

1.8 milligrams per pound (4 milliliters per 100 kilograms or 4 milliliters per 220 pounds).

(ii) *Indications for use.* For use in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine.

(iii) *Limitations.* The safety of Tolazine™ has not been established in pregnant mares, lactating mares, horses intended for breeding, foals, or horses with metabolically unstable conditions. The safety of Tolazine™ has not been evaluated for reversing xylazine used as a preanesthetic to a general anesthetic. This drug is for use in horses only and not for use in food-producing animals. Users with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid accidental exposure to this product.

Accidental spillage on the skin should be washed off immediately with soap and water. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 25785, May 23, 1996]

§ 522.2476 Trenbolone acetate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 021641 for use as in paragraph (c) of this section.

(2) No. 000061 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

(b) *Related tolerances.* See § 556.739 of this chapter.

(c) *Conditions of use—(1) Steers fed in confinement for slaughter—(i) Amount.* Use 126 days prior to slaughter; should be reimplanted once after 63 days.

(A) 140 milligrams (mg) trenbolone acetate (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 140 mg trenbolone acetate (one implant consisting of 8 pellets, each of 7 pellets containing 20 milligrams trenbolone acetate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Heifers fed in confinement for slaughter—(i) Amount.* Use last 63 days prior to slaughter.

(A) 200 mg trenbolone acetate (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 200 mg of trenbolone acetate (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg of trenbolone acetate, and 1 pellet containing 29 mg of tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[66 FR 47961, Sept. 17, 2001, as amended at 69 FR 70056, Dec. 2, 2004; 74 FR 61517, Nov. 25, 2009]

§ 522.2477 Trenbolone acetate and estradiol.

(a) [Reserved]

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 021641 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(i)(E), (d)(1)(i)(F), (d)(1)(ii), (d)(1)(iii), (d)(2), and (d)(3) of this section.

(2) No. 000061 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(i)(G), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(D), (d)(2)(ii), (d)(2)(iii), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii) of this section.

(3) No. 000856 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(D), (d)(1)(ii),

§522.2477

21 CFR Ch. I (4–1–10 Edition)

(d)(1)(iii), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii) of this section.

(d) *Conditions of use*—(1) *Steers fed in confinement for slaughter*—(i) *Amount*.

(A) 120 milligrams (mg) trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(C) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose.

(D) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(E) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(F) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(G) 200 milligram (mg) trenbolone acetate and 40 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(ii) *Indications for use*. For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations*. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Heifers fed in confinement for slaughter*—(i) *Amount*. (A) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 7 pellets,

each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(A) of this section.

(B) 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of 8 pellets, each of 7 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose for use as in paragraphs (d)(2)(ii)(A) of this section.

(C) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 4 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

(D) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose for use as in paragraph (d)(2)(ii)(A) of this section.

(E) 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose for use as in paragraph (d)(2)(ii)(B) of this section.

(F) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use*. (A) For increased rate of weight gain and improved feed efficiency.

(B) For increased rate of weight gain.

(iii) *Limitations*. Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Pasture cattle (slaughter, stocker, and feeder steers and heifers)*—(i) *Amount*. (A) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 2 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of 3 pellets, each of 2 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[60 FR 4376, Jan. 23, 1995]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 522.2477, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Specifications.* Each implant dose consists of:

(1) 8 pellets, each pellet containing 25 milligrams (mg) trenbolone acetate and 3.5 mg estradiol benzoate.

(2) 4 pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

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

(c) *Related tolerances.* See §§ 556.240 and 556.739 of this chapter.

(d) *Conditions of use—(1) Steers fed in confinement for slaughter.* (i) For an implant as described in paragraph (a)(1) of this section:

(A) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate.

(B) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(C) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) For an implant as described in paragraph (a)(2) of this section:

(A) *Amount.* 100 mg trenbolone acetate and 14 mg estradiol benzoate.

(B) *Indications for use.* For increased rate of weight gain.

(C) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Heifers fed in confinement for slaughter—(i) Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate (as described in paragraph (a)(1) of this section).

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* Implant subcutaneously in ear only. Not for subsequent breeding dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[67 FR 78972, Dec. 27, 2002, as amended at 69 FR 67818, Nov. 22, 2004]

§ 522.2483 Triamcinolone.

(a) *Specifications.* Each milliliter of suspension contains 2 or 6 milligrams (mg) triamcinolone acetonide.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs and cats—(i) Amount—(A) Intramuscular or subcutaneous.* For inflammatory, arthritic, or allergic disorders, administer 0.05 to 0.1 mg per pound (lb) of body weight as a single injection. For dermatologic disorders, administer 0.1 mg per pound (lb) of body weight as a single injection. If symptoms recur, the dose may be repeated, or oral corticosteroid therapy may be instituted.

(B) *Intralesional.* Administer 1.2 to 1.8 mg, divided in several injections around the lesion, spaced 0.5 to 2.5 centimeters apart, depending on lesion size. At any one site, the dose injected should not exceed 0.6 mg. and should be well into the cutis to prevent rupture of the epidermis. When treating animals with multiple lesions, do not exceed a total dose of 6 mg.

(C) *Intra-articular and intrasynovial.* Administer 1 to 3 mg as a single injection, depending on the size of the joint