(2) Where EASA AD 2022–0096 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where paragraph (1) of EASA AD 2022–0096 specifies to ''inform all flight crews, and, thereafter, operate the aeroplane accordingly,'' this AD does not require those actions as those actions are already required by existing FAA operating regulations (see 14 CFR 91.9, 14 CFR 91.505, and 14 CFR 121.137).

(4) The ''Remarks'' section of EASA AD 2022–0096 does not apply to this AD.

(i) Additional FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or EASA; or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact Hye Yoon Jang, Aerospace Engineer, Large Aircraft Section, FAA, International Validation Branch, 2200 South 216th St., Des Moines, WA 98198; telephone 817–222–5584; email *Hye.Yoon.Jang@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2022–0096, dated May 31, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0096, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on November 16, 2022.

Christina Underwood,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–27018 Filed 12–13–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 528, and 558

[Docket No. FDA–2022–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (cNADAs) during April, May, and June 2022. FDA is 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 improve the accuracy and readability of the regulations.

DATES: This rule is effective December 14, 2022.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and cNADAs during April, May, and June 2022, 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 office of the Dockets Management Staff (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, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.*

FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS, ANADAS, AND CNADAS APPROVED DURING APRIL, MAY, AND JUNE 2022 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
April 28, 2022	141–137	Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.	PENNITRACIN MD (bacitracin Type A medicated article).	Supplemental approval for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler and replacement chickens.	FOI Summary	558.76
June 16, 2022	141–556	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.	VETMEDIN-CA1 (pimobendan) Chewable Tablets.	Conditional approval for the delay of onset of congestive heart failure in dogs with Stage B2 preclinical myxomatous mitral valve disease.	FOI Summary	516.1780

Also, FDA is amending the animal drug regulations to reflect approval of supplemental applications, as listed in table 2, to change the marketing status of dosage form antimicrobial animal drug products from over-the-counter (OTC) to veterinary prescription (Rx). These applications were submitted in voluntary compliance with the goals of the FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative as identified by guidance for industry #263, ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter,'' June 11, 2021 *(https://www.fda.gov/media/130610/download).*

TABLE 2—SUPPLEMENTAL APPLICATIONS APPROVED DURING APRIL, MAY, AND JUNE 2022 TO CHANGE THE MARKETING STATUS OF ANTIMICROBIAL ANIMAL DRUG PRODUCTS FROM OTC TO RX

Approval date	File No.	Sponsor	Product name	21 CFR section
May 31, 2022	008–769	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	TERRAMYCIN (oxytetracycline hydrochloride) Injectable Solution; LIQUAMYCIN (oxytetracycline hydrochloride) Injectable Solution.	522.1662a
June 7, 2022	007–981	Do	SOXISOL (sulfisoxazole) Tablets	520.2330

II. Changes of Sponsorship

The sponsors of the following approved applications have informed FDA that they have transferred ownership of, and all rights and interest in, the applications to another sponsor, as listed in table 3.

TABLE 3—CHANGES OF SPONSORSHIP DURING APRIL, MAY, AND JUNE 2022

File No.	Product name	Transferring sponsor	New sponsor	21 CFR section
119–688	CEFA–TABS (cefadroxil) Tablets	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.	HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652.	520.314
140–684	CEFA–DROPS (cefadroxil) Powder for Suspension.	Do	Do	520.314
141–217	ZEUTERIN (zinc gluconate) Injectable Solution.	Ark Sciences, Inc., 1101 East 33rd St., Suite B304, Baltimore, MD 21218.	Aiping Pharmaceutical, Inc., 350 W Wireless Blvd., Hauppauge, NY 11788.	522.2690
141–551	ZENALPHA (medetomidine hydrochloride and vatinoxan hydrochloride) Injectable Solution.	Vetcare Oy, P.O. Box 26 (Liedontie 45), Mäntsälä, Uusimaa, 04601, Finland.	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom.	522.1338

Following these changes of sponsorship, Ark Sciences, Inc. and Vetcare Oy are no longer the sponsor of an approved application. Accordingly, the drug labeler codes for these firms will be removed from § 510.600 (21 CFR 510.600).

