4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Approvals; Changes of Sponsor; Change of Sponsor's Name; Change of Sponsor's Address; Alfaxalone; Ivermectin and Clorsulon; Narasin; Triptorelin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during September 2012. FDA is also informing the public of the availability of summaries the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a change of sponsorship for four ophthalmic ointments, a change of sponsor's name, and a change of sponsor's address.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions during September 2012, as listed in table 1. With respect to these actions, FDA is also 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 through the Center for Veterinary Medicine's FOIA Electronic Reading Room. FOI Summaries may be found listed by application number at: http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/default.htm. Environmental Assessments (EAs) and Finding Of No Serious Impacts (FONSIs) may be found listed by the established name of the active pharmaceutical ingredient at: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm300656.htm.

Also, Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 065-015 for VETROPOLYCIN HC (bacitracin zinc, polymyxin B sulfate, neomycin sulfate, and

hydrocortisone) Ophthalmic Ointment, NADA 065-016 for VETROPOLYCIN (bacitracin zinc, neomycin sulfate, and polymyxin B sulfate) Ophthalmic Ointment, NADA 065-460 for VETROCLORICIN (chloramphenicol) Ophthalmic Ointment, and ANADA 200-273 for VETRO-GEN (gentamicin sulfate) Ophthalmic Ointment to Dechra Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom. Accordingly, the Agency is amending the regulations in 21 CFR part 524 to reflect these changes.

In addition, UDL Laboratories, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478, has informed FDA that it has changed its name to Mylan Institutional, Inc., and ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131 has informed FDA of a change of address to 344 Nassau St., Princeton, NJ 08540. Accordingly, the Agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes.

Table 1--Original and supplemental NADAs and ANADAs approved during July 2012

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-339	JBS United Animal Health II LLC, 322 S. Main St., Sheridan, IN 46069	OVUGEL (triptorelin acetate)	Original approval for the synchronization of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination.	529.2620	yes	CE[1]
141-340	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285	SKYCIS 100 (narasin) Type A medicated article	Original approval for use in medicated feed for increased rate of weight gain and improved feed efficiency in growing-finishing swine.	558.363	yes	EA/ FONSI[2]
141-342	Jurox Pty. Ltd., 85 Gardiner Rd., Rutherford, NSW 2320, Australia	ALFAXAN (alfaxalone) Intravenous Injectable Anesthetic for Cats and Dogs	Original approval for the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic, in dogs and cats.	522.52	yes	CE[1]
200-466	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Ft. Lenexa, KS 66215	SPARMECTIN Plus Clorsulon (ivermectin and clorsulon) Injection for Cattle	Original approval as a generic copy of NADA 140-833.	522.1193	yes	CE[1]

[1]The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an EA or an environmental impact statement (EIS) because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

[2]Based on its review of an EA submitted by the sponsor, the Agency has concluded that this action will not have a significant impact on the human environment and that an EIS is not required. A FONSI has been prepared.

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 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, 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), revise the entry for "ECO LLC"; alphabetically add entries for "Jurox Pty. Ltd.", "JBS United Animal Health II LLC", and "Mylan Institutional, Inc."; and remove the entry for "UDL Laboratories, Inc."; and

b. In the table in paragraph (c)(2), numerically add entries for "049480" and "051233" and revise the entries for "051079" and "066916".

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
* * * * * * *	
ECO LLC, 344 Nassau St., Princeton, NJ 08540	066916
* * * * * * *	
JBS United Animal Health II LLC, 322 S. Main St., Sheridan, IN 46069	051233
* * * * * * *	
Jurox Pty. Ltd., 85 Gardiner Rd., Rutherford, NSW 2320, Australia	049480
* * * * * * *	
Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478	051079
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
049480	Jurox Pty. Ltd., 85 Gardiner Rd., Rutherford, NSW 2320, Australia

* * * * * * *	
051079	Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478
* * * * * * *	
051233	JBS United Animal Health II LLC, 322 S. Main St., Sheridan, IN 46069
* * * * * * *	
066916	ECO LLC, 344 Nassau St., Princeton, NJ 08540
* * * * * * *	

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

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

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

4. Add § 522.52 to read as follows:

§ 522.52 Alfaxalone.

(a) Specifications. Each milliliter contains 10 milligrams (mg) alfaxalone.

(b) Sponsor. See No. 049480 in § 510.600(c) of this chapter.

