DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 526, 529, 556, and 558

[Docket No. FDA–2019–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of 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 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 October 7, 2019.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (CVM) (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 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 APRIL, MAY, AND JUNE 2019

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
April 11, 2019 ..	140–989	Syndel USA, 1441 W. Smith Rd., Ferndale, WA 98248.	PARASITE-S (formalin) Aqueous Formaldehyde Solution.	Freshwater-reared finfish.	Supplemental approval for the control of mortality in freshwater-reared finfish due to saprolegniasis associated with fungi in the family Saprolegniaceae.	FOI Summary.
May 6, 2019	141–288	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	EXCENEL RTU EZ (ceftiofur hydrochloride) Sterile Suspension.	Cattle and swine.	Supplemental approval providing for an increase in the maximum injection site volume in swine.	FOI Summary.
May 7, 2019	200–633	Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405.	DERACIN (chlortetracycline) plus DENAGARD (tiamulin hydrogen fumarate) Type C medicated swine feeds.	Swine	Original approval as a generic copy of NADA 141–011.	FOI Summary.
May 16, 2019 ...	200–598	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin, 18, Ireland.	ENROMED 100 (enrofloxacin) Antimicrobial Injectable Solution.	Cattle and swine.	Original approval as a generic copy of NADA 141–068.	FOI Summary.
May 21, 2019 ...	141–512	Elanco US Inc. 2500 Innovation Way, Greenfield, IN 46140.	EXPERIOR (lubabegron), RUMENSIN (monensin), and TYLAN (tylosin phosphate) Type C medicated feeds.	Cattle	Original approval for beef steers and heifers fed in confinement for slaughter during the last 14 to 91 days on feed for reduction of ammonia gas emissions per pound of live weight and hot carcass weight; for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes;* and for either improved feed efficiency or prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*	FOI Summary.
May 21, 2019 ...	141–514	Elanco US Inc. 2500 Innovation Way, Greenfield, IN 46140.	EXPERIOR (lubabegron) and RUMENSIN (monensin) Type C medicated feeds.	Cattle	Original approval for beef steers and heifers fed in confinement for slaughter during the last 14 to 91 days on feed for reduction of ammonia gas emissions per pound of live weight and hot carcass weight; and for either improved feed efficiency or prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*	FOI Summary.
May 30, 2019 ...	200–573	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin, 18, Ireland.	OXYMED LA (oxytetracycline injection).	Cattle and swine.	Original approval as a generic copy of NADA 113–232.	FOI Summary.

II. Change of Sponsor's Names and Addresses

Medicis Dermatologics, Inc., 8125 North Hayden Rd., Scottsdale, AZ 85258 has informed FDA that it has changed its name and address to Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807. Accordingly, we are amending § 510.600(c) to reflect these changes.

III. Technical Amendments

A section describing tolerances of hetacillin residues (21 CFR 556.316) has been added to subpart B of part 556. This section cross-references the sole hetacillin product approved for use in food-producing animals, an intramammary infusion for use in lactating dairy cows (21 CFR 526.1130). This new section codifies FDA's finding at the time of product approval that, because hetacillin is rapidly hydrolyzed to ampicillin, existing ampicillin tolerances provide appropriate tolerances for hetacillin in edible tissues of cattle (38 FR 31172, November 12, 1973). This amendment is being made to make the regulations more comprehensive.

FDA is also revising the regulations to reflect the approved conditions of use of sulfaquinoxaline soluble powder as a veterinary prescription product for oral administration to cattle as a drench. Finally, we are also revising the regulations for use of monensin in medicated goat feed to reflect the approved incorporation level. These actions are being taken to improve the accuracy of the regulations.

IV. 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, 526, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 520, 522, 526, 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, in the table in paragraph (c)(1), remove the entry for ''Medicis Dermatologics, Inc.'' and add an entry in alphabetic order for ''Bausch Health US, LLC''; and in the table in paragraph (c)(2), revise the entry for ''099207''.

The addition and revision 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
* * * * * * *	
Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807	099207
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
099207	Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.

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.

§ 520.812 [Amended]

■ 4. In § 520.812, in paragraph (a)(1)(i), remove ''2.7'' and in its place add ''22.7''.

■ 5. In § 520.2325b, revise paragraph (d)(3) to read as follows:

§ 520.2325b Sulfaquinoxaline drench.

* * * * *

(d) * * *

(3) *Limitations.* Not for use in lactating dairy cattle. A withdrawal period has not been established for this product in preruminating 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.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 7. In § 522.313b, revise paragraphs (a)(2) and (e)(1)(iii) to read as follows:

§ 522.313b Ceftiofur hydrochloride.