III. Change of Sponsor Address

Anivive Lifesciences, Inc., 3250 Airflite Way, Suite 400, Long Beach, CA 90807 has informed FDA that it has changed its address to 3777 Worsham Ave. Long Beach, CA 90808. As provided in the regulatory text, § 510.600 is amended to reflect this change.

IV. Technical Amendments

FDA is making the following amendments to improve the accuracy of the animal drug regulations:

- 21 CFR 510.600 is amended to remove Ark Sciences, Inc., and Vetcare Oy from the list of sponsors of approved applications and to revise the address for Anivive Lifesciences, Inc. A punctuation change is made in the codified name for Veátoquinol USA, Inc.
- 21 CFR 520.563 is amended to reflect the correct section title for diatrizoate oral solution.
- 21 CFR 520.2640 is amended to reflect sponsors' container contents and the dosage in parts per million of tylosin tartrate soluble powder for use in drinking water of turkeys and swine.
- 21 CFR 522.955 is amended to reflect drug labeler codes of application sponsors and to revise a pathogen name for florfenicol injectable solution in cattle.
- 21 CFR 522.2471 is amended to reflect a revised withdrawal period and human food safety warnings for tilmicosin injectable solution in sheep.
- The heading for Part 528 is revised to reflect a more accurate title.
- 21 CFR 558.95 is amended to reflect revised classes of cattle for use of bambermycins medicated feeds.
- 21 CFR 558.128 is amended to reflect approved incorporation rates for

chlortetracycline medicated feeds for cattle.

- 21 CFR 558.342 is amended to reflect all sponsors of approved applications for use of melengestrol medicated feeds in heifers.
- 21 CFR 558.450 is amended to reflect revised residue warnings for use of oxytetracycline medicated feeds in cattle.
- 21 CFR 558.455 is amended to reflect a revised indication for use of oxytetracycline with neomycin in medicated cattle feeds and an updated format.
- 21 CFR 558.575 is amended to reflect approved incorporations rates for use of sulfadimethoxine and ormetoprim in medicated feeds for salmonids and catfish.

V. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires **Federal Register** publication of ''notice[s] . . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document 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. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 510

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

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 528

Animal drugs.

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, 21 CFR parts 510, 516, 520, 522, 528, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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

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

■ 2. In § 510.600:

■ a. In the table in paragraph (c)(1), remove the entries for ''Ark Sciences, Inc.'' and ''Vetcare Oy''; revise the entries for ''Anivive Lifesciences, Inc.''; and ''Veátoquinol USA, Inc.''; and add in alphabetical order an entry for ''Aiping Pharmaceutical, Inc.''; and

■ b. In the table in paragraph (c)(2), add an entry for ''011788''; revise the entries for ''017030'' and ''086121''; and remove the entries for ''076175'' and ''086155''.

The revisions and additions 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
* * * * * * *	
Aiping Pharmaceutical, Inc., 350W Wireless Blvd., Hauppauge, NY 11788	011788
* * * * * * *	
Anivive Lifesciences, Inc., 3777 Worsham Ave., Long Beach, CA 90808	086121
* * * * * * *	
Vetoquinol USA, Inc., 4250 N Sylvania Ave., Fort Worth, TX 76137	017030
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
011788	Aiping Pharmaceutical, Inc., 350W Wireless Blvd., Hauppauge, NY 11788.
* * * * * * *	
017030	Vetoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137.
* * * * * * *	
086121	Anivive Lifesciences, Inc., 3777 Worsham Ave., Long Beach, CA 90808.
* * * * * * *	

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 4. Add § 516.1780 to subpart E to read as follows:

§ 516.1780 Pimobendan.

