical signs of severe cardiovascular or respiratory disease. Available data are inadequate to recommend use in pregnant animals. Avoid use during breeding season. Federal law restricts this drug to use by or on the order of a licensed veterinarian. The licensed veterinarian shall be a veterinarian engaged in zoo and exotic animal practice, wildlife management programs, or research.

[53 FR 40057, Oct. 13, 1988]

#### §522.313 Ceftiofur sodium powder for injection.

(a) *Specifications.* Ceftiofur sodium sterile powder for injection is reconstituted to form an aqueous solution containing the equivalent of 50 milligrams ceftiofur per milliliter.

(b) *Sponsor.* See 000009 in §510.600 of this chapter.

(c) *Related tolerances.* See §556.113 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 0.5 to 1.0 milligram of ceftiofur per pound of body weight intramuscularly or subcutaneously.

(ii) *Indications for use.* Treatment of bovine respiratory disease (shipping fever, pneumonia) associated with *Pasteurella hemolytica*, *P. multocida*, and *Haemophilus somnus* in beef and dairy cattle. Also, for the treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(iii) *Limitations.* Treatment should be repeated once every 24 hours for 3 days.