

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]

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

Sec.

528.1070 Bc6 recombinant deoxyribonucleic acid construct.

528.1092 opAFP-GHc2 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.

§ 528.1070 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. 086047 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.

[74 FR 6823, Feb. 11, 2009, as amended at 80 FR 34279, June 16, 2015]

§ 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]

§ 528.2010 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.

529.40 Albuterol.

529.56 Amikacin.

529.382 Chloramine-T.

529.400 Chlorhexidine tablets and suspension.

529.536 Detomidine.

529.539 Dexmedetomidine.

529.778 Doxycycline.

529.1030 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.