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Issued on January 14, 2020.

Dionne Palermo,

Acting Director, System Oversight Division,
Aircraft Certification Service.

[FR Doc. 2020-01043 Filed 1-23-20; 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, 529, 556, and 558

[Docket No. FDA-2019-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsor; Change of Sponsor's 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 July, August, and September 2019. 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 of the regulations.

DATES: This rule is effective January 24, 2020, except for amendatory instruction number 3 to 21 CFR 510.600, number 8 to 21 CFR 520.1807, number 21 to 21 CFR 529.1115, and number 24 to 21 CFR 556.513, which are effective February 3, 2020.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July, August, and September 2019, 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/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: <https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2019

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
July 1, 2019 ...	200-639	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	MONOVET (monensin) Type A Medicated Article.	Cattle and goats.	Original approval as a generic copy of NADA 095-735.	FOI Summary.
July 2, 2019 ...	141-519	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	PROHEART 12 (moxidectin) for Extended-Release Injectable Suspension.	Dogs	Original approval for prevention of heartworm disease caused by <i>Dirofilaria immitis</i> for 12 months in dogs 12 months of age and older; and for treatment of existing larval and adult hookworm (<i>Ancylostoma caninum</i> and <i>Uncinaria stenocephala</i>) infections.	FOI Summary.
July 5, 2019 ...	113-645	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	ESTRUMATE (cloprostenol injection) ...	Cattle	Supplemental approval for synchronization of estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows.	FOI Summary.
July 26, 2019	141-255	Syndel USA, 1441 W. Smith Rd., Ferndale, WA 98248.	35% PEROX-AID (hydrogen peroxide) Concentrated Immersion Solution.	Finfish	Supplemental approval for the control of mortality in freshwater-reared coldwater finfish, fingerling and adult freshwater-reared coolwater finfish, and fingerling and adult freshwater-reared warmwater finfish due to saprolegniasis associated with fungi in the family Saprolegniaceae; for the treatment and control of <i>Gyrodactylus</i> spp. in freshwater-reared salmonids; and for the control of mortality in freshwater-reared warmwater finfish due to external columnaris associated with <i>Flavobacterium columnare</i> .	FOI Summary.
August 27, 2019.	141-465	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	Avilamycin and monensin Type C medicated feeds.	Chickens	Supplemental approval of a revised age restriction caution statement for broiler feeds.	FOI Summary.
August 27, 2019.	141-467	Do.	Avilamycin and narasin Type C medicated feeds.	Chickens	Supplemental approval of a revised age restriction caution statement for broiler feeds.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2019—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
August 27, 2019.	141–495	Do.	Avilamycin and salinomycin Type C medicated feeds.	Chickens	Supplemental approval of a revised age restriction caution statement for broiler feeds.	FOI Summary.
September 3, 2019.	141–494	Do.	CREDELIO (lotilaner) Chewable Tablet.	Dogs	Supplemental approval for prevention of flea infestations for 1 month in dogs and puppies.	FOI Summary.
September 20, 2019.	200–642	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Monensin and tylosin phosphate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with TYLOVET (tylosin phosphate) Type A medicated articles in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 104–646.	FOI Summary.
September 20, 2019.	200–643	Do.	Monensin and tylosin phosphate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with TYLAN (tylosin phosphate) Type A medicated articles in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 104–646.	FOI Summary.
September 20, 2019.	200–644	Do.	Monensin, ractopamine hydrochloride, and tylosin phosphate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with OPTAFLEXX (ractopamine hydrochloride Type A medicated article) and TYLOVET (tylosin phosphate) Type A medicated article in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 141–224.	FOI Summary.
September 20, 2019.	200–645	Do.	Monensin, ractopamine hydrochloride, and tylosin phosphate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with ACTOGAIN (ractopamine hydrochloride Type A medicated article) and TYLOVET (tylosin phosphate) Type A medicated article in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 141–224.	FOI Summary.
September 20, 2019.	200–646	Do.	Monensin, ractopamine hydrochloride, and tylosin phosphate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with OPTAFLEXX (ractopamine hydrochloride Type A medicated article) and TYLAN (tylosin phosphate) Type A medicated article in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 141–224.	FOI Summary.
September 20, 2019.	200–647	Do.	Monensin, ractopamine hydrochloride, and tylosin phosphate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with ACTOGAIN (ractopamine hydrochloride Type A medicated article) and TYLAN (tylosin phosphate) Type A medicated article in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 141–224.	FOI Summary.
September 20, 2019.	200–648	Do.	Monensin, ractopamine hydrochloride, tylosin phosphate, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with OPTAFLEXX (ractopamine hydrochloride Type A medicated article), TYLOVET (tylosin phosphate) Type A medicated article, and MGA (melengestrol acetate Type A medicated article) in the manufacture of Type C medicated feeds as a generic copy of NADA 141–233.	FOI Summary.
September 20, 2019.	200–649	Do.	Monensin, ractopamine hydrochloride, tylosin phosphate, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with ACTOGAIN (ractopamine hydrochloride Type A medicated article), TYLOVET (tylosin phosphate) Type A medicated article, and MGA (melengestrol acetate Type A medicated article) in the manufacture of Type C medicated feeds as a generic copy of NADA 141–233.	FOI Summary.
September 20, 2019.	200–650	Do.	Monensin, ractopamine hydrochloride, tylosin phosphate, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with OPTAFLEXX (ractopamine hydrochloride Type A medicated article), TYLOVET (tylosin phosphate) Type A medicated article, and MGA (melengestrol acetate Type A medicated article) in the manufacture of Type C medicated feeds as a generic copy of NADA 141–233.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2019—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
September 20, 2019.	200–651	Do.	Monensin, ractopamine hydrochloride, tylosin phosphate, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with ACTOGAIN (ractopamine hydrochloride Type A medicated article), TYLAN (tylosin phosphate) Type A medicated article, and MGA (melengestrol acetate Type A medicated article) in the manufacture of Type C medicated feeds as a generic copy of NADA 141–233.	FOI Summary.

