

homozygous for the intentional genomic alteration lineage that are intended to be used as sources of food or human therapeutics including excipients, devices, drugs, or biological products.

(2) *Limitations.* Pigs of this lineage (possessing the intentional genomic alteration (*pPL657* rDNA construct)) should not be treated with aminoglycoside drugs and must only be housed in physically contained facilities specified in the approved application.

[86 FR 17064, Apr. 1, 2021]

§ 528.2010 Human lysosomal acid lipase recombinant deoxyribonucleic acid construct.

(a) *Specifications.* A single copy of a human lysosomal acid lipase (hLAL) recombinant deoxyribonucleic acid (rDNA) gene construct located at the SYN LAL-C site in chromosome 6 in a specific, diploid line (SBC LAL-C) of hemizygous and homozygous domestic chickens (*Gallus gallus*), derived from the lineage progenitor XLL 109.

(b) *Sponsor.* See No. 069334 in § 510.600 of this chapter.

(c) *Conditions of use—(1) Intended use.* The gene construct directs the expression of that encoding gene such that recombinant, human lysosomal acid lipase (rhLAL) protein intended for the treatment of human disease is present in SBC LAL-C chicken egg whites.

(2) *Limitations.* Food or feed from XLL 109 chickens is not permitted in the food or feed supply.

[81 FR 17608, Mar. 30, 2016]

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

- 529.56 Amikacin.
- 529.382 Chloramine-T.
- 529.400 Chlorhexidine tablets and suspension.
- 529.443 Ciclesonide.
- 529.536 Detomidine.
- 529.539 Dexmedetomidine.
- 529.778 Doxycycline.
- 529.1004 Formalin.
- 529.1044 Gentamicin in certain other dosage forms.
- 529.1044a Gentamicin solution for infusion.

- 529.1044b Gentamicin solution for dipping eggs.
- 529.1115 Halothane.
- 529.1150 Hydrogen peroxide.
- 529.1186 Isoflurane.
- 529.1350 Meloxicam.
- 529.1660 Oxytetracycline.
- 529.1940 Progesterone intravaginal inserts.
- 529.2110 Sevoflurane.
- 529.2464 Ticarcillin.
- 529.2503 Tricaine methanesulfonate.
- 529.2620 Triptorelin.

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

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

§ 529.56 Amikacin.

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

(b) *Sponsors.* See Nos. 054771 and 058198 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; 79 FR 10973, Feb. 27, 2014; 86 FR 14821, Mar. 19, 2021]

§ 529.382 Chloramine-T.

(a) *Specifications.* Chloramine-T trihydrate powder for solution.

(b) *Sponsor.* See No. 086009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.118 of this chapter.

(d) *Conditions of use—(1) Freshwater-reared salmonids—(i) Amount.* 12 to 20 milligrams per liter (mg/L) water in a continuous flow water supply or as a static bath once per day for 60 minutes on consecutive or alternative days for three treatments.

(ii) *Indications for use.* For the control of mortality in freshwater-reared salmonids due to bacterial gill disease associated with *Flavobacterium* spp.