Rules and Regulations

Federal Register
Vol. 81, No. 110
Wednesday, June 8, 2016

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 556, and 558

[Docket No. FDA–2016–N–0002]

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

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 March and April 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 applications and the voluntary withdrawals of approval of applications that occurred in January and February.

DATES: This rule is effective June 8, 2016 except for the amendments to 21 CFR 520.1696b, 520.2325a, 520.2261a, 558.248, and 558.625, which are effective June 20, 2016.

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 March and April 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 MARCH AND APRIL 2016

File No.	Sponsor	Product name	Action	21 CFR section	FOIA summary	NEPA review
141–392	Elanco Animal Health, a Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	IMRESTOR (pegbovigrastim injection).	Original approval for the reduction in the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers.	522.1684	yes	EA/FONSI [1]
141–455	Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211.	GALLIPRANT (grapiprant tablets).	Original approval for the control of pain and inflammation associated with osteoarthritis in dogs.	510.600 520.1084	yes	CE [2 3]
141–460	ECO LLC, 344 Nassau St., Princeton, NJ 08540.	AIVLOSIN 17% (tylvalosin tartrate) Type A Medicated Article.	Original approval for control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.	558.633	yes	CE [2 4]

[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).

[2] 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.

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

[4] CE granted under 21 CFR 25.33(d)(5).

II. Changes of Sponsorship

Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201 (Bayer) has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved applications to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland:

File No.	Product name	21 CFR section
099–169	Oxytocin Injection	522.1680
124–241	PVL Oxytocin Injectable Solution	522.1680
200–069	OvaCyst (gonadorelin diacetate tetrahydrate) Injection	522.1077
200–253	ProstaMate (dinoprost tromethamine) Injectable Solution	522.690

Bayer has also transferred sponsorship of NADA 141–070 for RAPINOVET (propofol) Injectable Emulsion to iVaoes Animal Health, 4300 SW 73rd Ave., suite 110, Miami, FL 33155. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these changes of sponsorship.

III. Withdrawals of Approval

In addition, during March and April 2016, the following two 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
007–076 [1]	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	SULFA–NO_X Liquid (sulfaquinoxaline) 3.44% Solution	520.2325a
008–244 [1]	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	SULFA–NO_X Concentrate (sulfaquinoxaline) 12.85% Solution.	520.2325a
041–955 [1]	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	Erythromycin Medicated Premix	558.248
049–729 [1]	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	PURINA Sulfa (sulfamethazine) 12.5% Solution	520.2261a
100–128 [1]	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	Supersweet Medipak TYLAN 10	558.625
200–307 [1]	Vetoquinol N.-A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada J5T 3S5.	Penicillin G Potassium Soluble Powder	520.1696b

[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 NADAs 007–076, 008–244, 041–955, 049–729, 100–128, and ANADA 200–307, and all supplements and amendments thereto, is withdrawn, effective June 20, 2016. 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 the section heading for 21 CFR 520.1430 does not accurately reflect the new animal drug for which approved conditions of use are codified. At this time, we are amending the section heading to read ''Mibolerone'' rather than ''Megestrol acetate tablets.'' This action is being taken 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 and 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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, parts 510, 520, 522, 556, 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. In § 510.600:

■ a. In the table in paragraph (c)(1), alphabetically add entries for ''Aratana Therapeutics, Inc.'' and ''iVaoes Animal Health'' and revise entry for ''Huvepharma AD;'' and

■ b. In the table in paragraph (c)(2), revise the entry for ''016592'' and numerically add entries for ''086026'' and ''086064.''

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
* * * * * * *	
Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211	086026
* * * * * * *	
Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria	016592
* * * * * * *	
iVaoes Animal Health, 4300 SW 73rd Ave., suite 110, Miami, FL 33155	086064
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
016592	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria
* * * * * * *	
086026	Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211
* * * * * * *	
086064	iVaoes Animal Health, 4300 SW 73rd Ave., suite 110, Miami, FL 33155
* * * * * * *	

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.

■ 4. Add § 520.1084 to read as follows:

§ 520.1084 Grapiprant.

(a) *Specifications.* Each tablet contains 20, 60, or 100 milligrams (mg) grapiprant.

(b) *Sponsor.* See No. 086026 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 0.9 mg/lb (2 mg/kg) once daily by mouth.

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

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

■ 5. Revise the heading of § 520.1430 to read as follows:

§ 520.1430 Mibolerone.

* * * * *

§ 520.1696b [Amended]

■ 6. Effective June 20, 2016, in § 520.1696b, in paragraph (b), remove ''059320,''.

