4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 558

[Docket No. FDA-2013-N-0002]

New Animal Drugs; Enrofloxacin; Tilmicosin; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications and abbreviated new animal drug applications during February 2013. FDA is also informing the public of the availability of summaries 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 is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during February 2013, 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 (CVM) FOIA Electronic Reading Room: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.

In addition, the animal drug regulations are being amended at 21 CFR 510.600 to correct the spelling of a street name in the sponsor's address, and at 21 CFR 558.618 to clarify the dosage of tilmicosin phosphate in medicated feeds for beef and non-lactating dairy cattle.

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 February 2013

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
200-495	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP,	ENROFLOX 100 (enrofloxacin) Injectable Solution	Original approval as a generic copy of NADA	522.812	yes	CE[1]

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
	Northern Ireland		141-068			
200-509	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	TILMOVET 90 (tilmicosin phosphate) Type A medicated article	Original approval as a generic copy of NADA 141-064	558.618	yes	CE[1]
200-531	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	TYLOVET 100 (tylosin phosphate) and RUMENSIN (monensin) Type A medicated articles	Original approval as a generic copy of NADA 104-646	558.355	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 environmental assessment or an environmental impact statement 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 522

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feed.

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, 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, in the table in paragraph (c)(1), in the entry for "Huvepharma AD", remove "Haitov" and in its place add "Haytov"; and in the table in paragraph (c)(2), in the entry for "016592", remove "Haitov" and in its place add "Haytov".

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. In § 522.812, revise paragraphs (b) and (e)(3)(ii); and add introductory text to paragraph (e)(2) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

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

(1) No. 000859 for use of products described in paragraph (a) as in paragraph (e) of this section; and

(2) No. 055529 for use of product described in paragraph (a)(2) as in paragraphs (e)(2)(i)(B), (e)(2)(ii)(B), (e)(2)(iii), (e)(3)(i), and (e)(3)(iii) of this section.

* * * * *

(e) * * *

(2) Cattle. Use the product described in paragraph (a)(2) of this section as follows:

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(3) * * *

(ii) Indications for use--(A) For the treatment and control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, Streptococcus suis, Bordetella bronchiseptica, and Mycoplasma hyopneumoniae.

(B) For the treatment and control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, and Streptococcus suis.

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

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

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

6. In § 558.355, remove and reserve paragraph (f)(3)(ix); and in paragraphs (f)(3)(ii)(b) and (f)(3)(xii)(b), add a new last sentence to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(ii) * * *

(b) * * * Tylosin provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.

* * * * *

(xii) * * *

(b) * * * Tylosin provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.

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§ 558.618 [Amended]

7. Amend § 558.618 as follows:

a. In paragraph (b), remove "No. 000986" and in its place add "Nos. 000986 and 016592";

b. In the table in paragraph (e)(1)(i), in the "Sponsor" column, add ", 016592"after "000986";

c. In the table in paragraph (e)(1)(ii), in the "Sponsor" column, remove "000986";

d. In the table in paragraph (e)(2)(i), in the "Limitations" column, in the first sentence, remove "12.5 milligrams/kilogram/head/day" and in its place add "12.5 mg tilmicosin/kg of bodyweight/day"; and

e. In the table in paragraphs (e)(2)(ii) and (e)(2)(iii), in the "Limitations" column, in the first sentence, remove "12.5 milligrams tilmicosin/kilogram/head/day" and in its place add "12.5 mg tilmicosin/kg of bodyweight/day".

Dated: March 26, 2013.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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