4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA-2017-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.

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 October, November, and December 2017. 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 reflect changes of sponsorship of applications and a change of a sponsor's name and address.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 October, November, and December 2017, 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 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 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 October, November, and December 2017

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 27, 2017	141-467	Elanco US Inc. 2500 Innovation Way, Greenfield, IN 46140	Avilamycin and narasin Type C medicated feeds	Chickens	Original approval for use of INTREPITY (avilamycin) and MONTEBAN (narasin) Type A medicated articles to manufacture Type C medicated broiler chicken feeds for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*, and the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima*	FOI Summary; EA/FONSI[1]
October 27, 2017	141-466	Elanco US Inc. 2500 Innovation Way, Greenfield, IN 46140	Avilamycin, narasin, and nicarbazin Type C medicated feeds	Chickens	Original approval for use of INTREPITY (avilamycin) and MAXIBAN (narasin and nicarbazin) Type A medicated articles to manufacture Type C medicated broiler chicken feeds for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*, and the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima*	FOI Summary; EA/FONSI[1]
November 9, 2017	106-111	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007	TELAZOL (tiletamine and zolazepam for injection)	Dogs	Supplemental approval for intravenous administration in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic	FOI Summary
November 21, 2017	200-473	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	TYLOVET (tylosin tartrate) Soluble Powder	Chickens	Supplemental approval for the control of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens	FOI Summary

November 30, 2017	097-505	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007	Lincomycin Type B and Type C medicated feeds	Swine	Supplemental approval for use of LINCOMIX (lincomycin) Type A medicated articles to manufacture Type B and Type C medicated swine feeds for reduction in the severity of the effects of respiratory disease associated with *Mycoplasma hyopneumoniae*	
December 11, 2017	141-441	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	IVERHART MAX (ivermectin, pyrantel pamoate, praziquantel) Soft Chew	Dogs	Original approval of a soft chewable tablet to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection and for the treatment and control of roundworm (*Toxocara canis, Toxascaris leonina*), hookworm (*Ancylostoma caninum, Uncinaria stenocephala, Ancylostoma braziliense*), and tapeworm (*Dipylidium caninum, Taenia pisiformis*) infections	FOI Summary
December 12, 2017	200-617	Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405	Chlortetracycline and lasalocid Type B and Type C medicated feeds	Cattle	Original approval for use of DERACIN (chlortetracycline) and BOVATEC (lasalocid) Type A medicated articles to manufacture Type B and Type C medicated cattle feeds as a generic copy of NADA 141-250	

[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. Changes of Sponsorship

Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211 has informed FDA that it has transferred ownership of, and all rights and interest in, the following application to Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140:

File No.	Product Name	21 CFR Section
141-455	GALLIPRANT (grapiprant) Tablets	520.1084

Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to HQ Specialty Pharma Corp., 120 Rte. 17 North, suite 130, Paramus, NJ 07652:

File No.	Product Name	21 CFR Section
055-097	DRY-MAST (pen G procaine/dihydrostreptomycin sulfate) Infusion	526.1696b

Ridley Block Operations Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Ridley USA, Inc., 111 W. Cherry St., suite 500, Mankato, MN 56001:

File No.	Product Name	21 CFR Section
141-187	CRYSTALYX IONO-LYX (lasalocid) Type C Medicated Protein Block	558.311

Ridley U.S. Holdings, Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002-8500 has informed FDA that it has transferred ownership of, and all rights and interest in,

the following application to Ridley USA, Inc., 111 W. Cherry St., suite 500, Mankato, MN 56001:

File No.	Product Name	21 CFR Section
033-733	SWEETLIX BLOAT-GUARD (poloxalene) Pressed Block	520.1840

Accordingly, the animal drug regulations are being amended to reflect these changes of sponsorship. Following these withdrawals of approval, neither Ridley Block Operations, Inc. nor Ridley U.S. Holdings, Inc. is the sponsor of an approved application. Accordingly, these firms will be removed from the list of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)).

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 526

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, 520, 522, 526, 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 "Ridley Block Operations, Inc." and revise the entry for "Ridley U.S. Holdings, Inc."; and in the table in paragraph (c)(2), remove the entry for "068287" and revise the entry for "067949".

The revisions 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
* * * * * * *	
Ridley USA, Inc., 111 W. Cherry St., suite 500, Mankato, MN 56001	067949
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
067949	Ridley USA, Inc., 111 W. Cherry St., suite 500, Mankato, MN 56001
* * * * * * *	

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.

