§ 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.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]
PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

§ 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]

§ 529.400 Chlorhexidine tablets and suspension.

(a) Specification. Each tablet and each 28-milliliter syringe of suspension contain 1 gram of chlorhexidine dihydrochloride.¹

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

(c) Conditions of use—(1) Amount. Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet dissolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.

(2) Indications for use. For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.¹

(3) Limitations. Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by §514.111 of this chapter, but may require bioequivalency and safety information.