§ 520.2261a [Amended]

■ 7. Effective June 20, 2016, in § 520.2261a, in paragraph (b), remove ''Nos. 016592 and 061623'' and in its place add ''No. 016592''.

§ 520.2325a [Amended]

■ 8. Effective June 20, 2016, in § 520.2325a, remove paragraph (a)(2) and redesignate paragraphs (a)(3) and (4) as paragraphs (a)(2) and (3).

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.690 [Amended]

■ 10. In § 522.690, in paragraph (b)(3), remove ''000859'' and in its place add ''061623''.

§ 522.1077 [Amended]

■ 11. In § 522.1077, in paragraph (b)(3), remove ''000859 and 050604'' and in its place add ''050604 and 061623''.

§ 522.1680 [Amended]

■ 12. In § 522.1680, in paragraph (b), remove ''000859''.

■ 13. Add § 522.1684 to read as follows:

§ 522.1684 Pegbovigrastim.

(a) *Specifications.* Each pre-filled, single-dose syringe contains 15 milligrams of pegbovigrastim.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle*—(1) *Amount.* Administer the first dose (syringe) by subcutaneous injection 7 days prior to the cow's or heifer's anticipated calving date. If necessary, the first dose may be administered within a range of 4 to 10 days prior to the anticipated calving date to accommodate management schedules. Administer the second dose (syringe) by subcutaneous injection within 24 hours after calving.

(2) *Indications for use.* For the reduction in the incidence of clinical mastitis in the first 30 days of lactation in periparturient dairy cows and periparturient replacement dairy heifers.

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

§ 522.2005 [Amended]

■ 14. In § 522.2005, in paragraph (b)(1), remove ''000859'' and in its place add ''086064''.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 15. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 16. In § 556.748, revise paragraph (c) to read as follows:

§ 556.748 Tylvalosin.

* * * * *

(c) *Related conditions of use.* See §§ 520.2645 and 558.633 of this chapter.

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 § 558.4, in paragraph (d), in the ''Category I'' table, add an entry in alphabetical order for ''Tylvalosin'' to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY I

Drug	Assay limits percent Type A	Type B maximum (200x)	Assay limits percent Type B/C
* *	* *	* *	*
Tylvalosin	90–110	3.86 g/lb	85–115
* *	* *	* *	*

* * * * *

§ 558.248 [Amended]

■ 19. Effective June 20, 2016, in § 558.248, revise paragraphs (a) and (b) and remove and reserve paragraph (d)(1)(iii).

The revisions read as follows:

§ 558.248 Erythromycin.

(a) *Specifications.* Type A medicated articles containing 5 or 10 percent erythromycin thiocyanate.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

* * * * *

§ 558.625 [Amended]

■ 20. Effective June 20, 2016, in § 558.625, remove paragraph (b)(3) and redesignate paragraphs (b)(4) and (5) as paragraphs (b)(3) and (4).

■ 21. Add § 558.633 to read as follows:

§ 558.633 Tylvalosin.

(a) *Specifications.* Type A medicated articles containing 77.12 grams tylvalosin per pound as tylvalosin tartrate.

(b) *Sponsor.* See No. 066916 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.748 of this chapter.

(d) *Special considerations*—(1) Federal law restricts tylvalosin medicated feeds to use under a veterinary feed directive (VFD) and the professional supervision of a licensed veterinarian. See § 558.6 of this chapter for additional requirements.

(2) VFDs for tylvalosin shall not be refilled.

(3) An expiration date of 1 week is required for tylvalosin Type C medicated swine feeds in pelleted or crumbled form.

(e) *Conditions of use in swine*—(1) *Amount.* Administer 38.6 grams tylvalosin per ton of Type C medicated feed (42.5 ppm) as the sole ration for 14 consecutive days.

(2) *Indications for use.* For the control of porcine proliferative enteropathy (PPE) associated with *Lawsonia intracellularis* infection in groups of swine in buildings experiencing an outbreak of PPE.

Dated: May 31, 2016.

Tracey Forfa,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2016–13517 Filed 6–7–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA–2016–N–0002]

New Animal Drugs; Withdrawal of Approval of a New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of five new animal drug applications (NADAs) and an abbreviated new animal drug application (ANADA). This action is being taken at the sponsors' request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective June 20, 2016.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The sponsors of the following applications have requested that FDA withdraw approval of the NADAs and ANADA listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product name	21 CFR section
007–076 [1]	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	SULFA–NOX Liquid (sulfaquinoxaline) 3.44% Solution	520.2325a
008–244 [1]	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	SULFA–NOX Concentrate (sulfaquinoxaline) 12.85% Solution.	520.2325a