(c) Conditions of use in cats and dogs—(1) Amount—(i) Cats—(A) Induction of general anesthesia. Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 2.2 to 9.7 mg/kilogram (kg) for cats that did not receive a preanesthetic or 1.0 to 10.8 mg/kg for cats that received a preanesthetic.

(B) Maintenance of general anesthesia following induction. Administer an intravenous bolus containing 1.1 to 1.3 mg/kg to provide an additional 7 to 8 minutes of anesthesia in

preanesthetized cats; a dose containing 1.4 to 1.5 mg/kg provides an additional 3 to 5 minutes anesthesia in unpreanesthetized cats.

(ii) Dogs—(A) Induction of general anesthesia. Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 1.5 to 4.5 mg/kg for dogs that did not receive a preanesthetic or 0.2 to 3.5 mg/kg for dogs that received a preanesthetic.

(B) Maintenance of general anesthesia following induction. Administer an intravenous bolus containing 1.2 to 1.4 mg/kg to provide an additional 6 to 8 minutes of anesthesia in preanesthetized dogs; a dose of 1.5 to 2.2 mg/kg provides an additional 6 to 8 minutes of anesthesia in unpreanesthetized dogs.

(2) Indications for use. For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic, in dogs and cats.

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

5. In § 522.1193, revise paragraph (b) to read as follows:

§ 522.1193 Ivermectin and clorsulon.

* * * * *

(b) Sponsors. See Nos. 050604, 055529, and 058005 in § 510.600(c) of this chapter.

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

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

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

§ 524.154 [Amended]

7. In § 524.154, in paragraph (a)(2), remove “025463” and in its place add “043264”; and in paragraph (b)(3), remove the first sentence.

§ 524.155 [Amended]

8. In § 524.155, in paragraph (a)(2), remove “025463” and in its place add “043264”; and in paragraph (b)(3), remove the first and second sentences.

§ 524.390 [Amended]

9. In § 524.390, in paragraph (b), remove “025463” and in its place add “043264”.

§ 524.1044c [Amended]

10. In § 524.1044c, in paragraph (b), remove “025463” and in its place add “043264”.

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

12. Add § 529.2620 to read as follows:

§ 529.2620 Triptorelin.

(a) Specifications. Each milliliter of gel contains 100 micrograms (mcg) triptorelin as triptorelin acetate.

(b) Sponsor. See No. 051233 in § 510.600(c) of this chapter.

(c) Conditions of use in swine—(1) Amount. Administer 200 mcg intravaginally approximately 96 hours after weaning.

(2) Indications for use. For the synchronization of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination.

(3) Limitations. Not approved for use in gilts. Safety and effectiveness have not been evaluated in these animals. Should not be used in sows with obvious reproductive tract abnormalities.

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

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

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

14. In § 558.363, add paragraphs (a)(8) and (c); revise paragraph (d)(1)(xi)(B); redesignate paragraph (d)(2) as paragraph (d)(3); and add new paragraph (d)(2) to read as follows:

§ 558.363 Narasin.

(a) * * *

(8) To 000986: 45.4 grams per pound for use as in paragraph (d)(2) of this section.

* * * * *

(c) Special considerations. An expiration date of 2 months (8 weeks) is required for narasin Type C medicated swine feeds.

(d) * * *

(1) * * *

(xi) * * *

(B) Limitations. For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and tylosin as provided by 000986 in § 510.600(c) of this chapter.

(2) Growing-finishing swine--(i) Amount per ton. Narasin, 13.6 to 27.2 grams.

(A) Indications for use. For increased rate of weight gain when fed for at least 4 weeks.

(B) Limitations. Feed continuously for at least 4 weeks to swine during the growing-finishing period as the sole ration. No increased benefit in rate of weight gain has been shown when narasin concentrations in the diet are greater than 13.6 g/ton. Effectiveness has not been demonstrated when fed for durations less than 4 weeks. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Swine being fed with narasin should not have access to feeds containing pleuromutilins (e.g., tiamulin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(ii) Amount per ton. Narasin, 18.1 to 27.2 grams.

(A) Indications for use. For increased rate of weight gain and improved feed efficiency when fed for at least 4 weeks.

(B) Limitations. Feed continuously for at least 4 weeks to swine during the growing-finishing period as the sole ration. No increased benefit in rate of weight gain has been shown when narasin concentrations in the diet are greater than 13.6 g/ton. Effectiveness has not been demonstrated when fed for durations less than 4 weeks. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Swine being fed with narasin should not have access to feeds containing pleuromutilins (e.g., tiamulin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

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Dated: October 17, 2012

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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