

(d) *Conditions of use in lactating cows*—(1) *Amount*. Infuse the contents of one syringe (50 mg pirlimycin) into each infected quarter. 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; 79 FR 10973, Feb. 27, 2014; 86 FR 13188, Mar. 8, 2021]

PART 528—INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS

Sec.		
528.1080	Bc2371	recombinant deoxyribonucleic acid construct.
528.1092	opAFP-GHc2	recombinant deoxyribonucleic acid construct.
528.2001	pPL657	recombinant deoxyribonucleic acid construct.
528.2010	Human lysosomal acid lipase recombinant deoxyribonucleic acid construct.	

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

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

§ 528.1080 Bc2371 recombinant deoxyribonucleic acid construct.

(a) *Specifications and intended use*. A single copy of Bc2371, a human Factor VII recombinant deoxyribonucleic acid (rDNA) gene construct, located on chromosome 3p1.1–2 in a diploid line (R69) of hemizygous and homozygous

New Zealand white rabbits (*Oryctolagus cuniculus*).

(b) *Sponsor*. See No. 086047 in § 510.600 of this chapter.

(c) *Conditions of use*—(1) *Intended use*. The construct directs gene expression of recombinant human Factor VII (hFVII) in the mammary gland such that recombinant hFVII zymogen is present in the rabbit milk, enabling purification and activation of recombinant hFVIIa intended for the treatment of hemophilia A or B in humans with inhibitors to Factors VIII and IX.

(2) *Limitations*. Food or feed from R69 rabbits is not permitted in the food or feed supply.

[84 FR 12494, Apr. 2, 2019]

§ 528.1092 opAFP-GHc2 recombinant deoxyribonucleic acid construct.

(a) *Specifications*. A single copy of the α -form of the *opAFP-GHc2* recombinant deoxyribonucleic acid (rDNA) construct at the α -locus in the EO-1 α lineage of triploid, hemizygous, all-female Atlantic salmon (*Salmo salar*).

(b) *Sponsor*. See No. 086053 in § 510.600 of this chapter.

(c) *Indications for use*. Significantly more of these Atlantic salmon grow to at least 100 grams within 2,700 Celsius degree-days than their comparators.

(d) *Limitations*. These Atlantic salmon are produced as eyed-eggs and grown-out only in physically-contained, freshwater culture facilities specified in an FDA-approved application.

[80 FR 73104, Nov. 24, 2015]

§ 528.2001 pPL657 recombinant deoxyribonucleic acid construct.

(a) *Specifications*. *pPL657* in the *glycoprotein galactosyltransferase alpha-1,3 (GGTA1)* gene in domestic pigs.

(b) *Sponsor*. See No. 086134 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Intended use*. *pPL657* rDNA construct in the *glycoprotein galactosyltransferase alpha-1,3* gene (*GGTA1*) in the lineage of domestic pigs (*Sus scrofa domesticus*) hemizygous and homozygous for the intentional genomic alteration resulting in undetectable endogenous galactose alpha-1,3-galactose sugar residues on biological derivatives of domestic pigs

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.