DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA–2018–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship; Change of a Sponsor's Name and 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) and abbreviated new animal drug applications (ANADAs) during April, May, and June 2018. 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 make technical amendments to improve the accuracy and readability of the regulations.

DATES: This rule is effective December 18, 2018.

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. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during April, May, and June 2018, 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. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/AboutFDA/CentersOffices/Officeof Foods/CVM/CVMFOIAElectronic ReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/AnimalVeterinary/Products/Approved AnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING APRIL, MAY, AND JUNE 2018

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
May 4, 2018	141–481	Kindred Biosciences, Inc., 1555 Bayshore Hwy., Suite 200, Burlingame, CA 94010.	MIRATAZ (mirtazapine transdermal ointment).	Cats	Original approval for the management of weight loss in cats.	FOI Summary.
May 15, 2018	141–501	Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506–2002.	SEMINTRA (telmisartan oral solution).	Cats	Original approval for the control of systemic hypertension in cats.	FOI Summary.
May 25, 2018	141–063	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	NUFLOR (florfenicol), Injectable Solution.	Cattle	Supplemental approval to provide human food safety information for the use of the inactive ingredient *n*-methyl-2-pyrrolidone (NMP).	FOI Summary.
May 31, 2018	141–495	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	INTEPRITY (avilamycin) and BIO-COX (salinomycin sodium) Type C medicated feeds.	Chickens ..	Original approval for the prevention of mortality caused by necrotic enteritis and for the prevention of coccidiosis in broiler chickens.	FOI Summary.
June 6, 2018	141–342	Jurox Pty. Ltd., 85 Gardiner Rd., Rutherford, NSW 2320, Australia.	ALFAXAN (alfaxalone), Injectable Solution.	Dogs and cats.	Supplemental approval providing for addition of preservatives and use of a multidose vial.	FOI Summary.
June 14, 2018	098–379	Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	CYSTORELIN (gonadorelin), Injectable Solution.	Cattle	Supplemental approval for use with cloprostenol sodium to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows and beef cows.	FOI Summary, 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).

II. Technical Amendments

With the approval of NADA 141–481, Kindred Biosciences, Inc. is now the sponsor of an approved application. Accordingly, we are amending § 510.600(c) to add the name, address, and drug labeler code of this sponsor.

Piramal Healthcare Ltd., Piramal Tower, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013, India, has informed FDA that it has changed its name and address to Piramal Enterprises Ltd., Ananta, Agastya Corporate Park, Opp Fire Brigade, Kamani Junction, LBS Mag Kurla (West), Mumbai, 400070, India. We are amending § 510.600(c) to reflect this change.

We are also making technical amendments to update the scientific name of a pathogenic bacterium and to accurately list the concentrations of active ingredients in an otic dosage form new animal drug. We are also making a technical amendment to correct the sponsor of epsiprantel tablets. These actions are being taken to improve the accuracy of the regulations.

In addition, we are reformatting the regulations to create a tabular display of

the approved uses of narasin and a separate section for uses of a fixed-ratio, combination drug Type A medicated article containing narasin and nicarbazin. These actions are being taken to improve the readability, consistency, and accuracy of the regulations.

III. 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 Parts 520, 522, and 524

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, 21 CFR parts 510, 520, 522, 524, 556, 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, in the table in paragraph (c)(1), alphabetically add an entry for ''Kindred Biosciences, Inc.'' and remove the entry for ''Piramal Healthcare Ltd.'' and add an entry for ''Piramal Enterprises Ltd.'' in its place; and in the table in paragraph (c)(2), revise the entry for ''065085'' and numerically add an entry for ''086078'' 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
* * * * * * *	
Kindred Biosciences, Inc., 1555 Bayshore Hwy., Suite 200, Burlingame, CA 94010	086078
* * * * * * *	
Piramal Enterprises Ltd., Ananta, Agastya Corporate Park, Opp Fire Brigade, Kamani Junction, LBS Mag Kurla (West), Mumbai, 400070, India	065085
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
065085	Piramal Enterprises Ltd., Ananta, Agastya Corporate Park, Opp Fire Brigade, Kamani Junction, LBS Mag Kurla (West), Mumbai, 400070, India.
* * * * * * *	
086078	Kindred Biosciences, Inc., 1555 Bayshore Hwy., Suite 200, Burlingame, CA 94010.
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.88f [Amended]

■ 4. In § 520.88f, in paragraph (c)(2), remove ''lacerations) due to *S. aureus, Streptococcus* spp., *E. coli*'' and in its place add ''lacerations) due to *S. aureus, Enterococcus faecalis, E. coli*''.

