pounds of body weight (40 milligrams per 12 pounds of body weight).

(iv) Cattle: Short duration, 20 milligrams per 5 pounds of body weight; longer duration, 40 milligrams per 7 pounds of body weight.

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

(4) NAS/NRC status: The conditions of use specified in this paragraph are NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter, but may require bioequivalency and safety information.

[40 FR 25812, June 19, 1975, as amended at 49 FR 8434, Mar. 7, 1984; 53 FR 23390, June 22, 1988; 53 FR 40728, Oct. 18, 1988; 62 FR 35076, June 30, 1997]

§ 522.2444 Sodium thiopental implantation or injectable dosage forms.

§ 522.2444a Sodium thiopental for injection.

(a) *Specifications.* The drug contains sodium thiopental sterile powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical and other procedures. It is also used to induce anesthesia in dogs and cats which then have surgical anesthesia maintained by use of a volatile anesthetic.

(2) It is administered as follows:

(i) For brief anesthesia (6 to 10 minutes) a dosage of 6 to 9 milligrams per pound of body weight is suggested.

(ii) To obtain anesthesia of 15 to 25 minutes duration the suggested dosage is 10 to 12 milligrams per pound of body weight.

(iii) Use of a preanesthetic tranquilizer or morphine will decrease the dosage of sodium thiopental required, provide for smoother induction and smoother recovery, and sometimes prolong the recovery period. If morphine is used as a preanesthetic agent the dose of the barbiturate can be reduced as much as 40 to 50 percent. When a tranquilizer is administered the barbiturate dosage can be reduced 10 to 25 percent.

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

§ 522.2444b Sodium thiopental, sodium pentobarbital for injection.

(a) *Specifications.* Each gram of the drug contains 750 milligrams of sodium thiopental and 250 milligrams of sodium pentobarbital sterile powder for dilution with sterile water for injection.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used as an anesthetic for intravenous administration to dogs and cats during short to moderately long surgical procedures.

(2) It is administered as follows:

(i) For total anesthesia, it is given at approximately 10 to 12 milligrams per pound of body weight over a period of 3.5 to 5 minutes.

(ii) When preanesthetic medication is used, it is important to wait at least an hour before administering thiopental and sodium pentobarbital for injection, and the dosage necessary for anesthesia is reduced. Usually ½ to ⅔ the normal amount is adequate.

(3) 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 47 FR 14149, Apr. 2, 1982; 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 522.2470 Tiletamine hydrochloride and zolazepam hydrochloride for injection.

(a) *Specifications.* Tiletamine hydrochloride and zolazepam hydrochloride for injection when reconstituted with sterile distilled water provides tiletamine hydrochloride and zolazepam hydrochloride equivalent to 50 milligrams of tiletamine base and 50 milligrams of zolazepam base per milliliter of solution.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* It is used for restraint or for anesthesia combined with muscle relaxation in cats and in dogs for restraint and minor procedures of short

duration (30 minutes) requiring mild to moderate analgesia.

(2) *Amount.* Expressed as milligrams of the drug combination:

(i) In healthy dogs: An initial intramuscular dosage of 3 to 4.5 milligrams per pound of body weight for diagnostic purposes; 4.5 to 6 milligrams per pound of body weight for minor procedures of short duration such as repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the total dose given should not exceed 12 milligrams per pound of body weight. The maximum total safe dose is 13.6 milligrams per pound of body weight.

(ii) In healthy cats: An initial intramuscular dosage of 4.4 to 5.4 milligrams per pound of body weight is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 milligrams per pound of body weight for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations, and other procedures of short duration. Initial dosages of 6.5 to 7.2 milligrams per pound of body weight are recommended for ovariohysterectomy and onychectomy. When supplemental doses are required, such individual supplemental doses should be given in increments that are less than the initial dose and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 milligrams per pound of body weight.

(3) *Limitations.* Discard unused reconstituted solution after 48 hours. Not for use in dogs and cats with pancreatic disease, or with severe cardiac or pulmonary dysfunction. Not for use in pregnant animals. Not for use in cats suffering with renal insufficiency. The dosage should be reduced in geriatric dogs and cats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 15328, Apr. 9, 1982, as amended at 51 FR 24142, July 2, 1986; 67 FR 67521, Nov. 6, 2002]

§ 522.2471 Tilmicosin.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) tilmicosin base as tilmicosin phosphate.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.735 of this chapter.

(d) *Special considerations.* (1) Not for human use. Use of this antibiotic in humans may prove fatal. Do not use in automatically powered syringes.

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

(e) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 10 to 20 milligrams per kilograms (mg/kg) of body weight as a single subcutaneous injection.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*.

(iii) *Limitations.* Do not use in female dairy cattle 20 months of age or older. Use of this antibiotic in this class of cattle may cause milk residues. Do not slaughter within 42 days of last treatment.

(2) *Sheep*—(i) *Amount.* 10 mg/kg body weight as a single subcutaneous injection.

(ii) *Indications for use.* For the treatment of ovine respiratory disease (ORD) associated with *Mannheimia* (*P.) haemolytica*.

(iii) *Limitations.* Do not slaughter within 28 days of last treatment.

[67 FR 72367, Dec. 5, 2002, as amended at 75 FR 9334, Mar. 2, 2010]

§ 522.2474 Tolazoline hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains tolazoline hydrochloride equivalent to 100 milligrams of base activity.

(b) *Sponsor.* See No. 061690 in § 510.600(c) of this chapter.

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

(1) *Horses*—(i) *Amount.* Administer slowly by intravenous injection 4 milligrams per kilogram of body weight or