(Lat. 37°19′31″ N., long. 79°12′04″ W.)
Falwell Airport, VA
(Lat. 37°22′41″ N., long. 79°07′20″ W.)

That airspace extending upward from the surface to and including 3,400 feet MSL within a 4.5-mile radius of Lynchburg Municipal-Preston Glenn Field Airport, excluding the portion within a .5-mile radius of Falwell Airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be published continuously in the Airport/Facility Directory.

Paragraph 6004 Class E Airspace Designated as an Extension to a Class D Surface Area.

* * * * *

AEA VA E4 Lynchburg, VA [Corrected]

Lynchburg Regional-Preston Glenn Field Airport, Lynchburg, VA
(Lat. 37°19′31″ N., long. 79°12′04″ W.)
Lynchburg VORTAC
(Lat. 37°15′17″ N., long. 79°14′11″ W.)

That airspace extending upward from the surface within 2.7 miles each side of the Lynchburg VORTAC 020° and 200° radials extending from the 4.5-mile radius of Lynchburg Municipal-Preston Glenn Field Airport to 1 mile south of the VORTAC, and within 1.8 miles each side of the Lynchburg VORTAC 022° radial extending from the 4.5-mile radius of the airport to 11.3 miles northeast of the VORTAC. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be published continuously in the Airport/Facility Directory.

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AEA VA E5 Lynchburg, VA [Corrected]

Lynchburg Regional-Preston Glenn Field Airport, Lynchburg, VA
(Lat. 37°19′31″ N., long. 79°12′04″ W.)
Lynchburg VORTAC
(Lat. 37°15′17″ N., long. 79°14′11″ W.)
Falwell Airport, VA
(Lat. 37°22′41″ N., long. 79°07′20″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Lynchburg Regional-Preston Glenn Field, and within 2.7 miles each side of the Lynchburg VORTAC 200° radial extending from the 6.5-mile radius to 7.4 miles south of the VORTAC, and within 3.1 miles each side of the Lynchburg VORTAC 022° radial extending from the 6.5-mile radius to 21.3 miles northeast of the VORTAC, and within a 6.5-mile radius of Falwell Airport.

Issued in College Park, Georgia, on March 23, 2016.

Jim Dickinson,

Acting Manager, Operations Support Group, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2016–07079 Filed 3–29–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 528, 529, 556, and 558

[Docket No. FDA–2015–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during November and December 2015. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect changes of sponsorship of applications that occurred in November and December 2015.

DATES: This rule is effective March 30, 2016.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during November and December 2015, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING NOVEMBER AND DECEMBER 2015

File No.	Sponsor	Product name	Action	21 CFR Section	FOIA Summary	NEPA Review
141–453	Alexion Pharmaceuticals, Inc., 33 Hayden Ave., Lexington, MA 02421.	hLAL rDNA construct in SBC LAL–C chickens.	Original approval for expression of a human gene for recombinant human lysosomal acid lipase (rhLAL) protein in chicken egg whites.	528.2010	yes	EA/FONSI [1]
141–456	Orion Corp., Orionintie 1, 02200 Espoo, Finland.	SILEO (dexmedetomidine oromucosal gel).	Original approval for the treatment of noise aversion in dogs.	529.539	yes	CE [2 3]
141–246	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901.	AQUAFLOR (florfenicol) Type A medicated article.	Supplemental approval of revised representative labeling for Type C medicated feeds; technical amendments revising the expiration of veterinary feed directives (VFDs) and the description of tolerances for fish.	556.283, 558.261	no	CE [2 4]

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING NOVEMBER AND DECEMBER 2015—Continued

File No.	Sponsor	Product name	Action	21 CFR Section	FOIA Summary	NEPA Review
141–258	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901.	ZILMAX (zilpaterol hydrochloride) Type A medicated article.	Supplemental approval of a cattle muscle tolerance and of new determinative and confirmatory procedures for residues of zilpaterol in cattle liver and muscle.	556.765	yes	CE[2 4]
141–361	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	PULMOTIL AC (tilmicosin phosphate) Concentrate Solution.	Supplemental approval for the control of swine respiratory disease associated with *Mycoplasma hyopneumoniae* in the presence of Porcine Reproductive and Respiratory Syndrome Virus (PRRSV).	520.2471	yes	EA/FONSI[1]

[1] The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).
[2] The Agency has determined that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not have a significant effect on the human environment.
[3] CE granted under 21 CFR 25.33(d)(1).
[4] CE granted under 21 CFR 25.33(a)(1).