§ 520.816 [Amended]

■ 5. In § 520.816, in paragraph (b), remove ''050604'' and in its place add ''054771''.

■ 6. Add § 520.2335 to read as follows:

§ 520.2335 Telmisartan.

(a) *Specifications.* Each milliliter of solution contains 10 milligrams (mg) telmisartan.

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

(c) *Conditions of use*—(1) *Amount.* Administer 1.5 mg/kilogram (kg) (0.68 mg/pound (lb)) orally twice daily for 14 days, followed by 2 mg/kg (0.91 mg/lb) orally once daily.

(2) *Indications for use.* For the control of systemic hypertension in cats.

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

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 8. Revise § 522.1077 to read as follows:

§ 522.1077 Gonadorelin.

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 43 micrograms (µg) of gonadorelin as gonadorelin acetate;

(2) 100 µg of gonadorelin as gonadorelin acetate;

(3) 43 µg of gonadorelin as gonadorelin diacetate tetrahydrate; or

(4) 50 µg of gonadorelin as gonadorelin hydrochloride.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 000061 for use of the 43-µg/mL product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(iv), and (d)(2) of this section.

(2) No. 068504 for use of the 100-µg/mL product described in paragraph (a)(2) as in paragraphs (d)(1)(ii), (d)(1)(v), and (d)(2) of this section.

(3) No. 061623 for use of the 43-µg/mL product described in paragraph (a)(3) as in paragraphs (d)(1)(i) and (d)(2) of this section.

(4) No. 050604 for use of the 43-µg/mL product described in paragraph (a)(3) as in paragraphs (d)(1)(i), (d)(1)(vi), and (d)(2) of this section.

(5) No. 054771 for use of the 50-µg/mL product described in paragraph (a)(4) as in paragraphs (d)(1)(iii), (d)(1)(vii), and (d)(2) of this section.

(c) *Special considerations.* Concurrent luteolytic drug use is approved as follows:

(1) Cloprostenol injection for use as in paragraph (d)(1)(iv) of this section as provided by No. 000061 in § 510.600(c) of this chapter.

(2) Cloprostenol injection for use as in paragraph (d)(1)(v) and (d)(1)(vi) of this section as provided by No. 068504 in § 510.600(c) of this chapter.

(3) Dinoprost injection for use as in paragraph (d)(1)(vii) of this section as provided by No. 054771 in § 510.600(c) of this chapter.

(d) *Conditions of use in cattle*—(1) *Indications for use and amounts*—(i) For the treatment of ovarian follicular cysts in dairy cattle: Administer 86 µg gonadorelin (No. 000061) or 100 µg gonadorelin diacetate tetrahydrate (Nos. 061623 and 050604) by intramuscular or intravenous injection.

(ii) For the treatment of ovarian follicular cysts in dairy cattle: Administer 100 µg gonadorelin by intramuscular or intravenous injection.

(iii) For the treatment of ovarian follicular cysts in cattle: Administer 100 µg gonadorelin by intramuscular injection.

(iv) For use with cloprostenol injection to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows: Administer to each cow 86 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 86 µg gonadorelin by intramuscular injection.

(v) For use with cloprostenol sodium to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows and beef cows: Administer to each cow 100 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 100 µg gonadorelin by intramuscular injection.

(vi) For use with cloprostenol sodium to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows and beef cows: Administer to each cow 100 µg gonadorelin diacetate tetrahydrate by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 100 µg gonadorelin diacetate tetrahydrate by intramuscular injection.

(vii) For use with dinoprost injection to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows: Administer to each cow 100 to 200 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 25 mg dinoprost by intramuscular injection, followed 30 to 72 hours later by 100 to 200 µg gonadorelin by intramuscular injection.

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

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 9. The authority citation for part 524 continues to read as follows:

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

■ 10. In § 524.957, revise paragraph (a) to read as follows:

§ 524.957 Florfenicol, terbinafine, and mometasone otic solution.

(a) *Specifications.* Each single-dose, prefilled dropperette contains 1 milliliter (mL) of a solution containing 16.6 milligrams (mg) florfenicol, 14.8 mg terbinafine (equivalent to 16.6 mg terbinafine hydrochloride), and 2.2 mg mometasone furoate.