(a) * * *

(2) Ceftiofur hydrochloride equivalent to 50 mg ceftiofur equivalents in the inactive vehicles polyoxyethylene sorbitan monooleate (polysorbate 80) in a caprylic/capric triglyceride suspension; or

* * * * *

(e) * * *

(1) * * *

(iii) *Limitations.* For products described in paragraphs (a)(1) and (3) of this section: Treated swine must not be slaughtered for 4 days following the last treatment. For products described in paragraph (a)(2) of this section: Treated swine must not be slaughtered for 6 days following the last treatment when injection site volumes are greater than 5 mL up to the maximum injection site volume of 15 mL. Treated swine must not be slaughtered for 4 days when injection site volumes are less than or equal to 5 mL.

* * * * *

■ 8. In § 522.812, revise paragraphs (b)(1) and (2) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(1) Nos. 000859, 026637, and 055529 for use of product described in paragraph (a)(1) as in paragraph (e)(1); and

(2) Nos. 000859, 055529, and 061133 for use of product described in paragraph (a)(2) as in paragraphs (e)(2) and (3) of this section.

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PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 9. The authority citation for part 526 continues to read as follows:

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

■ 10. In § 526.1130, revise the section heading, redesignate paragraph (c) as paragraph (d), and add new paragraph (c).

The revision and addition read as follows:

§ 526.1130 Hetacillin.

* * * * *

(c) *Related tolerances.* See § 556.316 of this chapter.

* * * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 12. In § 529.1030, revise paragraph (b) and add paragraphs (d)(1)(iv) and (d)(2)(iv) to read as follows:

§ 529.1030 Formalin.

* * * * *

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

(1) No. 050378 for use as in paragraph (d) of this section.

(2) Nos. 049968 and 067188 for use as in paragraphs (d)(1)(i), (ii), and (iii), (d)(2)(i), (ii), and (iii), and (d)(3) of this section.

(d) * * *

(1) * * *

(iv) *Freshwater-reared finfish.* For the control of mortality due to saprolegniasis associated with fungi in the family Saprolegniaceae.

(2) * * *

(iv) For the control of mortality in freshwater-reared finfish due to saprolegniasis associated with fungi in the family Saprolegniaceae: In tanks and raceways, administer 150 μL/L (ppm) for 60 minutes per day on alternate days for three treatments.

* * * * *

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

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

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

■ 14. Add § 556.316 to read as follows:

§ 556.316 Hetacillin.

(a) [Reserved]

(b) *Tolerances.* The tolerances for ampicillin (marker residue for hetacillin) are:

(1) *Cattle. Edible tissues:* 0.01 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 526.1130 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 § 558.4, in paragraph (d), in the ''Category II'' table, revise the row entry for ''Tilmicosin'' 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]
*	*	* * *	* *
Tilmicosin	90–110	37.9 g/lb (8.35%)	Swine Type B/C feed: 85–115 Cattle Type B feed: 85–115 Cattle Type C feed: 80–110
*	*	* * *	* *

* * * * *

■ 17. In § 558.330, revise paragraph (d) to read as follows:

§ 558.330 Lubabegron.

* * * * *

(d) *Conditions of use*—(1) It is used in cattle feed as follows:

Lubabegron fumarate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 1.25 to 4.54	.....	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight during the last 14 to 91 days on feed.	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron.	058198
(ii) 1.25 to 4.54	Monensin, 5 to 40.	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight and for improved feed efficiency during the last 14 to 91 days on feed.	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 50 to 480 mg monensin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	058198
(iii) 1.25 to 4.54.	Monensin, 10 to 40.	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 14 to 91 days on feed.	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	058198

(2) Lubabegron may also be used in combination with:

(i) Tylosin as in § 558.625.

(ii) [Reserved]

■ 18. In § 558.355, in paragraph (f)(6)(i), in the ''Monensin in grams/ton'' column, remove ''5 to 40'' and in its place add ''20''; and redesignate paragraphs (f)(7)(iv) through (xi) as paragraphs (f)(7)(v) through (xii) and add new paragraph (f)(7)(iv).

The addition reads as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(7) * * *

(iv) Lubabegron as in § 558.330.

* * * * *

■ 19. In § 558.625, redesignate paragraphs (e)(2)(vii) through (xv) as paragraphs (e)(2)(ix) through (xvii), and add new paragraphs (e)(2)(vii) and (viii).

The additions read as follows:

§ 558.625 Tylosin.

* * * * *

(e) * * *

(2) * * *

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(vii) 8 to 10	Monensin, 5 to 40 plus lubabegron fumarate, 1.25 to 4.54.	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight; for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes,* and for improved feed efficiency during the last 14 to 91 days on feed.	Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day, 50 to 480 mg monensin/head/day, and 60 to 90 mg tylosin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	058198
(viii) 8 to 10	Monensin, 10 to 40 plus lubabegron fumarate, 1.25 to 4.54.	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight, for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes,* and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 14 to 91 days on feed.	Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day, 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, up to 480 mg/head/day, and 60 to 90 mg tylosin/head/day during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preruminating calves. Do not use in calves to be processed for veal.	058198
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Dated: September 27, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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