II. Changes of Sponsorship

Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201 (Bayer) has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved applications to Cronus Pharma LLC, 2 Tower Center Blvd., Suite 1101, East Brunswick, NJ 08816:

File No.	Product name	21 CFR section
055–002	TEVCOSIN (chloramphenicol) Injectable Solution	522.390
094–170	Phenylbutazone Tablets, USP 100 mg and 200 mg	520.1720a
123–815	Dexamethasone Sodium Phosphate Injection	522.540
141–245	TRIBUTAME (chloroquine phosphate, embutramid, lidocaine) Euthanasia Solution	522.810
200–178	Amikacin Sulfate Injection, 50 mg/mL	522.56
200–193	Clindamycin Hydrochloride Oral Liquid	520.447
200–248	Pyrantel Pamoate Suspension; 2.27 and 4.54 mg	520.2043
200–265	Praziquantel Tablets	520.1870
200–287	GBC (Gentamicin Sulfate Betamethasone Valerate Clotrimazole) Ointment	524.1044g
200–297	Ivermectin Chewable Tablets	520.1193
200–298	Clindamycin Hydrochloride Capsules	520.446
200–365	ROBINUL–V (glycopyrrolate) Injectable Solution	522.1066
200–382	Furosemide Syrup 1%	520.1010

Bayer has also informed FDA that it has transferred ownership of, and all rights and interest in, approved ANADA 200–342 for Pyrantel Pamoate Paste to Farnam Companies, Inc., 301 West Osborn Rd., Phoenix, AZ 85013–3928.

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506–2002 has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved applications to Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria:

File No.	Product name	21 CFR section
006–084[1]	SULMET (sulfamethazine) Drinking Water Solution	520.2261a
008–774	SULMET (sulfamethazine) Injectable Solution	522.2260
033–373[1]	VETSULID (sulfachlorpyridazine)	520.2200
040–181[1]	VETSULID (sulfachlorpyridazine) Oral Suspension	520.2200
055–012[1]	CHLORONEX SULMET (chlortetracycline bisulfate/sulfamethazine bisulfate) Soluble Powder.	520.445
055–018[1]	AUREOMYCIN (chlortetracycline HCl) Tablets 25 mg	520.443
055–039[1]	AUREOMYCIN (chlortetracycline HCl) Soluble Oblets	520.443
065–071[1]	AUREOMYCIN (chlortetracycline HCl) Soluble Powder	520.441
065–269[1]	POLYOTIC (tetracycline hydrochloride) Soluble Powder	520.2345d
065–440[1]	CHLORONEX (chlortetracycline HCl or chlortetracycline bisulfate) Soluble Powder	520.441
122–271[1]	SULMET (sulfamethazine) Oblets	520.2260a
122–272[1]	SULMET (sulfamethazine sodium) Soluble Powder	520.2261b

[1] These NADAs were identified as being affected by guidance for industry #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,'' December 2013.

In addition, Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408 (Novartis) has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved applications to Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140.

File No.	Product name
134–644	DENAGARD (tiamulin) Soluble Powder.
139–472	DENAGARD (tiamulin) Type B Medicated Feed.
140–915	INTERCEPTOR (milbemycin oxime) Tablets.
140–916	DENAGARD (tiamulin) Liquid Concentrate.
141–011	DENAGARD (tiamulin) plus CTC (chlortetracycline).
141–026	PROGRAM (lufenuron) Suspension.
141–029	PERCORTEN–V (desoxycorticosterone pivalate) Injectable Suspension.
141–035	PROGRAM (lufenuron).
141–062	PROGRAM (lufenuron) Cat Flavor Tabs.
141–084	SENTINEL (lufenuron and milbemycin oxime) Flavor Tabs.
141–105	PROGRAM (lufenuron) 6-Month Injectable for Cats.
141–120	CLOMICALM (clomipramine) Tablets.
141–163	MILBEMITE (milbemycin oxime) Otic Solution.
141–175	CAPSTAR (nitenpyram) Tablets.
141–203	DERAMAXX (deracoxib) Chewable Tablets.
141–204	SENTINEL Flavor Tabs and CAPSTAR Flea Management System.
141–205	PROGRAM Flavor Tabs and CAPSTAR Flea Management System.
141–218	ATOPICA (cyclosporine) Capsules.
141–320	ONSIOR (robenacoxib) Tablets.
141–329	ATOPICA (cyclosporine) Oral Solution for Cats.
141–333	SENTINEL SPECTRUM (milbemycin oxime, lufenuron, praziquantel) Chewable Tablets.
141–338	INTERCEPTOR SPECTRUM (milbemycin oxime and praziquantel) Chewable Tablets.
141–437	OSURNIA (florfenicol, betamethasone acetate, and terbinafine) Otic Gel.
141–443	ONSIOR (robenacoxib) Injection.
200–517	ZOBUXA (enrofloxacin) Tablets.
200–519	FLORVIO (florfenicol) 2.3% Concentrate Solution.