II. Changes of Sponsor

The sponsors of the following approved applications have informed

FDA that they have transferred ownership of, and all rights and interest in, these applications to another sponsor:

File No.	Product name	Transferring sponsor	New sponsor	21 CFR section
140–872	POSILAC (sometribove zinc) Injectable Suspension.	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	Union Agener, Inc., 1788 Lovers Ln., Augusta, GA 30901.	522.2112
141–457	ENTYCE (capromorelin) Oral Solution.	Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211.	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	520.292
141–461	NOCITA (bupivacaine liposome injectable suspension).	Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211.	Do.	522.224
200–180	Ampicillin Trihydrate (ampicillin trihydrate) Powder for Injection.	G. C. Hanford Mfg. Co., P.O. Box 1017, Syracuse, NY 13201.	HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652.	522.90b
200–273	VETRO–GEN (gentamicin sulfate) Veterinary Ophthalmic Ointment.	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom.	Putney, Inc., One Monument Sq., Suite 400, Portland, ME 04101.	524.1044c
200–388	GB (gentamicin sulfate and betamethasone valerate) Topical Spray.	American Pharmaceuticals and Cosmetics, Inc., 1401 Joel East Rd., Fort Worth, TX 76140.	Do.	524.1044f
200–490	Carprofen (carprofen) Chewable Tablets.	Dragon Fire Holding Co., Inc., 2619 Skyway Dr., Grand Prairie, TX 75052.	Do.	520.490

Following these changes of sponsorship, American Pharmaceuticals and Cosmetics, Inc.; Aratana Therapeutics, Inc.; and Dragon Fire Holding Co., Inc. are no longer the sponsor of an approved application. Accordingly, the regulations in parts 510, 520, 522, and 524 are being amended to reflect these changes.

