

etorphine hydrochloride injection, veterinary, the use of which is provided for in § 522.883, in wild and exotic animals.

(3) *Limitations.* For use in wild or exotic animals only. Do not use in domestic food-producing animals. Do not use 30 days before, or during, the hunting season in free-ranging wild animals that might be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Distribution is restricted to veterinarians engaged in zoo and exotic animal practice, wildlife management programs, and researchers.

[79 FR 16187, Mar. 25, 2014]

§ 522.728 Dipyrone.

(a) *Specifications.* Each milliliter of solution contains 500 milligrams (mg) dipyrone.

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

(c) *Conditions of use in horses—(1) Amount.* Administer 30 mg per kilogram of body weight (13.6 mg per pound) by intravenous injection, once or twice daily at a 12-hour interval for up to 3 days.

(2) *Indications for use.* For control of pyrexia in horses.

(3) *Limitations.* Do not use in horses intended for human consumption. Do not use in any food-producing animals, including lactating dairy animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[85 FR 18119, Apr. 1, 2020, as amended at 88 FR 14898, Mar. 10, 2023]

§ 522.770 Doramectin.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams of doramectin.

(b) *Sponsors.* See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.222 of this chapter.

(d) *Conditions of use—(1) Cattle—(i) Amount.* 200 micrograms per kilogram (10 milligrams per 110 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. To control infections and to protect from reinfection with *Cooperia*

oncophora and *Haemonchus placei* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

(iii) *Limitations.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle for human consumption within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Swine—(i) Amount.* 300 micrograms per kilogram (10 milligrams per 75 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.

(iii) *Limitations.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Administer as a single intramuscular injection. Do not slaughter swine for human consumption within 24 days of treatment.

[61 FR 53321, Oct. 11, 1996, as amended at 62 FR 44410, Aug. 21, 1997; 62 FR 62242, Nov. 21, 1997; 63 FR 68183, Dec. 10, 1998; 64 FR 13509, Mar. 19, 1999; 79 FR 16187, Mar. 25, 2014; 84 FR 32992, July 11, 2019; 88 FR 55564, Aug. 16, 2023]

§ 522.772 Doramectin and levamisole.

(a) *Specifications.* Each milliliter of solution contains 5 milligrams (mg) of doramectin and 150 mg levamisole hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See §§ 556.222 and 556.350 of this chapter.

(d) *Conditions of use—(1) Cattle—(i) Amount.* Inject subcutaneously in the neck as a single dose at a dosage of 0.2 mg doramectin (0.91 mg/lb) and 6 mg of levamisole hydrochloride per kg (2.72 mg/lb) of body weight.

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms (adults and fourth stage larvae): *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata*, *Haemonchus placei*, *Trichostrongylus axei*, *T.*

§ 522.784

colubriiformis, *T. longispicularis* (adults only), *Oncophora*, *Cooperia pectinata* (adults only), *C. punctata*, *C. surnabada*, *Bunostomum phlebotomum* (adults only), *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum*, *Trichuris* spp. (adults only) and *Nematodirus helvetianus* (adults only); lungworms (adults and fourth stage larvae): *Dictyocaulus viviparus*; eyeworms (adults): *Thelazia* spp.; grubs (parasitic stages): *Hypoderma bovis* and *H. lineatum*; sucking lice: *Haematopinus eurysternus*, *Linognathus vituli*, and *Solenopotes capillatus*; mange mites: *Psoroptes bovis* and *Sarcoptes scabiei* in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age. Not for use in beef bulls intended for breeding over 1 year of age, dairy calves, and veal calves.

(iii) *Limitations*. Cattle must not be slaughtered for human consumption within 15 days following last treatment with this drug product. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows; use in these cattle may cause drug residues in milk and/or in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[88 FR 14898, Mar. 10, 2023; 89 FR 85426, Oct. 28, 2024]

§ 522.784 Doxylamine.

(a) *Specifications*. Each milliliter contains 11.36 milligrams (mg) of doxylamine succinate.

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

(c) *Conditions of use*—(1) *Amount*—(i) *Horses*: Administer 25 mg per hundred pounds of body weight by intramuscular, subcutaneous, or slow intravenous injection.

(ii) *Dogs and cats*: Administer 0.5 to 1 mg per pound of body weight by intramuscular or subcutaneous injection. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect.

(2) *Indications for use*. For use in conditions in which antihistaminic ther-

21 CFR Ch. I (4–1–25 Edition)

apy may be expected to alleviate some signs of disease in horses, dogs, and cats.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16187, Mar. 25, 2014]

§ 522.800 Droperidol and fentanyl.

(a) *Specifications*. Each milliliter of solution contains 20 milligrams (mg) of droperidol and 0.4 mg of fentanyl citrate.

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

(c) *Conditions of use*—(1) *Amount*. (i) For analgesia and tranquilization, administer as follows:

(A) 1 milliliter (mL) per 15 to 20 pounds (lbs) of body weight by intramuscular injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight; or

(B) 1 mL per 25 to 60 lbs of body weight by intravenous injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight.

(ii) For general anesthesia, administer as follows:

(A) Administer 1 mL per 40 lbs of body weight by intramuscular injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight and followed in 10 minutes by an intravenous administration of sodium pentobarbital at the rate of 3 mg per pound of body weight; or

(B) Administer 1 mL per 25 to 60 lbs of body weight by intravenous injection in conjunction with atropine sulfate administered at the rate of 0.02 mg per pound of body weight and followed within 15 seconds by an intravenous administration of sodium pentobarbital at the rate of 3 mg per pound of body weight.

(2) *Indications for use*. As an analgesic and tranquilizer and for general anesthesia.

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

[79 FR 16187, Mar. 25, 2014]