As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these changes of sponsorship. Elanco US, Inc., is retaining Novartis' drug labeler code (058198). Accordingly, the animal drug regulations need only be amended in § 510.600(c) to add Elanco US, Inc., who previously was not the sponsor of an approved application. Cronus Pharma LLC will also be added as a new listing. Following these changes of sponsorship, Novartis is no longer the sponsor of an approved application and will be removed from § 510.600(c).

III. Technical Amendments

FDA has noticed the animal drug regulations in 21 CFR part 556 contain tolerances for residues in edible tissues for sulfathiazole, which is no longer the subject of an approved application (79 FR 15540, March 20, 2014). Accordingly, § 556.690 is being removed. FDA has also noticed that the animal drug regulations in 21 CFR 558.4 (§ 558.4) contain assay limits for ronnel and sulfaethoxypyridazine in medicated feed. As there is no longer an approved application for use of either of these drugs in medicated feed, the table for Category II drugs in § 558.4 is being amended to remove assay limits in medicated feed for both drugs. These actions are being taken to improve the accuracy of the regulations.

In addition, FDA is taking this opportunity to revise the spelling of a bacitracin salt to a preferred form, bacitracin methylenedisalicylate, and to correct the spelling of a genus of pathogenic bacteria, *Haemophilus.* These actions are being taken to improve the accuracy of the regulations.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, 528, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, 528, 529, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for ''Novartis Animal Health US, Inc.'' and add entries for ''Cronus Pharma LLC'' and ''Elanco US, Inc.'' in alphabetical order; and in the table in paragraph (c)(2), revise the entry for ''058198'' and add an entry for ''069043'' in numerical order to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Cronus Pharma LLC, 2 Tower Center Blvd., Suite 1101, East Brunswick, NJ 08816	069043
* * * * * * *	
Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140	058198
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
058198	Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140
* * * * * * *	
069043	Cronus Pharma LLC, 2 Tower Center Blvd., Suite 1101, East Brunswick, NJ 08816
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.88b [Amended]

■ 4. In § 520.88b, in paragraph (b)(1)(ii)(B), remove ''*Hemophilus''* and in its place add ''*Haemophilus''.*

■ 5. In § 520.154b:

■ a. Revise the section heading.

■ b. In paragraph (a), remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

The revision reads as follows:

§ 520.154b Bacitracin methylenedisalicylate and streptomycin sulfate powder.

* * * * *

§ 520.441 [Amended]

■ 6. In § 520.441, in paragraphs (b)(2) and (d)(4)(iii)(C), remove ''000010'' and in its place add ''016592''; and in in paragraphs (d)(1)(i)(A)(*1*), (d)(2)(i)(A)(*1*), (d)(4)(iii)(B), and (d)(4)(iv)(B), remove ''*Hemophilus''* and in its place add ''*Haemophilus''.*

§ 520.443 [Amended]

■ 7. In § 520.443, in paragraph (b), remove ''No. 054628'' and in its place add ''Nos. 016592 and 054628''; and in paragraphs (d)(1)(i), (d)(2)(i), and (d)(3)(i), remove ''*Hemophilus''* and in its place add ''*Haemophilus''.*

§ 520.445 [Amended]

■ 8. In § 520.445, in paragraph (b), remove ''000010'' and in its place add ''016592''.

§ 520.446 [Amended]

■ 9. In § 520.446, in paragraph (b)(1), remove ''No. 054771'' and in its place add ''Nos. 054771 and 069043''.

§ 520.447 [Amended]

■ 10. In § 520.447, in paragraph (b), remove ''Nos. 000859, 051311, 054771, 058829, and 061623'' and in its place add ''Nos. 051311, 054771, 058829, 061623, and 069043''.

