is seen in 3 to 5 days, reevaluate diagnosis; a complete blood count should be done periodically for prolonged use; not for use in horses intended for food; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 241, Jan. 4, 1983, as amended at 48 FR 23180, May 24, 1983; 48 FR 42809, Sept. 20, 1983; 61 FR 5507, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.2615 Tripelennamine hydrochloride injection.

(a) *Specifications.* Each milliliter of aqueous solution contains 20 milligrams of tripelennamine hydrochloride.

(b) *Sponsor.* See Nos. 053501 and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.741 of this chapter.

(d) *Conditions of use*—(1) *Amount*—(i) *Dogs, cats, and horses.* For intramuscular use only at a dose of 0.5 milligram per pound of body weight.

(ii) *Cattle.* Administer intravenously or intramuscularly at a dose of 0.5 milligram per pound of body weight.

(2) *Indications for use.* For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(3) *Limitations.* Do not use in horses intended for food purposes. Treated cattle must not be slaughtered for food during treatment and for 4 days following the last treatment. Milk that has been taken during treatment and for 24 hours (two milkings) after the last treatment must not be used for food. A withdrawal period has not been established for this product in preruminating 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.

[51 FR 44450, Dec. 10, 1986, as amended at 61 FR 29480, June 11, 1996; 62 FR 4164, Jan. 29, 1997]

§ 522.2640 Tylosin injectable dosage forms.

§ 522.2640a Tylosin injection.

(a) *Specifications.* Each milliliter of sterile solution of 50 percent propylene glycol with 4 percent benzyl alcohol contains 50 to 200 milligrams of tylosin activity (as tylosin base). Tylosin conforms to the appropriate antibiotic standard. Tylosin contains at least 95 percent tylosin as a combination of tylosin A, tylosin B, tylosin C, and tylosin D of which at least 80 percent is tylosin A as determined by a method entitled ''Determination of Factor Content in Tylosin by High Performance Liquid Chromatography,'' which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20001.

(b) *Sponsors.* (1) See No. 000986 in § 510.600(c) of this chapter for use in paragraphs (e)(1), (2), and (3) of this section.

(2) See No. 000010 in § 510.600(c) of this chapter for use as in paragraphs (e)(1) and (2) of this section.

(c) *NAS/NRC status.* These conditions of use are NAS/NRC reviewed and found effective. NADA's for these uses need not include effectiveness data as specified by § 514.111 of this chapter but may require bioequivalency and safety information.

(d) *Related tolerances.* See § 556.740 of this chapter.

(e) *Conditions of use*—(1) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* 8 milligrams per pound of body weight once daily.

(ii) *Indications for use.* Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with *Pasteurella multocida* and *Corynebacterium pyogenes;* foot rot (necrotic pododermatitis) and calf diphtheria caused by *Fusobacterium necrophorum* and metritis caused by *Corynebacterium pyogenes.*

(iii) *Limitations.* Administer intramuscularly for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear. Do not inject more than 10 milliliters per site. Do not use in lactating dairy cattle. Use a 50-milligram-per-milliliter solution for calves weighing less than 200 pounds. Do not administer within 21 days of slaughter.