Food and Drug Administration, HHS

§ 522.246 Butorphanol.

(a) Specifications. Each milliliter of solution contains butorphanol (as butorphanol tartrate) in the following amounts:

(1) 0.5 milligrams (mg);
(2) 2 mg; or
(3) 10 mg

(b) Sponsors. See sponsors in §510.600(c) of this chapter as follows:

(1) No. 000856 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section; for use of the product described in paragraph (a)(2) as in paragraph (d)(2) of this section; and for use of the product described in paragraph (a)(3) as in paragraph (d)(3) of this section.

(2) No. 059130 for use of the product described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(3) Nos. 000061, 059130, and 061690 for use of the product described in paragraph (a)(3) as in paragraph (d)(3) of this section.

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

(d) Conditions of use—(1) Dogs—(i) Amount. Administer 0.025 mg per pound of body weight by subcutaneous injection at intervals of 6 to 12 hours, as required. If necessary, increase dose to a maximum of 0.05 mg per pound of body weight. Treatment should not normally be required for longer than 7 days.

(ii) Indications for use. For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.

(2) Cats—(i) Amount. Administer 0.2 mg per pound of body weight by subcutaneous injection. Dose may be repeated up to 4 times per day. Do not treat for more than 2 days.

(ii) Indications for use. For the relief of pain in cats caused by major or