§ 520.823 [Amended]

■ 11. In § 520.823, in paragraph (d)(2)(ii), remove ''*Hemophilus''* and in its place add ''*Haemophilus''.*

§ 520.1010 [Amended]

■ 12. In § 520.1010, in paragraph (b)(3), remove ''Nos. 000859 and 058829'' and in its place add ''Nos. 058829 and 069043''.

§ 520.1193 [Amended]

■ 13. In § 520.1193, in paragraph (b)(2), remove ''Nos. 000859 and 051311'' and in its place add ''Nos. 051311 and 069043''.

§ 520.1720a [Amended]

■ 14. In § 520.1720a, in paragraph (b)(2), remove ''Nos. 000859 and 054628'' and in its place add ''Nos. 054628 and 069043''.

■ 15. In § 520.1870, revise paragraph (b) to read as follows:

§ 520.1870 Praziquantel tablets.

* * * * *

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter for use of the product described in paragraph (a)(1) of this section as in paragraph (c)(1) of this section; and for use of the product described in paragraph (a)(2) of this section as in paragraph (c)(2) of this section.

* * * * *

§ 520.2043 [Amended]

■ 16. In § 520.2043, in paragraph (b)(1), remove ''Nos. 000859, 054771, and 058829'' and in its place add ''Nos. 054771, 058829, and 069043''.

§ 520.2044 [Amended]

■ 17. In § 520.2044, in paragraph (b)(2), remove ''000859'' and in its place add ''017135''.

§ 520.2200 [Amended]

■ 18. In § 520.2200, in paragraph (b), remove ''000010'' and in its place add ''016592''.

§ 520.2260a [Amended]

■ 19. In § 520.2260a, in paragraph (a)(1), remove ''000010'' and in its place add ''016592''.

§ 520.2261a [Amended]

■ 20. In § 520.2261a, in paragraph (b), remove ''000010'' and in its place add ''016592''.

§ 520.2261b [Amended]

■ 21. In § 520.2261b, in paragraph (b), remove ''000010'' and in its place add ''016592''.

§ 520.2345d [Amended]

■ 22. In § 520.2345d, in paragraphs (b)(5), (d)(1)(iii), and (d)(2)(iii), remove ''000010'' and in its place add ''016592''; and in paragraphs (d)(1)(ii) and (d)(2)(ii), remove ''*Hemophilus''* and in its place add ''*Haemophilus''.*

■ 23. In § 520.2471, revise paragraph (d)(2) to read as follows:

§ 520.2471 Tilmicosin.

* * * * *

(d) * * *

(2) *Indications for use*—(i) For the control of swine respiratory disease associated with *Pasteurella multocida* and *Haemophilus parasuis* in groups of swine in buildings where a respiratory disease outbreak is diagnosed.

(ii) For the control of swine respiratory disease associated with *Mycoplasma hyopneumoniae* in the presence of Porcine Reproductive and Respiratory Syndrome Virus (PRRSV) in groups of swine in buildings where a respiratory disease outbreak is diagnosed.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 24. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.56 [Amended]

■ 25. In § 522.56, in paragraph (b), remove ''000859'' and in its place add ''069043''.

§ 522.390 [Amended]

■ 26. In § 522.390, in paragraph (b), remove ''Nos. 000859 and 054771'' and in its place add ''Nos. 054771 and 069043''.

§ 522.540 [Amended]

■ 27. In § 522.540, in paragraph (e)(2), remove ''000859'' and in its place add ''069043''.

§ 522.810 [Amended]

■ 28. In § 522.810, in paragraph (b), remove ''000859'' and in its place add ''069043''.

§ 522.1066 [Amended]

■ 29. In § 522.1066, in paragraph (b), remove ''Nos. 000859 and 054771'' and in its place add ''Nos. 054771 and 069043''.

§ 522.1662a [Amended]

■ 30. In § 520.1662a, in paragraphs (b)(3)(i)(*b*), (c)(3)(i), (d)(3)(i)(*a*), (e)(3)(i)(*b*), (g)(3)(i)(*b*), and (k)(3)(ii), remove ''*Hemophilus''* and in its place add ''*Haemophilus''.*

§ 522.2260 [Amended]

■ 31. In § 522.2260, in paragraph (b), remove ''000010'' and in its place add ''016592''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 32. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1044g [Amended]

■ 33. In § 522.1044g, in paragraph (b)(3), remove ''000859'' and in its place add ''069043''.

PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

■ 34. The authority citation for 21 CFR part 528 continues to read as follows:

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

■ 35. Add § 528.2010 to read as follows:

§ 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.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 36. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 37. Add § 529.539 to read as follows:

§ 529.539 Dexmedetomidine.

(a) *Specifications.* Each milliliter of gel contains 0.09 milligrams (mg) dexmedetomidine (equivalent to 0.1 mg dexmedetomidine hydrochloride).

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

(c) *Conditions of use*—(1) *Amount.* Administer onto the oral mucosa between the dog's cheek and gum at a dose of 125 micrograms per square meter.

(2) *Indications for use.* For the treatment of noise aversion in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 38. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 39. In § 556.70, in paragraph (b), remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''; and add paragraph (c) to read as follows:

§ 556.70 Bacitracin.

* * * * *

(c) *Related conditions of use.* See §§ 520.154a, 520.154c, 558.76, and 558.78 of this chapter.

■ 40. In § 556.283, revise paragraphs (b)(3) and (4) to read as follows:

§ 556.283 Florfenicol.

* * * * *

(b) * * *

(3) *Freshwater-reared finfish (other than catfish) and salmonids.* The tolerance for florfenicol amine (the marker residue) in muscle/skin (the target tissues) is 1 ppm.

(4) *Catfish.* The tolerance for florfenicol amine (the marker residue) in muscle (the target tissues) is 1 ppm.

* * * * *

§ 556.690 [Removed]

■ 41. Remove § 556.690.

■ 42. In § 556.765, revise paragraph (b)(1)(i) and add paragraphs (b)(1)(ii) and (c) to read as follows:

§ 556.765 Zilpaterol.

* * * * *

(b) * * *

(1) * * *

(i) *Liver (the target tissue).* The tolerance for zilpaterol (the marker residue) is 12 parts per billion (ppb).

(ii) *Muscle.* The tolerance for zilpaterol (the marker residue) is 10 ppb.

* * * * *

(c) *Related conditions of use.* See § 558.665 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 43. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

§ 558.4 [Amended]

■ 44. In § 558.4, in paragraph (d), in the ''Category I'' table, in the ''Drug''

column, remove ''Bacitracin methylene disalicylate'' and in its place add '' Bacitracin methylenedisalicylate''; and in the ''Category II'' table, remove the entries for ''Ronnel'' and ''Sulfaethoxypyridazine''.

§ 558.55 [Amended]

■ 45. In § 558.55, in paragraph (d)(2)(ii), in the ''Combination in grams per ton'' and ''Limitations'' columns, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.58 [Amended]

■ 46. In § 558.58, in paragraph (e)(4), in the ''Limitations'' column, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.68 [Amended]

■ 47. In § 558.68, remove paragraph (e)(3).

■ 48. In § 558.76, remove paragraph (e)(2), redesignate paragraph (e)(3) as paragraph (e)(2), and revise redesignated paragraph (e)(2) to read as follows:

§ 558.76 Bacitracin methylenedisalicylate.

* * * * *

(e) * * *

(2) Bacitracin methylenedisalicylate may also be used in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Clopidol as in § 558.175.

(iv) Decoquinate as in § 558.195.

(v) Diclazuril as in § 558.198.

(vi) Fenbendazole as in § 588.258.

(vii) Halofuginone hydrobromide as in § 558.265.

(viii) Ivermectin as in § 558.300.

(ix) Lasalocid as in § 558.311.

(x) Monensin as in § 588.355.

(xi) Narasin as in § 558.363.

(xii) Nicarbazin alone and with narasin as in § 558.366.

(xiii) Robenidine as in § 558.515.

(xiv) Salinomycin as in § 558.550.

(xv) Semduramicin as in § 558.555.

(xvi) Zoalene as in § 558.680.

