



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 529, 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 Name

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 November and December 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 the change of sponsorship of an application and a change of a sponsor's name.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], except for [amendments 2.a and 2.c](#) to 21 CFR 510.600, and the amendments to 21 CFR 522.313c and 529.1186, which are 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 November and December 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 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 November and December 2016

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
November 10, 2016	141-474	Elanco US, Inc. 2500 Innovation Way, Greenfield, IN 46140	ITRAFUNGOL (itraconazole oral solution)	Cats	Original approval for the treatment of dermatophytosis caused by <u>Microsporum canis</u> in cats.	FOI Summary
November 16, 2016	141-443	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140	ONSIOR (robenacoxib) Injection	Dogs	Supplemental approval for the control of postoperative pain and inflammation associated with soft tissue surgery in dogs by subcutaneous injection; and for the use of oral tablets to complete the dosing regimen of a maximum of 3 days.	FOI Summary
December 12, 2016	141-452	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	SIMPARICA (sarolaner) Chewables	Dogs	Supplemental approval for the treatment and control of infestations of <u>Ixodes scapularis</u> (black-legged tick) in dogs.	FOI Summary
December 16, 2016	141-473	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	LINCOMIX (lincomycin phosphate) plus STENOROL (halofuginone hydrobromide) Type C medicated feeds	Chickens	Original approval for use in two-way, combination drug Type C medicated broiler feeds for control of necrotic enteritis and prevention of coccidiosis in broiler chickens.	FOI Summary
December 21, 2016	200-589	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861	FLORCON (florfenicol) 2.3% Concentrate Solution	Swine	Original approval of a generic copy of NADA 141-206.	FOI Summary
December 29, 2016	141-475	VetDC, Inc., 320 E. Vine Dr., suite 218, Fort Collins, CO 80524	TANOVEA-CA1 (rabacfosadine for injection)	Dogs	Conditional approval for the treatment of lymphoma in dogs.	FOI Summary

Following the conditional approval of NADA 141-175, VetDC, Inc. will now be included in the list of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)).

II. Change of Sponsorship

ECO LLC, 344 Nassau St., Princeton, NJ 08540 has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-600 for WORMX (pyrantel pamoate) Flavored Tablets to Sergeant's Pet Care Products, Inc., 10077 S. 134th St., Omaha, NE 68138. The regulations will be amended to reflect this change of sponsorship.

III. Withdrawals of Approval

During November and December 2016, the following sponsors requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product Name	21 CFR Section
135-773	Baxter Healthcare Corp., One Baxter Pkwy., Deerfield, IL 60015	AERRANE (isoflurane USP)	529.1186
200-421	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045	Ceftiofur (ceftiofur sodium) for Injection	522.313c

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADA 135-773 and 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. Following this withdrawal of approval, neither Baxter Healthcare Corp. nor Hospira, Inc. is the sponsor of an approved application.

IV. Technical Amendments

iVaoes Animal Health, 4300 SW 73rd Ave., suite 110, Miami, FL 33155 has informed FDA that it has changed its name to Ivaoes Animal Health. Accordingly, we are amending § 510.600 (c) to reflect this change of sponsor name. We are also making several technical amendments to improve the accuracy of the regulations.

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 Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 529

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, 516, 520, 522, 529, 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. Amend § 510.600 as follows:

a. Effective [INSERT DATE 10 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER], in the table in paragraph (c)(1), remove the entries for "Baxter Healthcare Corp." and "Hospira, Inc.";

b. Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], in the table in paragraph (c)(1), revise the entry for "iVaoes Animal Health" and alphabetically add an entry for "VetDC, Inc.";

c. Effective [INSERT DATE 10 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER], in the table in paragraph (c)(2), remove the entries for "000409" and "010019"; and

d. Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], in the table in paragraph (c)(2), revise the entry for "086064" and numerically add an entry for "086072".

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
* * * * *	
Ivaoes Animal Health, 4300 SW 73rd Ave., suite 110, Miami, FL 33155	086064
* * * * *	
VetDC, Inc., 320 E. Vine Dr., suite 218, Fort Collins, CO 80524	086072

(2) ***

Drug labeler code	Firm name and address

086064	Ivaoes Animal Health, 4300 SW 73rd Ave., suite 110, Miami, FL 33155

086072	VetDC, Inc., 320 E. Vine Dr., suite 218, Fort Collins, CO 80524

PART 516--NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

3. The authority citation for part 516 continues to read as follows:

Authority: 360ccc, 360ccc-2, 371.

4. Add § 516.2065 to read as follows:

§ 516.2065 Rabacfosadine.

