

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.515 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount*. Infuse 50 mg into each infected quarter. Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

(2) *Indications for use*. For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *Staphylococcus* species such as *Staphylococcus aureus* and *Streptococcus* species such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations*. Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000; 73 FR 811, Jan. 4, 2008]

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.
529.536	Detomidine.
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.
529.1350	Meloxicam.
529.1660	Oxytetracycline.
529.1940	Progesterone intravaginal inserts.
529.2150	Sevoflurane.
529.2464	Ticarcillin powder.
529.2503	Tricaine methanesulfonate.
529.2620	Triptorelin.

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 000859 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, as amended at 78 FR 17597, Mar. 22, 2013]

§ 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.¹

(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 genitalia. Use a clean, sterile inseminating

pipette for administering solutions and suspensions. Treatment may be repeated in 48 to 72 hours.¹

[43 FR 10705, Feb. 23, 1979]

§ 529.536 Detomidine.

(a) *Specifications*. Each milliliter of gel contains 7.6 milligrams (mg) of detomidine hydrochloride.

(b) *Sponsor*. See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 0.018 mg per pound (mg/lb) (0.040 mg/kilogram (kg) sublingually.

(2) *Indications for use*. For sedation and restraint.

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

[75 FR 21163, Apr. 23, 2010, as amended at 76 FR 16533, Mar. 24, 2011]

§ 529.1030 Formalin.

(a) *Specifications*. Formalin is an aqueous solution containing approximately 37 percent by weight of formaldehyde gas, U.S.P.

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

(1) Nos. 049968, 050378, and 067188 for use as in paragraphs (d)(1)(iii), (d)(1)(iv), (d)(1)(v), (d)(2)(iii), (d)(2)(iv), (d)(2)(v), and (d)(3).

(2) No. 051212 for use as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(2)(i), (d)(2)(ii), and (d)(3).

(c) [Reserved]

(d) *Conditions of use*. It is added to environmental water as follows:

(1) *Indications for use*. (i) Select finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Ichthyobodo* spp., *Ambiphrya* spp., *Epistylis* spp., and *Trichodina* spp., and monogenetic trematodes *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp., on salmon, trout, catfish, largemouth bass, and bluegill.

(ii) Select finfish eggs. For control of fungi of the family Saprolegniaceae on salmon, trout, and esocid eggs.

(iii) Penaeid shrimp. For control of external protozoan parasites *Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.

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.