

(2) [Reserved]

[61 FR 14482, Apr. 2, 1996, as amended at 61 FR 29479, June 11, 1996]

**§ 522.2483 Sterile triamcinolone acetonide suspension.**

(a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams triamcinolone acetonide.

(b) *Sponsor.* See 000010 and 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount—(i) Dogs and cats—(a) Intramuscular or subcutaneous.* Single injection of 0.05 to 0.1 milligram (mg.) per pound of body weight in inflammatory, arthritic, or allergic disorders. Single injection of 0.1 mg. per pound of body weight in dermatologic disorders. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted.<sup>1</sup>

(b) *Intralesional.* 1.2 to 1.8 mg., divided in several injections, spaced around the lesion at 0.5 to 2.5 centimeters apart depending on the size. At any one site the dose injected should not exceed 0.6 mg. and should be well into the cutis to prevent rupture of the epidermis. When treating animals with multiple lesions, do not exceed a total dose of 6 mg.

(c) *Intra-articular and intrasynovial.* Single injection of 1 to 3 mg. dose, dependent on size of joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 3 mg.

(ii) *Horses—(a) Intramuscular or subcutaneous.* Single injection of 0.01 to 0.02 mg. per pound of body weight. Usual dose, 12 to 20 mg.

(b) *Intra-articular and intrasynovial.* Single injection of 6 to 18 mg. dose, dependent on size of joint and severity of symptoms. After 3 or 4 days, repeat dosage if indicated. If initial results are inadequate or too transient, dosage may be increased, not to exceed 18 mg.

(2) *Indications for use.* Treatment of inflammation and related disorders in dogs, cats, and horses;<sup>1</sup> and manage-

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

ment and treatment of acute arthritis and allergic and dermatologic disorders in dogs and cats.

(3) *Limitations.* (i) Do not use in viral infections. With bacterial infections, appropriate antibacterial therapy should be used.

(ii) Do not use in animals with tuberculosis, chronic nephritis, or cushingoid syndrome, except for emergency therapy.

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

(iv) 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.

(v) Do not use in the treatment of laminitis.

(vi) Intra-articular injection in equine leg injuries may produce osseous metaplasia.

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

[43 FR 4976, Feb. 7, 1978, as amended at 50 FR 41490, Oct. 11, 1985; 52 FR 1903, Jan. 16, 1987; 53 FR 40728, Oct. 18, 1988; 62 FR 35077, June 30, 1997]

**§ 522.2582 Triflupromazine hydrochloride injection.**

(a) *Specifications.* Triflupromazine hydrochloride injection contains 20 milligrams of triflupromazine hydrochloride in each milliliter of sterile aqueous solution.

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

(c) *Conditions of use.* (1) The drug is used in dogs, cats, and horses to relieve anxiety and to help control psychomotor overactivity as well as to increase the tolerance of animals to pain and pruritus. The drug is indicated in various office and clinical procedures which require the aid of a tranquilizer, antiemetic, or preanesthetic.<sup>1</sup>

(2) The drug is administered to dogs either intravenously at a dosage level of 0.5 to 1 milligram per pound of body weight daily, or intramuscularly at a dosage level of 1 to 2 milligrams per