4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, and 558

[Docket No. FDA-2015-N-0002]

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

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 January and February 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 several non-substantive changes. These technical amendments are being made to improve the accuracy of the regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], except for the amendment to 21 CFR 522.1004, 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, 240-276-9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January and February 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 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 January and February 2015

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Sections	FOIA Summary	NEPA Review
141-435	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410	ADVANTUS (imidacloprid) Chewable Tablets	Original approval for the treatment of flea infestations on dogs and puppies	520.1156	yes	CE[1,2]
141-418	Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967	BETAVET (betamethasone sodium phosphate and betamethasone acetate) Injectable Suspension	Original approval for the control of pain and inflammation associated with osteoarthritis in horses	522.167	yes	CE[1,2]
200-527	Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101	Enrofloxacin Antibacterial Injectable Solution	Original approval as a generic copy of NADA 140-913	522.812	yes	CE[1,3]
200-576	Akorn Animal Health, Inc., 1925 West Field Ct., suite 300, Lake Forest, IL 60045	Gentamicin Sulfate Ophthalmic Solution	Original approval as a generic copy of NADA 099-008	524.1044a	yes	CE[1,3]
141-280[4]	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901	ZILMAX (zilpaterol hydrochloride) plus RUMENSIN (monensin) plus TYLAN (tylosin phosphate) plus MGA (melengestrol acetate) Type A medicated articles	Supplemental approval to provide for component feeding of combination drug Type C medicated feeds to heifers fed in confinement for slaughter	558.665	yes	CE[1,5]
141-406	Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640	NEXGARD (afoxolaner) Chewable Tablets	Supplemental approval for the treatment and control of an additional tick species in dogs and puppies	520.43	yes	CE[1,2]

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

[4]This application is affected by guidance for industry (GFI) #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.

[5]CE granted under 21 CFR 25.33(a)(2).

In addition during January and February 2015, ownership of, and all rights and interest in, the following approved applications have been transferred as follows:

NADA/ ANADA	Previous Sponsor	New Animal Drug Product Name	New Sponsor	21 CFR Section
141-098	Abbott Laboratories, North Chicago, IL 60064	PROPOFLO (propofol) Injectable Suspension	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	522.2005
141-103	Abbott Laboratories, North Chicago, IL 60064	SEVOFLO (sevoflurane) Inhalation Anesthetic	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	529.2150
141-346	Abbott Laboratories, North Chicago, IL 60064	OROCAM (meloxicam) Oral Spray	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	529.1350
141-434	Abbott Laboratories, North Chicago, IL 60064	SIMBADOL (buprenorphine) Injectable Solution	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	522.230
200-070	Abbott Laboratories, North Chicago, IL 60064	ISOFLO (isoflurane) Inhalation Anesthetic	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	529.1186
048-480	ADM Alliance Nutrition., Inc., 1000 North 30th St., Quincy, IL 62305-3115	CHLORATET 90 and 100 (chlortetracycline) Type A medicated articles	Pharmgate LLC, 161 North Franklin Turnpike, suite 2C, Ramsey, NJ 07446	558.128
065-256	ADM Alliance Nutrition., Inc., 1000 North 30th St., Quincy, IL 62305-3115	CHLORTET-SOLUBLE-O (chlortetracycline) Powder	Pharmgate LLC, 161 North Franklin Turnpike, suite 2C, Ramsey, NJ 07446	520.441
200-197	Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764-6067	Streptomycin Oral Solution	Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria	520.2158
141-084	Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408	SENTINEL (milbemycin oxime and lufenuron) FLAVOR TABS	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	522.1143
141-204	Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408	SENTINEL (milbemycin oxime and lufenuron) FLAVOR TABS and CAPSTAR (nitenpyram) Tablets Flea Management Program	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	520.1510
141-333	Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408	SENTINEL SPECTRUM (milbemycin oxime/ lufenuron/praziquantel) Tablets	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	520.1447
141-067	OPK Biotech, LLC, 11 and 39 Hurley St., Cambridge, MA	OXYGLOBIN (hemoglobin glutamer-200 (bovine))	Hemoglobin Oxygen Therapeutics, LLC, 674 Souder Rd., Souderton, PA 18964	522.1125

At this time, the regulations are being amended to reflect these changes of sponsorship.

