4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, and 558

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

New Animal Drugs; Altrenogest; Dexamethasone; Florfenicol

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 April 2012. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: FDA's Center for Veterinary Medicine (CVM) is adopting use of a monthly Federal Register document to codify approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs). CVM will no longer publish a separate rule for each action. This approach will allow a more efficient use of available resources.

In this document, FDA is amending the animal drug regulations to reflect the original and supplemental approval actions during April 2012, as listed in table 1 of this document. FDA is also informing the public of the availability, where applicable, of environmental review documents 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.

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.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During April 2012

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-246	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901	AQUAFLOR (florfenicol) Type A medicated article	Supplemental approval to: (1) Increase the permitted concentrations in Type C feeds; (2) add an indication for the control of mortality due to columnaris disease associated with Flavobacterium columnare; (3) add an indication for the control of mortality due to streptococcal septicemia associated with Streptococcus iniae in freshwater-reared warmwater finfish; and (4) increase the withdrawal period to 15 days. This approval renders § 516.1215 obsolete.	516.1215 558.261	yes	EA/ FONSI[1]
200-456	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861	Dexamethasone Injectable Solution	Original approval of a generic copy of NADA 012-559.	522.540	yes	CE[2]
200-481	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France	ALTRESYN (altrenogest) Solution 0.22%	Original approval of a generic copy of NADA 131-310.	520.48	yes	CE[2]

[1]Based on its review of an environmental assessment (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 environmental impact statement is not required. A finding of no significant impact (FONSI) has been prepared.

[2]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.

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 and 522

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, 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. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for "Ceva Sante Animale"; and in the table in paragraph (c)(2), numerically add an entry for "013744" to 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
* * * * *	
Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France	013744
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
013744	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France
* * * * *	

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

3. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc-1, 360ccc-2, 371.

§ 516.1215 [Removed]

4. Remove § 516.1215.

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

6. In § 520.48, revise paragraph (b) to read as follows:

§ 520.48 Altrenogest.

* * * * *

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

(1) No. 000061 for use as in paragraph (d) of this section.

(2) No. 013744 for use as in paragraph (d)(1) of this section.

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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 § 522.540, revise the section heading and paragraphs (a)(2)(ii) and (a)(3)(iii) to read as follows:

§ 522.540 Dexamethasone.

(a) * * *

(2) * * *

(ii) Sponsors. See Nos. 054925 and 058005 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) * * *

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

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

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

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

10. In § 558.261, revise paragraphs (a)(2) and (c)(2)(i), and the table in paragraph (e)(2) to read as follows:

§ 558.261 Florfenicol.

(a) * * *

(2) 500 grams per kilogram for use as in paragraph (e)(2) of this section.

* * * * *

(c) * * *

(2) * * *

(i) For freshwater-reared finfish, must not exceed 15 days from the date of issuance.

* * * * *

(e) * * *

(2) * * *

Florfenicol in grams/ton of feed	Indications for use	Limitations
(i) 182 to 2,724	Catfish: For the control of mortality due to enteric septicemia of catfish associated with Edwardsiella ictaluri.	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 milligrams (mg) florfenicol per kilogram (kg) of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

Florfenicol in grams/ton of feed	Indications for use	Limitations
(ii) 182 to 1,816	Freshwater-reared salmonids: For the control of mortality due to coldwater disease associated with Flavobacterium psychrophilum and furunculosis associated with Aeromonas salmonicida.	Feed as a sole ration for 10 consecutive days to deliver 10 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.
(iii) 182 to 2,724	Freshwater-reared finfish: For the control of mortality due to columnaris disease associated with Flavobacterium columnare.	Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish for freshwater-reared warmwater finfish and 10 mg florfenicol per kg of fish for other freshwater-reared finfish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

Florfenicol in grams/ton of feed	Indications for use	Limitations
(iv) 273 to 2,724	Freshwater-reared warmwater finfish: For the control of mortality due to streptococcal septicemia associated with Streptococcus iniae.	Feed as a sole ration for 10 consecutive days to deliver 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. For catfish, a dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter.

Dated: May 24, 2012.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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