* * * * *

■ 11. Add § 524.1448 to read as follows:

§ 524.1448 Mirtazapine transdermal ointment.

(a) *Specifications.* Each gram of ointment contains 20 milligrams (mg) mirtazapine.

(b) *Sponsor.* See No. 086078 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer topically by applying a 1.5 inch ribbon of ointment (approximately 2 mg) on the inner pinna of the cat's ear once daily for 14 days. Alternate the daily application of ointment between the left and right inner pinna of the ears.

(2) *Indications for use.* For the management of weight loss in cats.

(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

■ 12. The authority citation for part 556 continues to read as follows:

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

■ 13. In § 556.428, add paragraph (c) to read as follows:

§ 556.428 Narasin.

* * * * *

(c) *Related conditions of use.* See §§ 558.363 and 558.364 of this chapter.

■ 14. Revise § 556.445 to read as follows:

§ 556.445 Nicarbazin.

(a) [Reserved]

(b) *Tolerances.* A tolerance of 4 parts per million is established for residues of nicarbazin in uncooked chicken muscle, liver, skin, and kidney.

(c) *Related conditions of use.* See §§ 558.364 and 558.366 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 16. In § 558.68, revise paragraph (e)(1)(ii) and add paragraph (e)(1)(v) to read as follows:

§ 558.68 Avilamycin.

* * * * *

(e) * * *

(1) * * *

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*		*	*	*
(ii) 13.6 to 40.9	Monensin, 90 to 110.	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens;* and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*.	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age. See § 558.355(d) of this chapter. Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	058198
*		*	*	*
(v) 13.6 to 40.9	Salinomycin sodium, 40 to 60.	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens;* and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*.	Feed as the sole ration for 21 consecutive days. Feed to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens.* Not approved for use with pellet binders. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. Do not feed to laying hens producing eggs for human consumption. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.	058198

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■ 17. In § 558.76, remove and reserve paragraph (e)(1)(viii); redesignate paragraphs (e)(2)(xiii) through (xvii) as paragraphs (e)(2)(xiv) through (xviii); add new paragraph (e)(2)(xiii); and revise newly redesignated paragraph (e)(2)(xiv).

The addition and revision read as follows:

§ 558.76 Bacitracin methylendisalicylate.

* * * * *

(e) * * *

(2) * * *

(xiii) Narasin and nicarbazin as in § 558.364.

(xiv) Nicarbazin as in § 558.366.

* * * * *

■ 18. In § 558.78, add paragraph (d)(3)(vii) to read as follows:

§ 558.78 Bacitracin zinc.

* * * * *

(d) * * *

(3) * * *

(vii) Nicarbazin as in § 558.366.

* * * * *

■ 19. In § 558.95, revise paragraph (d)(5)(viii); redesignate paragraphs (d)(5)(ix) through (xi) as paragraphs (d)(5)(x) through (xii); and add new paragraph (d)(5)(ix).

The revision and addition read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(5) * * *

(viii) Narasin as in § 558.363.

(ix) Narasin and nicarbazin as in § 558.364.

* * * * *

§ 558.128 [Amended]

■ 20. In § 558.128, in paragraph (e)(3)(iv), in the ''Limitations'' column, at the end of the second sentence, add ''Chlortetracycline and bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.''

§ 558.325 [Amended]

■ 21. In § 558.325, in paragraph (e)(1)(iv), in the ''Combination in grams/ton'' column, remove ''Decoquinate, 2.72'' and in its place add ''Decoquinate, 27.2''.

■ 22. Revise § 558.363 to read as follows:

§ 558.363 Narasin.

(a) *Specifications.* Type A medicated articles containing 36, 45, 54, 72, and 90 grams narasin per pound.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.428 of this chapter.

(d) *Special considerations.* An expiration date of 2 months (8 weeks) is required for narasin Type C medicated swine feeds.

