Food and Drug Administration, HHS

§ 522.2444 Sodium thiopental for injection.

(a) Specifications. The drug is a sterile dry powder. It is reconstituted aseptically with sterile distilled water, water for injection, or sodium chloride injection, to a desired concentration of 0.5 to 4 percent sodium thiamylal.

(b) Sponsors. See code Nos. 000010 and 000856 in §510.500(c) of this chapter.

(c) Conditions of use. (1) It is used as an ultra-short-acting anesthetic in dogs, cats, swine, horses, and cattle.

(ii) When diluted aseptically to the desired concentration and administered intravenously to effect, the average single dose is:

(i) Dogs and cats: 8 milligrams per pound of body weight (when used with a preanesthetic, generally one-half the normal dose).

(ii) Swine: 40 milligrams per 5 pounds of body weight.

(iii) Horses: Light anesthesia, 1 gram per 500 pounds to 1,100 pounds of body weight; deep anesthesia, 1 gram per 300 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.

§ 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.

(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.