(a) *Specifications.* Each chewable tablet contains 1.25, 2.5, 5, or 10 milligrams (mg) pimobendan.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Administer orally at a total daily dose of 0.23 mg per pound (0.5 mg per kilogram) body weight, using a suitable combination of whole or half tablets. The total daily dose should be divided into two portions administered approximately 12 hours apart.

(2) *Indications for use in dogs.* For the delay of onset of congestive heart failure in dogs with Stage B2 preclinical myxomatous mitral valve disease (2019 ACVIM Consensus Statement). Stage B2 preclinical myxomatous mitral valve disease (MMVD) refers to dogs with asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 5. The authority citation for part 520 continues to read as follows:

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

§ 520.314 [Amended]

■ 6. In § 520.314, in paragraph (b), remove ''000010'' and in its place add ''042791''.

■ 7. In § 520.563, revise the section heading to read as follows:

§ 520.563 Diatrizoate.

* * * * *

■ 8. In § 520.2330, amend paragraph (c)(3) by adding a sentence to the end of the paragraph.

§ 520.2330 Sulfisoxazole tablets.

* * * * *

(c) * * *

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

■ 9. In § 520.2640, revise paragraphs (a), (b), (e)(2)(i), and (3)(i) to read as follows:

§ 520.2640 Tylosin.

(a) *Specifications.* Each container of soluble powder contains tylosin tartrate equivalent to:

(1) 100 grams (g) tylosin base, or

(2) 256 g tylosin base.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section:

(1) Nos. 016592 and 058198 for use of the 100-g container as in paragraph (e) of this section

(2) No. 061133 for use of the 100-or 256-g container as in paragraphs (e)(1)(i)(A), (e)(1)(ii), (e)(2), (e)(3), and (e)(4) of this section.

* * * * *

(e) * * *

(2) * * *

(i) *Amount.* 2 grams per gallon (528 ppm) for 2 to 5 days as the sole source of drinking water. Treated turkeys should consume enough medicated drinking water to provide 60 mg tylosin per pound of body weight per day.

* * * * *

(3) * * *

(i) *Amount.* 250 mg per gallon (66 ppm) as the only source of drinking water for 3 to 10 days, depending on the severity of the condition being treated.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 10. The authority citation for part 522 continues to read as follows:

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

■ 11. In § 522.955, revise paragraphs (b)(3), (d)(1)(ii)(A)(*2*), (d)(1)(ii)(B)(*2*), and (d)(1)(ii)(C) to read as follows:

§ 522.955 Florfenicol.

* * * * *

(b) * * *

(3) Nos. 058005 and 058198 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(1)(ii) of this section.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(A) * * *

(*2*) *Indications for use.* For treatment of BRD associated with *Mannheimia haemolytica, Pasteurella multocida*, and *Histophilus somni.* For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus.*

(B) * * *

(2) *Indications for use.* For control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni.*

(C) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days of the last intramuscular treatment. Nos. 000061, 058005, and 058198: Animals intended for human consumption must not be slaughtered within 38 days of subcutaneous treatment. No. 055529: Animals intended for human consumption must not be slaughtered within 33 days of subcutaneous treatment. This product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established in pre-ruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

§ 522.1338 [Amended]

■ 12. In 522.1338, in paragraph (b), remove ''086155'' and in its place add ''043264''.

■ 13. In § 522.1662a, revise paragraph (e)(1); add paragraphs (e)(3)(i)(D), (e)(3)(ii)(C), and (e)(3)(iii)(D); and remove paragraphs (e)(3)(iv) through (vii) to read as follows:

§ 522.1662a Oxytetracycline hydrochloride injection.

* * * * *

(e) * * *

(1) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) oxytetracycline hydrochloride.

* * * * *

(3) * * *

(i) * * *

(D) Treatment must be discontinued at least 22 days prior to slaughter. Not for use in lactating dairy animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) * * *

(C) Treatment must be discontinued at least 22 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) * * *

(D) Do not administer to laying hens unless the eggs are used for hatching only. Treatment must be discontinued at least 5 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 14. In § 522.2471, revise paragraph (e)(2)(iii) to read as follows:

§ 522.2471 Tilmicosin.