III. Change of Sponsor's Address

Halocarbon Products Corp., 887 Kinderkamack Rd., River Edge, NJ 07661 has informed FDA that it has changed its address to 6525 The Corners Pkwy., Suite 200, Peachtree Corners, GA 30092. Accordingly, we are amending § 510.600(c) to reflect this change.

IV. Withdrawals of Approval

Fleming Laboratories, Inc., P.O. Box 34384, Charlotte, NC 28234, has requested that FDA withdraw approval of NADA 010–005 for use of WAZINE (dipiperazine sulfate and piperazine hydrochloride) Soluble Powders

because the product is no longer manufactured or marketed. Following this withdrawal of approval, Fleming Laboratories, Inc., is no longer the sponsor of an approved application. Accordingly, it will be removed from the list of sponsors of approved applications in § 510.600(c). In addition, Fleming Laboratories, Inc.'s product was the only piperazine product approved for use in food-producing animals. Accordingly, tolerances for piperazine will be removed from part 556.

Also, Halocarbon Products Corp., 6525 The Corners Pkwy., Suite 200, Peachtree Corners, GA 30092, has requested that FDA withdraw approval of ANADA 200–200 for use of Halothane USP (halothane) because the product is no longer manufactured or marketed.

Lastly, Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103, has requested that FDA withdraw approval of ANADA 200–472 for use of Fomepizole Injection because the

product is no longer manufactured or marketed.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADA 010–005 and ANADAs 200–200 and 200–472, and all supplements and amendments thereto, is withdrawn effective February 3, 2020. As provided in the regulatory text of this document, the animal drug regulations in parts 510, 520, 556, and 529 are amended to reflect these actions.

V. Technical Amendments

FDA is revising the regulations at 21 CFR 520.2520d to reflect the approved conditions of use of trichlorfon, phenothiazine, and piperazine soluble powder for oral administration to horses as an anthelmintic. This information was deleted in error during redesignation (79 FR 28833, May 20, 2014). FDA is also revising the regulations at 21 CFR 520.2612 to reflect the currently approved dosage for trimethoprim and sulfadiazine

suspension for oral administration to horses as an antimicrobial. Lastly, FDA is revising the assay limits for ncarbazine medicated feeds at 21 CFR 558.4(d) in the “Category II” table. These actions are being taken to improve the accuracy of the regulations.

VI. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (the 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, 524, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

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, 529, 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:

- a. In the table in paragraph (c)(1):
- i. Remove the entries for “American Pharmaceuticals and Cosmetics, Inc.”, “Aratana Therapeutics, Inc.”, and “Dragon Fire Holding Co., Inc.”;
- ii. Revise the entry for “Halocarbon Products Corp.”; and
- iii. Add an entry in alphabetical order for “Union Agener, Inc.”;
- b. In the table in paragraph (c)(2):
- i. Revise the entry for “012164”;
- ii. Remove the entries for “065531”, “076033”, and “086026”; and
- iii. Add an entry in numerical order for “086106”.
- 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
*	*	*	*	*	*	*
Halocarbon Products Corp.,	6525 The Corners Pkwy.,	Suite 200,	Peachtree Corners,	GA 30092	012164
*	*	*	*	*	*	*
Union Agener, Inc.,	1788 Lovers Ln.,	Augusta,	GA 30901		086106
*	*	*	*	*	*	*

(2) * * *

Drug labeler code	Firm name and address					
*	*	*	*	*	*	*
012164	Halocarbon Products Corp.,	6525 The Corners Pkwy.,	Suite 200,	Peachtree Corners,	GA 30092
*	*	*	*	*	*	*
086106	Union Agener, Inc.,	1788 Lovers Ln.,	Augusta,	GA 30901	
*	*	*	*	*	*	*

§ 510.600 [Amended]

- 3. Effective February 3, 2020, § 510.600 is further amended, in the table in paragraph (c)(1), remove the entry for “Fleming Laboratories, Inc.”; and in the table in paragraph (c)(2), remove the entry for “015565”.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

- 4. The authority citation for part 520 continues to read as follows:

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

§ 520.292 [Amended]

- 5. In § 520.292, in paragraph (b), remove “086026” and in its place add “058198”.

