Food and Drug Administration, HHS

§ 522.800 Droperidol and fentanyl citrate injection.

(a) Specifications. Droperidol and fentanyl citrate injection is a sterile solution containing 20 milligrams of droperidol and 0.4 milligram of fentanyl citrate per cubic centimeter.

(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter.

(c) Conditions of use. (1) It is used in dogs as an analgesic and tranquilizer and for general anesthesia.

(2) It is administered to horses at a dosage level of 25 mg per hundred pounds of body weight. It is administered to dogs and cats at a dosage level of 0.5 to 1 mg per pound of body weight. Doses may be repeated at 8 to 12 hours, if necessary, to produce desired effect. Intravenous route is not recommended for dogs and cats and should be injected slowly in horses. Intramuscular and subcutaneous administration should be by divided injection sites.\(^1\)

(3) Not for use in horses intended for food.\(^1\)

(4) Federal law restricts this drug to use by or on the order of a licensed veterinarian.\(^1\)

\(^1\)These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 524.113 of this chapter.