In addition, Paladin Labs (USA), Inc., 160 Greentree Dr., suite 101, Dover, DE 19904 has requested that FDA withdraw approval of NADA 141-075 for ANTIZOL-VET (fomepizole) Injection. Elsewhere in this issue of the Federal Register, FDA gave notice that approval of NADA 141-075, 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 being amended to reflect this voluntary withdrawal of approval.

Following these changes of sponsorship and withdrawal of approval, Hemoglobin Oxygen Therapeutics, LLC is now the sponsor of an approved application while OPK Biotech, LLC and Paladin Labs (USA), Inc., are no longer the sponsor of an approved application. Also, Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, has informed FDA that it has changed its name to Merial, Inc., and Intervet, Inc., 556 Morris Ave., Summit, NJ 07901, has informed FDA that it has changed its address to 2 Giralda Farms, Madison, NJ 07940. Accordingly, § 510.600 (21 CFR 510.600) is being amended to reflect these changes.

In addition, FDA is amending the tables in § 510.600(c) to remove listings for International Nutrition, Inc.; NutriBasics Co.; Seeco Inc.; Southern Micro-Blenders, Inc.; and Wellmark International because these firms are no longer the sponsor of an approved application. These technical amendments are being made 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 Parts 520, 522, 524, 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, 520, 522, 524, 529, 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.

2. Amend § 510.600 as follows:

a. In the table in paragraph (c)(1), remove the entries for "Contemporary Products, Inc.", "International Nutrition, Inc.", "NutriBasics Co.", "OPK Biotech, LLC", "Paladin Labs (USA), Inc.", "Seeco Inc.", "Southern Micro-Blenders, Inc.", and "Wellmark International";

b. In the table in paragraph (c)(1), revise the entries for "Intervet, Inc." and "Merial Ltd."; and add an entry, in alphabetical order, for "Hemoglobin Oxygen Therapeutics, LLC";

c. In the table in paragraph (c)(2), remove the entries for "011536", "043733", "046129", and "055462"; and

d. In the table in paragraph (c)(2), revise the entries for "000061", "050604", and "063075".

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
* * * * * * *	
Hemoglobin Oxygen Therapeutics, LLC, 674 Souder Rd., Souderton, PA 18964	063075
* * * * * * *	
Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	000061
* * * * * * *	
Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640	050604
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
000061	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940
* * * * * * *	
050604	Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640
* * * * * * *	
063075	Hemoglobin Oxygen Therapeutics, LLC, 674 Souder Rd., Souderton, PA 18964
* * * * * * *	

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.

4. In § 520.43, revise paragraph (c)(2) to read as follows:

§ 520.43 Afoxolaner.

* * * * *

(c) * * *

(2) Indications for use. Kills adult fleas; for the treatment and prevention of flea infestations (Ctenocephalides felis); for the treatment and control of black-legged tick (Ixodes scapularis), American dog tick (Dermacentor variabilis), lone star tick (Amblyomma americanum), and brown dog tick (Rhipicephalus sanguineus) infestations in dogs and puppies 8 weeks of age and older, weighing 4 lb of body weight or greater, for 1 month.

* * * * *

§ 520.441 [Amended]

5. In § 520.441, in paragraph (b)(4), remove "012286" and in its place add "069254".

6. Add § 520.1156 to read as follows:

§ 520.1156 Imidacloprid.

(a) Specifications. Each chewable tablet contains 7.5 or 37.5 milligrams (mg) imidacloprid.

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

(c) Conditions of use in dogs--(1) Amount. Administer daily one 7.5-mg chewable tablet to dogs weighing 4 to 22 pounds (lb) or one 37.5-mg chewable table to dogs weighing 23 to 110 lb.

(2) Indications for use. Kills adult fleas and is indicated for the treatment of flea infestations on dogs and puppies 10 weeks of age and older and weighing 4 lb or greater.

(3) Limitations. Do not give to puppies younger than 10 weeks of age or to dogs weighing less than 4 lb. Do not give more than one tablet a day.