§ 558.128 [Amended]

■ 49. In § 558.128, in paragraph (e)(7)(ii), remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.175 [Amended]

■ 50. In § 558.175, in paragraph (d)(2), in the ''Combination in grams per ton'' and ''Limitations'' columns, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.195 [Amended]

■ 51. In § 558.195, in paragraph (e)(1)(ii), in the ''Combination in grams/ton'' and ''Limitations'' columns, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.198 [Amended]

■ 52. In § 558.198, in paragraphs (d)(1)(ii) and (d)(2)(ii), in the ''Combination grams/ton'' and ''Limitations'' columns, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.258 [Amended]

■ 53. In § 588.258, in paragraphs (e)(2)(vi) and (vii), in the ''Combination in grams per ton'' and ''Limitations'' columns, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

■ 54. In § 558.261, redesignate paragraphs (c)(2)(i) and (ii) as paragraphs (c)(2)(ii) and (i), respectively, revise redesignated paragraph (c)(2)(ii), and add paragraph (c)(4) to read as follows:

§ 558.261 Florfenicol.

* * * * *

(c) * * *

(2) * * *

(ii) For fish must not exceed 6 months from the date of issuance.

* * * * *

(4) Type A medicated articles and medicated feeds intended for use in fish shall bear the following: ''Not for use in animals intended for breeding purposes. The effects of florfenicol on reproductive performance have not been determined. Toxicity studies in dogs, rats, and mice have associated the use of florfenicol with testicular degeneration and atrophy.''

* * * * *

§ 558.265 [Amended]

■ 55. In § 558.265, in paragraphs (d)(1)(vi) and (d)(2)(ii), remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.300 [Amended]

■ 56. In § 558.300, in paragraphs (e)(2) and (3), in the ''Combination in g/ton of feed'' column, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''; and in paragraph (e)(9), in the ''Combination in g/ton of feed '' and ''Limitations'' columns, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.311 [Amended]

■ 57. In § 558.311, in paragraphs (e)(1)(iv) and (x), in the ''Limitations'' column, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''; and in paragraph (e)(1)(xv), in the ''Combination in grams per ton'' and ''Limitations'' columns, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.355 [Amended]

■ 58. In § 558.355, in paragraphs (f)(1)(iii)(*b*), (f)(1)(xxiv), (f)(1)(xxix) introductory text, (f)(1)(xxix)(*b*), (f)(1)(xxx) introductory text, (f)(1)(xxx)(*b*), (f)(2)(ii) introductory text, (f)(2)(ii)(*b*), (f)(2)(iii) introductory text, (f)(2)(iii)(*a*), (f)(2)(iii)(*b*), (f)(4)(ii) introductory text, (f)(4)(ii)(*b*), (f)(4)(iii) introductory text, (f)(4)(iii)(*b*), (f)(4)(v) introductory text, and (f)(4)(v)(*b*), remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.363 [Amended]

■ 59. In § 558.363, in paragraphs (d)(1)(iv) introductory text, (d)(1)(iv)(B), and (d)(3)(ii), remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.366 [Amended]

■ 60. In § 558.366, in paragraph (d), in the ''Combination in grams per ton'' and ''Limitations'' columns, remove ''methylene disalicylate'' wherever it occurs and in its place add ''methylenedisalicylate''.

§ 558.450 [Amended]

■ 61. In § 558.450, in paragraph (d)(5)(v), in the ''Indications for Use'' column, remove ''*Hemophilus''* and in its place add ''*Haemophilus''.*

§ 558.515 [Amended]

■ 62. In § 558.515, in paragraph (d), in the ''Combination in grams per ton'' and ''Limitations'' columns, remove ''methylene disalicylate'' wherever it occurs and in its place add ''methylenedisalicylate''.

§ 558.550 [Amended]

■ 63. In § 558.550, in paragraphs (d)(1)(iii)(*a*), (d)(1)(iii)(*c*), (d)(1)(vi)(*a*), (d)(1)(xx)(A), (d)(1)(xx)(C), (d)(1)(xxi)(A), (d)(1)(xxi)(C), (d)(3)(ii) introductory text, (d)(3)(ii)(B), (d)(3)(iii) introductory text, (d)(3)(iii)(B), (d)(3)(v) introductory text, and (d)(3)(v)(B), remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''; and in paragraph (d)(1)(vi)(*c*), remove ''Bacitracin MD'' and in its place add ''Bacitracin methylenedisalicylate''.

§ 558.555 [Amended]

■ 64. In § 558.555, in paragraph (d)(2), in the ''Combination in grams per ton'' and ''Limitations'' columns, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

§ 558.680 [Amended]

■ 65. In § 558.680, in paragraphs (d)(1)(ii), (iii), (iv), (vi), (vii), and (viii) in the ''Combination in grams per ton'' and ''Limitations'' columns, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''; and in paragraph (d)(2)(ii), in the ''Combination in grams per ton'' column, remove ''methylene disalicylate'' and in its place add ''methylenedisalicylate''.