* * * * *

(e) * * *

(2) * * *

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 42 days of the last treatment. Not for use in lactating ewes producing milk for human consumption.

§ 522.2690 [Amended]

■ 15. In 522.2690, in paragraph (b), remove ''076175'' and in its place add ''011788''.

PART 528—INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS

■ 16. The authority citation for part 528 continues to read as follows:

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

■ 17. Revise the heading for part 528 to read as set forth above.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 18. The authority citation for part 558 continues to read as follows:

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

■ 19. In § 558.95, revise paragraphs (e)(4)(i) and (ii) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(e) * * *

(4) * * *

Bambermycins in grams/ton	Indications for use	Limitations	Sponsors
(i) 1 to 4	Growing beef steers and heifers fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency.	Feed continuously at a rate of 10 to 20 milligrams per head per day.	016592
(ii) 2 to 80	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers on pasture: For increased rate of weight gain.	Feed continuously on a hand-fed basis at a rate of 10 to 40 milligrams per head per day in 1 to 10 pounds of supplemental Type C medicated feed.	016592

* * * * *

■ 20. In § 558.128, revise paragraphs (e)(4)(x), (xi), (xiii), (xxx), and (xxxi) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(x) 500 to 2,000 g/ton to provide 10 mg/lb of body weight daily.	Laidlomycin, 5	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(xi) 500 to 4,000 g/ton to provide 10 mg/lb of body weight daily.	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day for not more than 5 days. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
*	*	*	*	*
(xiii) 500 to 1,200 g/ton to provide 10 mg/lb of body weight daily.	Lasalocid, 25 to 30 ..	Cattle fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously in complete feed to provide 10 mg chlortetracycline per lb body weight and not less than 250 mg or more than 360 mg lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
*	*	*	*	*
(xxx) 23.3 to 58.3 g/ton to provide 350 mg/head/day.	Laidlomycin, 5	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for increased rate of weight gain and improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xxxi) 14.6 to 116.7 g/ton to provide 350 mg/head/day.	Laidlomycin, 5 to 10	Cattle fed in confinement for slaughter: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline; and for improved feed efficiency.	Feed continuously at a rate of 30 to 75 mg laidlomycin propionate potassium per head per day. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.305(d) of this chapter. Laidlomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
*	*	*	*	*	*	*

* * * * *

■ 21. In § 558.342, revise paragraph (e)(1)(ii) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(1) * * *

Melengestrol acetate in mg/head/day	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*	*	*
(ii) 0.5	.....	Heifers intended for breeding: For suppression of estrus (heat).	Administer 0.5 to 2.0 lb/head/day of Type C feed containing 0.25 to 1.0 mg melengestrol acetate/lb to provide 0.5 mg melengestrol acetate/head/day. Do not exceed 24 days of feeding.	016592 054771 058198
*	*	*	*	*	*	*

* * * * *

■ 22. In § 558.450:

■ a. Revise paragraph (e)(4)(i);

■ b. Redesignate paragraphs (e)(4)(ii) through (v) as paragraphs (e)(4)(iii) through (vi);

■ c. Add new paragraph (e)(4)(ii); and

■ d. Revise newly redesignated paragraphs (e)(4)(iii) and (vi).

The addition and revisions read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(e) * * *

(4) * * *

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 10 mg/lb of body weight daily.	.....	Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. For No. 069254, withdraw 5 days before slaughter. For No. 066104, zero-day withdrawal period.	066104 069254
(ii) 10 mg/lb of body weight daily.	.....	Calves: For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days in milk replacer or starter feed. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. For No. 069254, withdraw 5 days before slaughter. For No. 066104, zero-day withdrawal period.	066104 069254
(iii) 75 mg/head/day.	.....	Growing cattle (over 400 lb): For reduction of incidence of liver abscesses.	Feed continuously. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.	066104 069254
*	*	*	*	*	*	*
(vi) 0.5 to 2.0 g/head/day.	.....	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 days before and after arrival in feedlots. This drug product is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.	066104 069254

* * * * *

■ 23. In § 558.455:

■ a. Redesignate paragraphs (e)(1)(ii) through (iv) as paragraphs (e)(1)(i) through (iii);

■ b. Redesignate paragraphs (e)(2)(ii) through (iv) as paragraphs (e)(2)(i) through (iii);

■ c. Revise paragraphs (e)(3) and (4); and

■ d. Add paragraph (e)(5).