§ 520.304 [Amended]

- 6. In § 520.304, in paragraph (b)(1), remove “062250, and 076033” and in its place add “and 062250”.

§ 520.1286 [Amended]

■ 7. In § 520.1286, in paragraph (c)(2), remove “for the treatment of flea infestations” and in its place add “for the treatment and prevention of flea infestations”.

§ 520.1807 [Removed]

■ 8. Effective February 3, 2020, § 520.1807 is removed.

■ 9. In § 520.2520d, revise the section heading and add paragraph (c) to read as follows:

§ 520.2520d Trichlorfon, phenothiazine, and piperazine.

* * * * *

(c) *Conditions of use in horses*—(1) *Amount*. 18.2 milligrams (mg) of trichlorfon, 12.5 mg of phenothiazine, and 40 mg of piperazine base per pound of body weight.

(2) *Indications for use*. For removal of bots (*Gastrophilus nasalis*, *Gastrophilus intestinalis*), large strongyles (*Strongylus vulgaris*), small strongyles, large roundworms (ascarids, *Parascaris equorum*), and pinworms (*Oxyuris equi*).

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 10. In § 520.2612, revise paragraph (c)(2)(i) to read as follows:

§ 520.2612 Trimethoprim and sulfadiazine suspension.

* * * * *

(c) * * *

(2) * * *

(i) *Amount*. Administer orally at a dosage of 24 mg combined active ingredients per kilogram body weight (10.9 mg/lb) twice daily for 10 days. Administered by volume at 2.7 mL per 45.4 kilograms of body weight (2.7 mL/100 lb).

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.90b [Amended]

■ 12. In § 522.90b, in paragraph (b), remove “010515” and in its place add “042791”.

§ 522.224 [Amended]

■ 13. In § 522.224, in paragraph (b), remove “086026” and in its place add “058198”.

■ 14. In § 522.460, add paragraph (b)(3), revise paragraphs (c)(1)(ii) and (iii), add paragraph (c)(1)(iv), and revise paragraph (c)(2) to read as follows:

§ 522.460 Cloprostenol.

* * * * *

(b) * * *

(3) No. 000061 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(iv) and (c)(2) of this section.

(c) * * *

(1) * * *

(ii) Administer 500 µg by intramuscular injection for abortion of unwanted pregnancies from mismatings from 1 week after mating until 5 months after conception; for unobserved (non-detected) estrus; for treatment of mummified fetus, luteal cysts, and pyometra or chronic endometritis in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(iii) Administer 500 µg by intramuscular injection as a single injection regimen or double injection regimen with a second injection 11 days after the first, for estrus synchronization in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(iv) For use with gonadorelin acetate 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.

(2) *Limitations*. Gonadorelin acetate for use in paragraph (c)(1)(iv) of this section as provided by No. 000061 in § 510.600(c) of this chapter.

■ 15. Revise § 522.1451 to read as follows:

§ 522.1451 Moxidectin microspheres for injection.

(a) *Specifications*. The drug product consists of two separate vials. One vial contains 10 percent moxidectin microspheres and the second vial contains a vehicle for constitution of the moxidectin microspheres.

(1) Each milliliter (mL) of constituted suspension contains 3.4 milligrams (mg) moxidectin.

(2) Each mL of constituted suspension contains 10 mg moxidectin.

(b) *Sponsor*. See No. 54771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount*. (i) Using the suspension described in paragraph (a)(1) of this section, administer 0.05 mL of the constituted suspension per kilogram (kg) of body weight (0.023 mL per

pound (lb)) as a single subcutaneous injection to provide 0.17 mg/kg body weight (0.0773 mg/lb).