Dated: March 25, 2016.

Tracey H. Forfa,

Deputy Director, Center for Veterinary Medicine.

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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1258

[FDMS No. NARA–16–0003; NARA–2016–018]

RIN 3095–AB90

Fees

AGENCY: National Archives and Records Administration (NARA).

ACTION: Direct final rule.

SUMMARY: The National Archives and Records Administration (NARA) is making a minor administrative revision to its fees regulation to set a time limit for requesting refunds of reproduction fees.

DATES: This rule is effective April 29, 2016, without further action, unless NARA receives adverse comments by April 19, 2016. If NARA receives an adverse comment, it will publish a timely withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments, identified by RIN 3095–AB90, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: Regulation_comments@nara.gov.* Include RIN 3095–AB90 in the subject line of the message.
- *Fax:* 301–837–0319. Include RIN 3095–AB90 in the subject line of the fax cover sheet.
- *Mail* (for paper, disk, or CD–ROM submissions. Include RIN 3095–AB90 on the submission): Regulations Comment Desk (External Policy Program, Strategy & Performance Division (SP)); Suite 4100; National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001
- *Hand delivery or courier:* Deliver comments to front desk at the address above.

Instructions: All submissions must include NARA's name and the regulatory information number for this rulemaking (RIN 3095–AB90). We may publish any comments we receive without changes, including any personal information you include.

FOR FURTHER INFORMATION CONTACT: Kimberly Keravuori, by email at *regulation_comments@nara.gov,* or by telephone at 301–837–3151.

SUPPLEMENTARY INFORMATION:

Background

NARA is authorized by 44 U.S.C. 2116(c) to charge reproduction fees when it reproduces documents for non-Federal individuals or entities. This includes official reproductions with the Archives seal, reproductions of archival holdings, and reproductions of operational records. The statute authorizes NARA to recoup its costs, equipment fees, and similar expenses, and to retain the fees as part of the National Archives Trust Fund. NARA promulgated regulations at 36 CFR 1258 to notify users of the fee structure and processes. Among these regulations is a section addressing refunds of these fees (36 CFR 1258.16). It is this provision that we are revising with this rulemaking.

Due to various factors, it is occasionally difficult for us to make a legible reproduction, particularly of old documents. We notify customers if we anticipate the reproduction will have questionable legibility, and request the customer's approval to proceed with the reproduction—and the fee charges. As a result, we do not provide refunds except in special cases; primarily if we have somehow processed an order incorrectly or it contains errors. However, the regulation's refund provision did not include a refund cut-off period after which a person who ordered a reproduction could no longer request a refund. Customers could request refunds for orders that were years old, which has occurred in several instances. We had no recourse but to process the refunds, which is not a reasonable business practice for orders that are multiple years old. This also caused a significant administrative burden, as NARA had discarded records for some of these orders at the end of their routine business life, in accord with our agency's official records schedule. For example, under records schedule 1807–2, orders made on our online ordering system (SOFA) are destroyed once they are one year old. A refund request five years after the customer received the reproduction not only is not reasonable, but occurs four years after we destroyed records of the order, making it impossible for us to determine if the customer was notified and approved the reproduction, whether there really was an error or something incorrect about the order, and similar issues.

As a result of these difficulties with refund requests on old orders, we are now revising 36 CFR 1258.16 to set a refund time limit. Customers will have four months from the order date in which to request a refund.

Regulatory Analysis

Review Under Executive Orders 12866 and 13563

Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (September 30, 1993), and Executive Order 13563, Improving Regulation and Regulation Review, 76 FR 23821 (January 18, 2011), direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). This proposed rule is not ''significant'' under section 3(f) of Executive Order 12866 because it merely modifies the window of opportunity in which customers may request refunds of reproduction fees. The Office of Management and Budget (OMB) has reviewed this regulation.

Review Under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*)

This review requires an agency to prepare an initial regulatory flexibility analysis and publish it when the agency publishes the proposed rule. This requirement does not apply if the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities (5 U.S.C. 603). NARA certifies, after review and analysis, that this proposed rule will not have a significant adverse economic impact on small entities because it merely modifies the window of opportunity in which customers may request refunds of reproduction fees.

Review Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

This proposed rule does not contain any information collection requirements subject to the Paperwork Reduction Act.