The revisions and addition read as follows:

§ 558.455 Oxytetracycline and neomycin.

* * * * *

(e) * * *

(3) *Swine.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount		Limitations	Sponsors
(i) To provide 10 mg/lb of body weight daily.	Swine: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; withdraw 5 d before slaughter.	066104 069254
(ii) To provide 10 mg/lb of body weight daily.	Breeding swine: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline.	Feed continuously for not more than 14 d; withdraw 5 d before slaughter.	066104 069254

(4) *Cattle.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) To provide 10 mg/lb of body weight daily.	Calves and beef and nonlactating dairy cattle: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; in feed or milk replacers. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.	066104 069254
(ii) To provide 10 mg/lb of body weight daily.	Calves (up to 250 lb): For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d; in milk replacers or starter feed. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Withdraw 5 d before slaughter.	066104 069254
(iii) To provide 75 mg/head/day.	Growing cattle (over 400 lb): For the reduction of the incidence of liver abscesses.	Feed continuously	066104 069254
(iv) To provide 0.5 to 2.0 g/head/ day.	Cattle: For prevention and treatment of the early stages of shipping fever complex.	Feed 3 to 5 d before and after arrival in feedlots. A withdrawal period has not been established for use in preruminating calves. Do not use in calves to be processed for veal. A milk discard time has not been established for use in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.	066104 069254

(5) *S.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) To provide 10 mg/lb of body weight daily.	Sheep: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 d. If symptoms persist after using for 2 or 3 days, consult a veterinarian. Treatment should continue 24 to 48 hours beyond remission of disease symptoms. Withdraw 5 d before slaughter.	66104, 069254
(ii) [Reserved].			

■ 24. In § 558.575, revise paragraphs (e)(3)(iv) and (v) to read as follows:

§ 558.575 Sulfadimethoxine and ormetoprim.

* * * * *

(e) * * *

(3) * * *

Sulfadimethoxine and ormetoprim amount	Indications for use	Limitations	Sponsors
* *	* *	* * *	
(iv) 630 to 3780 g/ton sulfadimethoxine and 126 to 756 g/ton ormetoprim to provide 50 milligrams (mg) of active ingredients per kilogram of body per day.	Salmonids: For the control of furunculosis in salmonids (trout and salmon) caused by *Aeromonas salmonicida* strains susceptible to sulfadimethoxine and ormetoprim combination.	Administer for 5 consecutive days. Withdraw 42 days before release as stocker fish or slaughter.	015331
(v) 630 to 3780 g/ton sulfadimethoxine and 126 to 756 g/ton ormetoprim to provide 50 mg of active ingredients per kilogram of body per day.	Catfish: For control of enteric septicemia of catfish caused by *Edwardsiella ictaluri* strains susceptible to sulfadimethoxine and ormetoprim combination.	Administer for 5 consecutive days. Withdraw 3 days before slaughter or release as stocker fish.	015331

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24106 Filed 12–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. FDA–2022–N–1128]

Defining Small Number of Animals for Minor Use Determination; Periodic Reassessment; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 14, 2022, for the final rule that appeared in the **Federal Register** of September 15, 2022. The direct final rule revises the ''small number of animals'' definition for dogs and cats in our existing regulation for new animal drugs for minor use or minor species. This document confirms the effective date of the direct final rule.

DATES: The effective date of December 14, 2022, for the direct final rule published September 15, 2022 (87 FR 56583) is confirmed.