(e) *Conditions of use.* It is used as follows:

(1) *Chickens*—

Narasin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 54 to 90		Broiler chickens: For prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal.	058198
(ii) 54 to 72	Bacitracin methylenedisalicylate, 10 to 50.	Broiler chickens: For prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 54 to 72	Bacitracin zinc, 4 to 50	Broiler chickens: For prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 54 to 72	Bambermycins, 1 to 2	Broiler chickens: For prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592

(2) *Swine*—

Narasin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 13.6 to 27.2		Growing-finishing swine: For increased rate of weight gain when fed for at least 4 weeks.	Feed continuously for at least 4 weeks to swine during the growing-finishing period as the sole ration. No increased benefit in rate of weight gain has been shown when narasin concentrations in the diet are greater than 13.6 g/ton. Effectiveness has not been demonstrated when fed for durations less than 4 weeks. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Swine being fed with narasin should not have access to feeds containing pleuromutilins (*e.g.*, tiamulin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.	058198
(ii) 18.1 to 27.2		Growing-finishing swine: For increased rate of weight gain and improved feed efficiency when fed for at least 4 weeks.	Feed continuously for at least 4 weeks to swine during the growing-finishing period as the sole ration. No increased benefit in rate of weight gain has been shown when narasin concentrations in the diet are greater than 13.6 g/ton. Effectiveness has not been demonstrated when fed for durations less than 4 weeks. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Swine being fed with narasin should not have access to feeds containing pleuromutilins (*e.g.*, tiamulin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.	058198

(3) Narasin single-ingredient Type A medicated articles may also be used in combination with:

(i) Avilamycin as in § 558.68.

(ii) [Reserved]

§ 558.364 [Redesignated as § 558.365]

■ 23. Redesignate § 558.364 as § 558.365.

■ 24. Add new § 558.364 to read as follows:

§ 558.364 Narasin and nicarbazin.

(a) *Specifications.* A fixed-ratio, combination drug Type A medicated article containing 36 grams narasin and 36 grams nicarbazin per pound.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Tolerances.* See §§ 556.428 and 556.445 of this chapter.

(d) *Conditions of use.* It is used as follows:

(1) *Chickens*—

Narasin and nicarbazin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27 to 45 of each drug.	.....	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal.	058198
(ii) 27 to 45 of each drug.	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iii) 27 to 45 of each drug.	Bacitracin methylenedisalicylate, 50.	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying hens. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 27 to 45 of each drug.	Bacitracin methylenedisalicylate, 100 to 200.	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 27 to 45 of each drug.	Bambermycins, 1 to 2	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 5 days before slaughter. Do not allow turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198

(2) Narasin and nicarbazin fixed-ratio, combination drug Type A medicated articles may also be used in combination with:

(i) Avilamycin as in § 558.68.

(ii) [Reserved]

■ 25. Revise § 558.366 to read as follows:

§ 558.366 Nicarbazin.

(a) *Specifications.* Type A medicated articles containing 25 percent nicarbazin.

(b) *Sponsors.* See Nos. 058198, 060728, and 066104 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(c) *Related tolerances.* See § 556.445 of this chapter.

(d) *Conditions of use.* It is used as follows:

(1) *Chickens*—

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 90.8 to 181.6	.....	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton.	066104
(ii) 90.8 to 181.6	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Nicarbazin as provided by No. 066104; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) 90.8 to 181.6 ...	Bacitracin methylenedisalicylate, 30.	Broiler chickens; As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Nicarbazin as provided by No. 066104; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	066104
(iv) 90.8 to 181.6 ...	Bacitracin methylenedisalicylate 50.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for outbreaks of coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Nicarbazin as provided by No. 066104; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 113.5	.....	Chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter.	058198 060728
(vi) 113.5	Bacitracin methylenedisalicylate, 30.	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter. Nicarbazin as provided by No. 066104; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	060728
(vii) 113.5	Bacitracin zinc, 4 to 50	Broiler chickens; aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency.	For broiler chickens only. Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter. Nicarbazin as provided by No. 066104, bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	054771 066104
(viii) 113.5	Bambermycins, 1 to 2	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter. Nicarbazin as provided by No. 066104; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592

(2) [Reserved]

§ 558.485 [Amended]

■ 26. In § 558.485, in paragraph (e)(2), in the ''Limitations'' column, remove ''Not for use in horses intended for food.'' and in its place add ''Do not use in horses intended for human consumption.''

Dated: December 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27238 Filed 12–17–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0864]

RIN 1625–AA00

Safety Zone; Tumon Bay, Tumon, GU

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a 190 yard radius of a fireworks barge located in Tumon Bay for the New Year's Eve Fireworks display. The Coast Guard believes this safety zone is necessary to protect the public from potential hazards created by the fireworks display fallout. This safety zone will prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Guam (COTP).

DATES: This rule is effective from 9 p.m. on December 31, 2018 through 1 a.m. on January 1, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2018–0864 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Chief Todd Wheeler, Waterways Management, U.S. Coast Guard; telephone 671–355–4566, email *wwmguam@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security