

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 74 FR 6823, Feb. 11, 2009, unless otherwise noted.

§ 528.1070 Bc6 recombinant deoxyribonucleic acid construct.

(a) *Specifications and indications for use.* Five copies of a human Bc6 recombinant deoxyribonucleic acid (rDNA) construct located at the GTC 155-92 site in a specific hemizygous diploid line of dairy breeds of domestic goats (*Capra aegagrus hircus*) directing the expression of the human gene for antithrombin (which is intended for the treatment of humans) in the mammary gland of goats derived from lineage progenitor 155-92.

(b) *Sponsor.* See No. 042976 in § 510.600 of this chapter.

(c) *Limitations.* Food or feed from GTC-155-92 goats is not permitted in the food or feed supply.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

- 529.40 Albuterol.
- 529.56 Amikacin.
- 529.400 Chlorhexidine tablets and suspension.
- 529.469 Competitive exclusion culture.
- 529.536 Detomidine.
- 529.1003 Flurogestone acetate-impregnated vaginal sponge.
- 529.1030 Formalin.
- 529.1044 Gentamicin sulfate in certain other dosage forms.
- 529.1044a Gentamicin sulfate intrauterine solution.
- 529.1044b Gentamicin sulfate solution.
- 529.1115 Halothane.
- 529.1150 Hydrogen peroxide.
- 529.1186 Isoflurane.
- 529.1455 Methoxyflurane.
- 529.1660 Oxytetracycline.
- 529.1940 Progesterone intravaginal inserts.
- 529.2150 Sevoflurane.
- 529.2464 Ticarcillin powder.
- 529.2503 Tricaine methanesulfonate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§ 529.40 Albuterol.

(a) *Specifications.* A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals.* See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (d) 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) Amount.* Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use.* For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) *Limitations.* Not for use in horses intended for food.

[67 FR 7072, Feb. 15, 2002]

§ 529.56 Amikacin.

(a) *Specifications.* Each milliliter (mL) of solution contains 250 milligrams of amikacin as amikacin sulfate.

(b) *Sponsors.* See Nos. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* Administer 2 grams (8 mL) diluted with 200 mL of sterile physiological saline by intrauterine infusion daily for 3 consecutive days.

(2) *Indications for use.* For treating genital tract infections (endometritis, metritis, and pyometra) in mares caused by susceptible organisms including *Escherichia coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17339, Mar. 29, 2011]