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-2015-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawals of Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) 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 2015. 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 applications and the voluntary withdrawals of approval of applications that occurred in September and October 2015.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], except for the amendments to 21 CFR 520.446, 520.2043, 558.625, and 558.630, 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 September and October 2015, 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 Center for Veterinary Medicine 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 2015

File No.	Sponsor	Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-440	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410	CLARO (florfenicol, terbinafine, mometasone furoate) Otic Solution	Original approval for the treatment of otitis externa in dogs	524.957	yes	CE[1,2]
141-449	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	SAFE-GUARD AquaSol (fenbendazole oral suspension) Suspension Concentrate	Original approval for the treatment and control of certain nematode worms in broiler chickens, replacement chickens intended to become breeding chickens, and breeding chickens	520.905a	yes	EA/ FONSI[3]
141-442	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	LUTALYSE HighCon (dinoprost tromethamine injection) Injection	Supplemental approval of subcutaneous route of administration	522.690	yes	CE[1,4]
108-901	Zoetis Inc. 333 Portage St., Kalamazoo, MI 49007	LUTALYSE (dinoprost tromethamine injection) Injection	Supplemental approval of revised indications for uses in cattle	522.690	no	CE[1,4]

[1]The Agency has determined that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not have a significant effect on the human environment.

[2]CE granted under 21 CFR 25.33(d)(1).

[3]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).

[4]CE granted under 21 CFR 25.33(a)(1).

II. Changes of Sponsorship

During September and October 2015, ownership of, and all rights and interest in, the following approved applications have been transferred as follows:

File No.	Previous Sponsor	Product Name	New Sponsor	21 CFR Section
141-440	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410	CLARO (florfenicol, terbinafine, mometasone furoate) Otic Solution	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	524.957
200-582	Orkeo USA, Inc., 77 Water St., New York, NY 10005	LONCOR 300 (florfenicol) Injectable Solution	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	522.955

As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these changes of sponsorship. Following the change of sponsorship of ANADA 200-582, Orkeo USA, Inc., is no longer the sponsor of an approved application.

III. Withdrawals of Approval

In addition, during September and October 2015, the following three sponsors have requested that FDA withdraw approval of the NADAs and ANADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product Name	21 CFR Section
140-680[1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405	TYLAN (tylosin phosphate) Premix	558.625
140-681[1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405	TYLAN SULFA G (tylosin phosphate and sulfamethazine) Premix	558.630

File No.	Sponsor	Product Name	21 CFR Section
200-028	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514	EVICT 300 (pyrantel pamoate) Suspension	520.2043
200-383	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	CLINDAROBE (clindamycin) Capsules	520.446

[1]These NADAs were identified as being affected by guidance for industry #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209," December 2013.

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADA 140-680, NADA 140-681, ANADA 200-028, and ANADA 200-383, 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 these voluntary withdrawals of approval.

IV. Technical Amendments

FDA has noticed that a previous sponsor of ANADA 200-383, Teva Canada Ltd., was no longer the sponsor of an approved application following a prior change of sponsorship. At this time, FDA is amending the regulation to remove the firm from the listings of sponsors of approved applications in 21 CFR 510.600. This action is being taken to improve the accuracy of the regulations.

FDA is also revising the special considerations for medicated feeds containing veterinary feed directive drugs to align with 21 CFR 558.6(a)(6), which was recently amended (80 FR 31708, June 3, 2015). This action is being taken to improve the consistency 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 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 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. In § 510.600:

a. In the table in paragraph (c)(1), remove the entries for "Orkeo USA, Inc." and "Teva Canada Ltd."; and

b. In the table in paragraph (c)(2), remove the entries for "043806" and "086050".

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.446 [Amended]

4. Effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], in § 520.446, in paragraph (b)(1), remove "Nos. 000859 and 054771" and in its place add "No. 054771".

5. In § 520.905a:

a. Revise paragraphs (a) and (e)(4)(i);

b. In paragraph (e)(4)(iii), remove the first sentence; and

c. Add paragraph (e)(5).

The revisions and addition read as follows:

§ 520.905a Fenbendazole suspension.

(a) Specifications. Each milliliter of suspension contains 100 milligrams (mg) fenbendazole for use as in paragraphs (e)(1), (2), (3), and (4) of this section; or 200 mg fenbendazole for use as in paragraph (e)(5) of this section.

* * * * *

(e) * * *

(4) * * *

(i) Amount. Administer orally 5 mg/kg of body weight (2.3 mg/lb). Retreatment may be needed after 4 to 6 weeks.

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(5) Chickens--(i) Amount. Administer orally via drinking water at a daily dose of 1 mg/kg body weight (0.454 mg/lb) for 5 consecutive days.

(ii) Indications for use. For the treatment and control of adult Ascaridia galli in broiler chickens and replacement chickens intended to become breeding chickens, and for the treatment and control of adult A. galli and Heterakis gallinarum in breeding chickens.

(iii) Limitations. Not for use in laying hens and replacement chickens intended to become laying hens.

§ 520.2043 [Amended]

6. Effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], in § 520.2043, in paragraph (b)(2), remove "Nos. 054771, 055246, 058829, and 059130" and in its place add "Nos. 000859, 054771, and 058829".

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

7. The authority citation for 21 CFR part 522 continues to read as follows:

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

8. In § 522.690, revise paragraphs (b)(2) and (d)(1)(i) and add paragraph (b)(3) to read as follows:

§ 522.690 Dinoprost.

* * * * *

(b) * * *

(2) No. 054771 for use of the 5 mg/mL product as in paragraphs (d)(1), (2), and (3) of this section.

(3) No. 000859 for use of the 5 mg/mL product as in paragraphs (d)(2), (3), and (4) of this section.

* * * * *

(d) * * *

(1) * * *

(i) Amount. 25 mg as a single intramuscular or subcutaneous injection.

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§ 522.955 [Amended]

9. In § 522.955(b)(2), remove "086050" and in its place add "000859".

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

10. The authority citation for 21 CFR part 524 continues to read as follows:

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

11. Add § 524.957 to read as follows:

§ 524.957 Florfenicol, terbinafine, and mometasone otic solution.

(a) Specifications. Each single-dose, prefilled dropperette contains 1 milliliter (mL) of a solution containing 15 milligrams (mg) florfenicol, 13.3 mg terbinafine, and 2 mg mometasone furoate.

(b) Sponsor. See No. 000859 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs--(1) Amount. Administer one dropperette (1 mL) per affected ear(s).

(2) Indications for use. For the treatment of otitis externa in dogs associated with susceptible strains of yeast (Malassezia pachydermatis) and bacteria (Staphylococcus pseudintermedius).

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

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

12. The authority citation for 21 CFR part 558 continues to read as follows:

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

13. In § 558.68, revise paragraph (c)(1) to read as follows:

§ 558.68 Avilamycin.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

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14. In § 558.261, revise paragraphs (c)(1) and (2) introductory text to read as follows:

§ 558.261 Florfenicol.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for florfenicol medicated feeds:

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15. In § 558.618, revise paragraph (c)(1) to read as follows:

§ 558.618 Tilmicosin.

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(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD)

drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

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§ 558.625 [Amended]

16. Effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], in § 558.625, remove paragraph (b)(5) and redesignate paragraph (b)(6) as paragraph (b)(5).

§ 558.630 [Amended]

17. Effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], in § 558.630, in paragraph (b)(2), remove "Nos. 054771 and 069254" and in its place add "No. 054771".

Dated: December 4, 2015.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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