



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA-2016-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of a New Animal Drug Application; Change of Sponsor; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 September and October 2016.

FDA is also 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 several applications and a change of a sponsor's address.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], except for the amendment to 21 CFR 524.1465, which is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 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 September and October 2016, 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 Division of Dockets Management (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:

<http://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:

<http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During September and October 2016

Approval date	File No.	Sponsor	Product name	Species	Effect of the action/indications for use	Public documents
October 26, 2016	141-465	Elanco US Inc, 2500 Innovation Way, Greenfield, IN 46140	INTEPRITY (avilamycin) and COBAN (monensin) Type C medicated feeds	Chickens	Original approval for the prevention of mortality caused by necrotic enteritis associated with <u>Clostridium perfringens</u> in broiler chickens; and as an aid in the prevention of coccidiosis caused by <u>Eimeria necatrix</u> , <u>E. tenella</u> , <u>E. acervulina</u> , <u>E. brunetti</u> , <u>E. mivati</u> , and <u>E. maxima</u>	FOI Summary
September 8, 2016	200-592	Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101	Amoxicillin Trihydrate and Clavulanate Potassium Tablets	Dogs	Original approval of a generic copy of NADA 055-099	FOI Summary

II. Change of Sponsorship

Sogeval S. A., 200 Avenue de Mayenne, 53000 Laval, France has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France:

File No.	Product Name	21 CFR Section
099-667	IMPOSIL (iron heptomer) Injection	522.1182
110-399	GLEPTOSIL (gleptoferron) Injection	522.1055

Following these changes of sponsorship, Sogeval S. A. is no longer the sponsor of an approved NADA. Accordingly, the firm's name, address, and drug labeler code are being removed from § 510.600(c) (21 CFR 510.600(c)).

In addition, Zoetis, Inc., 333 Portage St., Kalamazoo, MI 49007 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Kinetic Technologies, LLC, 961 Beasley St., suite 270, Lexington, KY 40509:

File No.	Product Name	21 CFR Section
006-417	RECOVR (tripeleppamine hydrochloride) Injection	522.2615
032-319	FUROX (furazolidone) Aerosol Powder	524.1005
038-838	ROBAXIN-V (methocarbamol) Injection	522.1380
108-687	PET DERM III (dexamethasone) Tablets	520.540c
111-369	Dexamethasone Sterile Solution	522.540

Following these changes of sponsorship, Kinetic Technologies, LLC is now the sponsor of an approved NADA. Accordingly, the firm's name, address, and drug labeler code are being added to § 510.600(c).

III. Withdrawals of Approval

In addition, Putney, Inc., One Monument Square, suite 400, Portland, ME 04101 has requested that FDA withdraw approval of ANADA 200-524 for Mupirocin Ointment 2% because the product is no longer manufactured or marketed.

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of ANADA 200-524, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect this voluntary withdrawal of approval.

IV. Technical Amendments

Wildlife Laboratories, Inc., 1401 Duff Dr., suite 600, Fort Collins, CO 80524 has informed FDA that it has changed its address to 1230 W. Ash St., suite D, Windsor, CO 80550. In addition, FDA has noticed that a sponsor name in § 510.600 does not reflect the particular punctuation used in this sponsor's applications and other correspondence. At this time, we are amending the list of sponsors of approved applications in § 510.600(c) to reflect this change of sponsor address and sponsor's punctuation.

This rule 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.

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 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 and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, 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.

§ 510.600 [Amended]

2. Revise § 510.600 as follows:

a. In the table in paragraph (c)(1):

i. In the entry for "Elanco US, Inc.", remove "Elanco US, Inc." and in its place add "Elanco US Inc.";

ii. Alphabetically add an entry for "Kinetic Technologies, LLC";

iii. Remove the entry for "Sogeval S. A."; and

iv. Revise the entry for "Wildlife Laboratories, Inc."

b. In the table in paragraph (c)(2):

i. Numerically add an entry for "051031";

ii. Revise the entry for "053923"

iii. In the entry for "058198", remove "Elanco US, Inc." and in its place add "Elanco US Inc."; and

iv. Remove the entry for "059120".

The additions and 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
* * * * *	
Kinetic Technologies, LLC, 961 Beasley St., suite 270, Lexington, KY 40509	051031
* * * * *	
Wildlife Laboratories, Inc., 1230 W. Ash St., suite D, Windsor, CO 80550	053923
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
051031	Kinetic Technologies, LLC, 961 Beasley St., suite 270, Lexington, KY 40509
* * * * *	
053923	Wildlife Laboratories, Inc., 1230 W. Ash St., suite D, Windsor, CO 80550
* * * * *	

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.

§ 520.88g [Amended]

4. In § 520.88g, in paragraph (b), remove "No. 054771" and in its place add "Nos. 026637 and 054771".

§ 520.540c [Amended]

5. In § 520.540c, in paragraph (b), remove "054771" and in its place add "051031".

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.

§ 522.540 [Amended]

7. In § 522.540, in paragraph (d)(2)(i), remove "054771" and in its place add "051031".

§ 522.1055 [Amended]

8. In § 522.1055, in paragraph (b), remove "059120" and in its place add "013744".

§ 522.1182 [Amended]

9. In § 522.1182, in paragraph (b)(3), remove "059120" and in its place add "013744".

§ 522.1380 [Amended]

10. In § 522.1380, in paragraph (b), remove "054771" and in its place add "051031".

§ 522.2615 [Amended]

11. In § 522.2615, in paragraph (b), remove "054771" and in its place add "051031".

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1005 [Amended]

13. In § 524.1005, in paragraph (b)(1), remove "054771" and in its place add "051031".

§ 524.1465 [Amended]

14. Effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], in § 524.1465, in paragraph (b), remove "026637".

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) 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; as provided by No. 058198 in § 510.600(c) of this chapter	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with <u>Clostridium perfringens</u> in broiler chickens; and as an aid in the prevention of coccidiosis caused by <u>Eimeria necatrix</u> , <u>E. tenella</u> , <u>E. acervulina</u> , <u>E. brunetti</u> , <u>E. mivati</u> , and <u>E. maxima</u> .	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 for additional required labeling.	058198

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Dated: February 21, 2017.Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-03677 Filed: 2/23/2017 8:45 am; Publication Date: 2/24/2017]