§ 520.1084 [Amended]

4. In § 520.1084, in paragraph (b), remove "086026" and in its place add "058198".

§ 520.1199 [Amended]

5. In § 520.1199, in paragraph (a) introductory text, remove "chewable tablet" and in its place add "chewable tablet or soft chewable tablet"; and in paragraph (c)(2), remove "Prevents" and in its place add "To prevent".

6. In § 520.2640, revise paragraphs (b)(1) and (2) to read as follows:

§ 520.2640 Tylosin.

* * * * *

(b) * * *

(1) Nos. 016592 and 058198 for use as in paragraph (e) of this section.

(2) No. 061623 for use as in paragraphs (e)(1)(i)(A), (e)(1)(ii), (e)(2), (e)(3), and (e)(4) of this section.

* * * * *

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. In § 522.2470, revise paragraphs (b) and (c) to read as follows:

§ 522.2470 Tiletamine and zolazepam for injection.

* * * * *

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(1) No. 054771 for use as in paragraph (c) of this section.

(2) Nos. 026637 and 051311 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii)(A), (c)(1)(iii) and (c)(2) of this section.

(c) *Conditions of use*--(1) *Dogs*--(i) *Amount*. Expressed as milligrams of the drug combination:

(A) An initial intramuscular dosage of 3 to 4.5 milligrams per pound (mg/lb) of body weight for diagnostic purposes; 4.5 to 6 mg/lb of body weight for minor procedures of short duration such as repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the total dose given should not exceed 12 mg/lb of body weight. The maximum total safe dose is 13.6 mg/lb of body weight.

(B) Administer intravenously at 1 to 2 mg/lb (2.2 to 4.4 mg/kg) body weight to effect for

induction of anesthesia followed by maintenance with an inhalant anesthetic.

(ii) *Indications for use*. (A) Intramuscular administration in dogs for restraint and minor procedures of short duration (30 minutes average) requiring mild to moderate analgesia.

(B) Intravenous administration in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic.

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

(2) *Cats*—(i) *Amount*. An initial intramuscular dosage of 4.4 to 5.4 mg/lb of body weight is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 mg/lb of body weight for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations, and other procedures of short duration. Initial dosages of 6.5 to 7.2 mg/lb of body weight are recommended for ovariohysterectomy and onychectomy. When supplemental doses are required, such individual supplemental doses should be given in increments that are less than the initial dose and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 mg/lb of body weight.

(ii) *Indications for use.* For restraint or for anesthesia combined with muscle relaxation.

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

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.

§ 526.1696b [Amended]

10. In § 526.1696b, in paragraph (b), remove "054628" and in its place add "042791".

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

12. In § 558.68, add paragraphs (e)(1)(iii) and (iv) to read as follows:

§ 558.68 Avilamycin**.**

* * * * *

(e) * * *

(1) * * *

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * * * *				
(iii) 13.6 to 40.9	Narasin, 54 to 90	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*; and for 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 chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens*. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by No. 058198 in § 510.600(c) of this chapter.	058198
(iv) 13.6 to 40.9	Narasin 27 to 45; nicarbazin 27 to 45	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*; and for 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 chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens*. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age. Do not allow adult turkeys, horses, or other equines	058198

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
			access to narasin formulations. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Withdraw 5 days before slaughter. Narasin and nicarbazin as provided by No. 058198 in § 510.600(c) of this chapter.	

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§ 558.128 [Amended]

13. In § 558.128, in paragraph (e)(4), in the "Sponsor" column, numerically add "069254" to paragraphs (e)(4)(ii), (vii), (viii), (ix), and (xviii) through (xxvi).

§ 558.311 [Amended]

14. In § 558.311, in paragraph (b)(9) and in paragraph (e)(1)(xix), in the "Sponsor" column, remove "068287" and in its place add "067949".

15. In § 558.325 revise paragraph (e)(2)(xiv) to read as follows:

§ 558.325 Lincomycin**.**

* * * * *

(e) * * *

(2) * * *

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
* * * * * * *				
(xiv) 100 to 200		For reduction in the severity of the effects of respiratory disease associated with *Mycoplasma hyopneumoniae.*	Feed as sole ration for 21 days	054771
* * * * * * *				

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Dated: March 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-06961 Filed: 4/4/2018 8:45 am; Publication Date: 4/5/2018]