FOR FURTHER INFORMATION CONTACT: Janah Maresca, Center for Veterinary Medicine (HVF–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–796–5079, email: *janah.maresca@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 15, 2022 (87 FR 56583), FDA solicited comments concerning the direct final rule for a 60-day period ending November 14, 2022. FDA stated that the effective date of the direct final rule would be on December 14, 2022, 30 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371. Accordingly, the amendments issued thereby are effective.

Dated: December 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–27147 Filed 12–13–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2022–0899]

Safety Zones; Fireworks Displays in the Fifth Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Delaware River, Philadelphia, PA; Safety Zone from 5:45 p.m. through 6:30 p.m. on December 31, 2022, and from 11:45 p.m. on December 31, 2022, through 12:30 a.m. on January 1, 2023, to provide for the safety of life on navigable waterways during two barge-based fireworks displays. Our regulation for marine events within the Fifth Coast Guard District identifies the regulated area for this event in Philadelphia, PA. During the enforcement period, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulation 33 CFR 165.506 will be enforced for the location identified in entry 10 of table 1 to paragraph (h)(1) from 5:45 p.m. through 6:30 p.m. on December 31, 2022, and from 11:45 p.m. on December 31, 2022, through 12:30 a.m. on January 1, 2023.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, you may call or email Petty Officer Dylan Caikowski, U.S. Coast Guard, Sector Delaware Bay, Waterways Management Division, telephone 215–271–4814, email *SecDelBayWWM@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone in table 1 to paragraph (h)(1) to 33 CFR 165.506, entry No. 10 for two barge-based fireworks displays from 5:45 p.m. through 6:30 p.m. on December 31, 2022, and from 11:45 p.m. on December 31, 2022, through 12:30 a.m. on January 1, 2023. This action is necessary to ensure safety of life on the navigable waters of the United States immediately prior to, during, and immediately after fireworks displays. Our regulation for safety zones of fireworks displays within the Fifth Coast Guard District, table 1 to paragraph (h)(1) to 33 CFR 165.506, entry 10 specifies the location of the regulated area as all waters of the Delaware River, adjacent to Penn's Landing, Philadelphia, PA, within a 500-yard radius of the fireworks barge position. The approximate position for the display is latitude 39°56′52″ N, longitude 075°8′9.28″ W. During the enforcement period, as reflected in § 165.506(d), vessels may not enter, remain in, or transit through the safety zone unless authorized by the Captain of the Port or designated Coast Guard patrol personnel on-scene.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide notification of this enforcement period via broadcast notice to mariners.

Dated: December 7, 2022.

Jonathan D. Theel,

Captain, U.S. Coast Guard, Captain of the Port Delaware Bay.

[FR Doc. 2022–27042 Filed 12–13–22; 8:45 am]

BILLING CODE 9110–04–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket No. 02–278; FCC 22–85; FRID 116788]

Telephone Consumer Protection Act of 1991; Petition for Declaratory Ruling of All About the Message, LLC

AGENCY: Federal Communications Commission.

ACTION: Declaratory ruling and order.

SUMMARY: In this document, the Federal Communications Commission (Commission) finds that ''ringless voicemail'' to wireless phones requires consumer consent because it is a ''call'' made using an artificial or prerecorded voice and thus is covered by of the 1991 Telephone Consumer Protection Act (TCPA). The Commission denies a request from All About the Message, LLC (AATM) to declare that ringless voicemail is not subject to of the TCPA and the Commission's implementing rules. The Commission also denies AATM's alternative request for a retroactive waiver of the Commission's rules.

DATES: The Declaratory Ruling and Order was effective November 21, 2022.

FOR FURTHER INFORMATION CONTACT: Mika Savir of the Consumer Policy Division, Consumer and Governmental Affairs Bureau, at *mika.savir@fcc.gov* or (202) 418–0384.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Declaratory Ruling and Order, FCC 22–85, CG Docket No. 02–278, adopted on November 14, 2022, and released on November 21, 2022. The full text of this document is available online at *https://*