(a) Specifications. Each vial of powder contains 16.4 milligrams (mg) rabacfosadine.

Each milliliter of constituted solution contains 8.2 mg rabacfosadine.

(b) Sponsor. See No. 086072 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs--(1) Amount. Administer rabacfosadine at 1 mg/kilogram body weight as a 30-minute intravenous infusion, once every 3 weeks, for up to 5 doses.

(2) Indications for use. For the treatment of lymphoma in dogs.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.370 [Amended]

6. In § 520.370, in paragraph (c)(2), remove "(group G, -hemolytic)" and in its place add "(group G, beta-hemolytic)".

7. In § 520.955, revise paragraph (b) to read as follows:

§ 520.955 Florfenicol.

* * * * *

(b) Sponsors. See Nos. 000061, 054925, and 058198 in § 510.600(c) of this chapter.

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8. Add § 520.1189 to read as follows:

§ 520.1189 Itraconazole.

(a) Specifications. Each milliliter (mL) of solution contains 10 milligrams (mg) of itraconazole.

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

(c) Conditions of use--(1) Amount. Administer 5 mg/kilogram (kg) (0.5 mL/kg) of body weight once daily on alternating weeks for 3 treatment cycles.

(2) Indications for use. For the treatment of dermatophytosis caused by Microsporum canis in cats.

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

§ 520.2041 [Amended]

9. In § 520.2041, in paragraph (b), remove "017135, 051311, and 066916" and in its place add "066916, 017135, and 051311".

10. In § 520.2086, revise paragraph (c)(2) to read as follows:

§ 520.2086 Sarolaner.

* * * * *

(c) * * *

(2) Indications for use. Kills adult fleas, and for the treatment and prevention of flea infestations (Ctenocephalides felis), and the treatment and control of tick infestations [Amblyomma americanum (lone star tick), Amblyomma maculatum (Gulf Coast tick), Dermacentor variabilis (American dog tick), Ixodes scapularis (black-legged tick), and Rhipicephalus sanguineus (brown dog tick)] for 1 month in dogs 6 months of age or older and weighing 2.8 pounds or greater.

* * * * *

§ 520.2325b [Amended]

11. In § 520.2325b, in paragraph (b), remove "050749" and in its place add "016592".

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.313c [Amended]

13. Effective [INSERT DATE 10 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER], in § 522.313c, in paragraph (b), remove "000409, 054771, and 068330" and in its place add "054771 and 068330".

14. In § 522.2075, revise paragraph (c) to read as follows:

§ 522.2075 Robenacoxib.

* * * * *

(c) Conditions of use--(1) Dogs--(i) Amount. Administer 0.91 mg per pound (2 mg/kilogram (kg)) by subcutaneous injection, once daily, for a maximum of 3 days. After the initial subcutaneous dose, subsequent doses can be given by subcutaneous injection or as the oral tablet in dogs weighing at least 5.5 pounds (2.5 kg) and at least 4 months of age, for a maximum of 3 total doses over 3 days, not to exceed 1 dose per day. See § 520.2075(c)(1) of this chapter.

(ii) Indications for use. For the control of postoperative pain and inflammation associated with soft tissue surgery in dogs at least 4 months of age for a maximum of 3 days.

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

(2) Cats--(i) Amount. Administer 0.91 mg per pound (2 mg/kg) by subcutaneous injection, once daily, for a maximum of 3 days.

(ii) Indications for use. For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats at least 4 months of age for a maximum of 3 days.

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

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.1186 [Amended]

16. Effective [INSERT DATE 10 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER], in § 529.1186, in paragraph (b), remove "010019,".

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

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

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

18. In § 558.325, revise paragraph (e)(1)(ii) to read as follows:

§ 558.325 Lincomycin.

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(e) * * *

(1) * * *

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
**	**	*	*	*
(ii) 2	Halofuginone 2.72	Broiler chickens: For the control of necrotic enteritis caused or complicated by <u>Clostridium</u> spp. or other organisms susceptible to lincomycin; and the prevention of coccidiosis caused by <u>Eimeria tenella</u> , <u>E. necatrix</u> , <u>E. acervulina</u> , <u>E. brunetti</u> , <u>E. mivati</u> , and <u>E. maxima</u> .	Feed continuously as sole ration. Withdraw 4 days before slaughter. Do not feed to laying chickens or waterfowl. Halofuginone hydrobromide as provided by No. 016592 in § 510.600 of this chapter.	016592

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Dated: February 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-03930 Filed: 2/28/2017 8:45 am; Publication Date: 3/1/2017]