§ 520.1443 [Amended]

7. In § 520.1443, in paragraph (b), remove "058198" and in its place add "051311".

§ 520.1447 [Amended]

8. In § 520.1447, in paragraph (b), remove "058198" and in its place add "051311".

9. In § 520.1510, in paragraph (d)(1)(ii)(B), remove "§ 520.1446(d)(1) of this chapter" and in its place add "§ 520.1443(d)(1)"; and revise the section heading and paragraph (b) to read as follows:

§ 520.1510 Nitenpyram.

* * * * *

(b) Sponsors. See sponsor numbers in § 510.600(c) of this chapter:

(1) No. 058198 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii)(A), and (d)(2) of this section.

(2) No. 051311 for use as in paragraphs (d)(1)(i)(B) and (d)(1)(ii)(B) of this section.

* * * * *

§ 520.2158 [Amended]

10. In § 520.2158, in paragraph (b), remove "Nos. 016592 and 055462" and in its place add "No. 016592".

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

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

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

12. Add § 522.167 to read as follows:

§ 522.167 Betamethasone sodium phosphate and betamethasone acetate.

(a) Specifications. Each milliliter (mL) of suspension contains 6 milligrams (mg) betamethasone (3.15 mg betamethasone sodium phosphate and 2.85 mg betamethasone acetate).

(b) Sponsor. See No. 010797 in § 510.600(c) of this chapter.

(c) Conditions of use in horses--(1) Amount. Administer 1.5 mL (9 mg total betamethasone) per joint by intra-articular injection. May be administered concurrently in up to two joints per horse.

(2) Indications for use. For the control of pain and inflammation associated with osteoarthritis in horses.

(3) Limitations. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.230 [Amended]

13. In § 522.230, in paragraph (b), remove "000044" and in its place add "054771".

14. In § 522.812, add paragraph (b)(3) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(3) No. 026637 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section.

* * * * *

§ 522.1004 [Removed]

15. Remove § 522.1004.

16. In § 522.2005, remove paragraph (b)(3); and revise paragraph (b)(2) to read as follows:

§ 522.2005 Propofol.

* * * * *

(b) * * *

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

* * * * *

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

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

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

18. Revise § 524.1044a to read as follows:

§ 524.1044a Gentamicin ophthalmic solution.

(a) Specifications. Each milliliter of solution contains gentamicin sulfate equivalent to 3 milligrams of gentamicin.

(b) Sponsors. See Nos. 000061 and 059399 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs and cats--(1) Amount. Administer 1 or 2 drops into the conjunctival sac 2 to 4 times a day.

(2) Indications for use. For the topical treatment of infections of the conjunctiva caused by susceptible bacteria.

(3) 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

19. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.1186 [Amended]

20. In § 529.1186, in paragraph (b), remove "000044" and add "054771," after “012164,”.

§ 529.1350 [Amended]

21. In § 529.1350, in paragraph (b), remove "000074" and in its place add "054771".

§ 529.2150 [Amended]

22. In § 529.2150, in paragraph (b), remove "000044" and add "054771," after "012164,".

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

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

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

§ 558.128 [Amended]

24. Amend §558.128 as follows:

a. In paragraph (b)(2), remove "No. 012286" and in its place add "No. 069254";

b. In paragraph (e)(3)(iv), in the "Limitations" column, remove "012286" and in its place add "069254"; and

c. In the tables in paragraphs (e)(1), (e)(2), (e)(3), and (e)(4), in the "Sponsor" column, remove "012286," wherever it occurs.

25. In § 558.665, add paragraph (e)(9) to read as follows:

§ 558.665 Zilpaterol.

* * * * *

(e) * * *

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(9) 6.8 to 24	Monensin 10 to 40, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to Eimeria bovis and E. zuernii; and for reduction of incidence of liver abscesses caused by Fusobacterium necrophorum and Arcanobacterium (Actinomyces) pyogenes; and for suppression of estrus (heat).	Feed continuously to heifers during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. See §§ 558.342(d), 558.355(d), and 558.625(c). Monensin and tylosin as provided by No. 000986; melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter. Withdrawal period: 3 days.	000061

Dated: April 3, 2015.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2015-08025 Filed: 4/7/2015 08:45 am; Publication Date: 4/8/2015]