(ii) Using the suspension described in paragraph (a)(2) of this section, administer 0.05 mL of the constituted suspension/kg of body weight (0.023 mL/lb) as a single subcutaneous injection to provide 0.5 mg/kg body weight (0.23 mg/lb).

(2) *Indications for use*—(i) *Suspension described in paragraph (a)(1) of this section*. For prevention of heartworm disease caused by *Dirofilaria immitis* in dogs 6 months of age and older; and for treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

(ii) *Suspension described in paragraph (a)(2) of this section*. For prevention of heartworm disease caused by *Dirofilaria immitis* for 12 months in dogs 12 months of age and older; and for treatment of existing larval and adult hookworm (*Ancylostoma caninum* and *Uncinaria stenocephala*) infections.

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

§ 522.2112 [Amended]

■ 16. In § 522.2112, in paragraph (b), remove “058198” and in its place add “086106”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1044c [Amended]

■ 18. In § 524.1044c, in paragraph (b), remove “043264” and in its place add “026637”.

§ 524.1044f [Amended]

■ 19. In § 524.1044f, in paragraph (b), remove “058829, and 065531” and in its place add “and 058829”.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 20. The authority citation for part 529 continues to read as follows:

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

§ 529.1115 [Amended]

■ 21. Effective February 3, 2020, in § 529.1115, in paragraph (b), remove “Nos. 012164 and 054771” and in its place add “No. 054771”.

■ 22. In § 529.1150, revise paragraph (c) to read as follows:

§ 529.1150 Hydrogen peroxide.

* * * * *

(c) *Conditions of use*—(1) *Indications and amount.* (i) Freshwater-reared finfish eggs for the control of mortality in due to saprolegniasis associated with fungi in the family Saprolegniaceae:

(A) For all coldwater and coolwater species of freshwater-reared finfish eggs: 500 to 1,000 mg per liter (/L) of culture water for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch, or

(B) For all freshwater-reared warmwater finfish eggs: 750 to 1,000 mg/L for 15 minutes in a continuous flow system once per day on consecutive or alternate days until hatch.

(ii) Freshwater-reared finfish for the control of mortality due to saprolegniasis associated with the fungi in the family Saprolegniaceae: For freshwater-reared coldwater finfish including salmonids (all life stages), freshwater-reared coolwater finfish fingerlings and adults, and freshwater-reared warmwater finfish fingerlings and adults: 75 mg/L for 60 minutes in continuous flow water supply or as a static bath once per day on alternate days for three treatments.

(iii) Freshwater-reared salmonids for the control of mortality due to bacterial gill disease associated with *Flavobacterium branchiophilum*: 100 mg/L for 30 minutes, or 50 to 100 mg/L for 60 minutes, in a continuous flow water supply or as a static bath once per

day on alternate days for three treatments.

(iv) Freshwater-reared salmonids for the treatment and control of *Gyrodactylus spp*: 100 mg/L for 30 minutes, or 50 to 100 mg/L for 60 minutes, in a continuous flow water supply or as a static bath once per day on alternate days for three treatments.

(v) Freshwater-reared coolwater and warmwater finfish fingerlings and adults for the control of mortality due to external columnaris disease associated with *Flavobacterium columnare*: 50 to 75 mg/L for 60 minutes in continuous flow water supply or as a static bath once per day on alternate days for three treatments.

(vi) Freshwater-reared coolwater finfish fry and warmwater finfish fry for the control of mortality due to external columnaris disease associated with *Flavobacterium columnare*: 50 mg/L for 60 minutes in continuous flow water supply or as a static bath once per day on alternate days for three treatments.

(2) *Limitations.* (i) Initial bioassay on a small number is recommended before treating the entire group.

(ii) Eggs: Some strains of rainbow trout eggs are sensitive to hydrogen peroxide treatment at a time during incubation concurrent with blastopore formation through closure, about 70 to 140 Daily Temperature Units, °C. Consider withholding treatment or using an alternate therapeutant during that sensitive time to reduce egg mortalities due to drug toxicity.

