

§ 522.23

522.2444b Sodium thiopental, sodium pentobarbital for injection.
522.2470 Tiletamine hydrochloride and zolazepam hydrochloride for injection.
522.2471 Tilmicosin phosphate injection.
522.2474 Tolazoline hydrochloride injection.
522.2476 Trenbolone acetate.
522.2477 Trenbolone acetate and estradiol.
522.2478 Trenbolone acetate and estradiol benzoate.
522.2483 Sterile triamcinolone acetonide suspension.
522.2582 Triflupromazine hydrochloride injection.
522.2610 Trimethoprim and sulfadiazine sterile suspension.
522.2615 Tripeleminamine hydrochloride injection.
522.2640 Tylosin injectable dosage forms.
522.2640a Tylosin injection.
522.2640b Tylosin tartrate for injection.
522.2662 Xylazine hydrochloride injection.
522.2670 Yohimbine injectable.
522.2680 Zeranol.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13858, Mar. 27, 1975, unless otherwise noted.

§ 522.23 Acepromazine maleate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 10 milligrams of acepromazine maleate.

(b) *Conditions of use.* See No. 000856 in § 510.600(c) of this chapter for use in dogs, cats, and horses as follows:

(1) *Indications for use.* It is used in dogs, cats, and horses as a tranquilizer.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight; Cats: 0.5 to 1.0 milligram per pound of body weight; Horses: 2.0 to 4.0 milligrams per 100 pounds of body weight.

(c) *Conditions of use.* See No. 000010 in § 510.600(c) of this chapter for use in dogs as follows:

(1) *Indications for use.* It is used in dogs as an aid in tranquilization and as a preanesthetic agent.

(2) *Amount.* Dogs: 0.25 to 0.5 milligram per pound of body weight.

(3) *Limitations.* The drug is administered intravenously, intramuscularly or subcutaneously with the dosage individualized depending upon the degree of tranquilization required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[46 FR 43831, Sept. 1, 1981, as amended at 53 FR 40727, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

21 CFR Ch. I (4-1-01 Edition)

§ 522.44 Sterile sodium acetazolamide.

(a) *Specifications.* Sterile sodium acetazolamide contains acetazolamide sodium complying with United States Pharmacopeia as a sterile powder with directions for reconstituting the product with sterile distilled water to furnish a product having a concentration of 100 milligrams acetazolamide activity per milliliter.

(b) *Sponsor.* See No. 010042 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an aid in the treatment of dogs with mild congestive heart failure and for rapid reduction of intraocular pressure.¹

(2) It is administered intramuscularly or intraperitoneally to dogs at a level of 5 to 15 milligrams per pound of body weight daily preferably administered in two or more divided doses.¹

(3) For use only by or on the order of a licensed veterinarian.¹

§ 522.46 Alfaprostol.

(a) *Specifications.* Each milliliter of sterile solution contains 1 milligram of alfaprostol.

(b) *Sponsor.* No. 055882 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used in horses as follows:

(1) *Amount.* For average mature mares, 6.0 micrograms per kilogram of body weight.

(2) *Indications for use.* To cause luteolysis in mares with active corpora lutea.

(3) *Limitations.* For intramuscular or subcutaneous use as a single injection. Not for horses intended for food. Alfaprostol is readily absorbed through the skin and can cause abortion and/or bronchial spasms. Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory

¹These conditions are NAS/NRC reviewed and deemed 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.