(iii) Finfish: Because finfish sensitivity to 35% PEROX-AID®

increases with increasing water temperature, consider administering initial treatments at the lower end of the treatment regimen or reducing water temperature before treatment. Do not use this product to treat northern pike (*Esox lucius*) or paddlefish (*Polyodon spathula*) of any age. Do not use this product to treat pallid sturgeon fry. Use with caution on walleye (*Sander vitreus*) and ornamental finfish.

(iv) Preharvest withdrawal time: Zero days.

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

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

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

§ 556.513 [Removed]

■ 24. Effective February 3, 2020, § 556.513 is removed.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 26. In § 558.4, in paragraph (d), revise the entry for “Nicarbazin (powder)” to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent ¹ Type A	Type B maximum (100x)	Assay limits percent ¹ Type B/C ²
* * *	* * *	* * *	* * *
Nicarbazin (powder)	96–104	9.08 g/lb (2.00%)	85–115/75–125
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■ 27. In § 558.68, revise paragraphs (e)(1)(ii), (iii), and (v) to read as follows:

§ 558.68 Avilamycin.

* * * * *

(e) * * *
(1) * * *

Avilamycin in grams/ton	Indications for use	Limitations	Sponsor
(ii) 13.6 to 40.9	Monensin, 90 to 110	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 <i>Clostridium perfringens</i> in broiler chickens. Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. Do not feed to chickens over 16 weeks of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. Do not allow horses or other equines access to feed containing avilamycin and monensin. Ingestion of monensin by horses has been fatal. Do not feed to chickens producing eggs for human consumption. Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	058198
(iii) 13.6 to 40.9	Narasin, 54 to 90	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 <i>Clostridium perfringens</i> . Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Do not feed to chickens producing eggs for human consumption. Narasin as provided by No. 058198 in § 510.600(c) of this chapter.	058198
(v) 13.6 to 40.9	Salinomycin sodium, 40 to 60	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 <i>Clostridium perfringens</i> . Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. May be fatal if fed to adult turkeys or to horses. Not approved for use with pellet binders. Do not feed to laying hens producing eggs for human consumption. Salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.	058198

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■ 28. In § 558.355, revise paragraphs (b) and (f)(6)(i) to read as follows:

§ 558.355 Monensin.

* * * * *

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

(1) No. 058198 for use as in paragraph (f) of this section.

(2) No. 016592 for use of a Type A medicated article containing 90.7 grams

monensin, USP, per pound as in paragraphs (f)(3), (f)(4)(vi), and (f)(6) of this section.

* * * * *

(f) * * *

(6) * * *

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 20	For the prevention of coccidiosis caused by <i>Eimeria crandallis</i> , <i>E. christensenii</i> , and <i>E. ninakohlyakimovae</i> .	Feed only to goats being fed in confinement. Do not feed to lactating goats. See paragraph (d)(11) of this section for provisions for monensin liquid Type C goat feeds.	058198

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§ 558.625 [Amended]

- 29. Amend § 558.625:
- a. By removing “monensin as provided by No. 058198” and adding in its place “monensin as provided by Nos. 016592 or 058198” in the “Limitations” column, in:
- 1. Paragraph (e)(2)(iv),
- 2. Paragraph (e)(2)(v),
- 3. Paragraph (e)(2)(x),
- 4. Paragraph (e)(2)(xi),
- 5. Paragraph (e)(2)(xii), and
- 6. Paragraph (e)(2)(xiii); and
- b. By adding “016592” in numerical order in the “Sponsors” column in:
- 1. Paragraph (e)(2)(x),
- 2. Paragraph (e)(2)(xi),
- 3. Paragraph (e)(2)(xii), and

■ 4. Paragraph (e)(2)(xiii).

Dated: January 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00421 Filed 1–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 529

[Docket No. FDA–2019–N–0002]

New Animal Drugs; Withdrawal of Approval of a New Animal Drug Application; Withdrawal of Approval of Abbreviated New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.