4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2014-N-0002]

New Animal Drugs; Ceftiofur Sodium; Gentamicin; Xylazine

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 (NADAs) and abbreviated new animal drug applications (ANADAs) during March 2014. 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 a change of sponsorship for an ANADA.

DATES: This rule is effective [INSERT 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 March 2014, 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 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.

Also, the regulations are being amended to reflect the previous approval of revised food safety warnings for ceftiofur sodium powder for injection. This amendment is 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.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During March 2014

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
200-468	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	GENTAMED-P for Poultry (gentamicin sulfate) Injection	Original approval as a generic copy of NADA 101-862	522.1044	yes	CE[1,2]
200-529	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	XYLAMED (xylazine) Injection	Original approval as a generic copy of NADA 047-956	522.2662	yes	CE[1,2]

[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.

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

List of Subjects in 21 CFR Part 522

Animal drugs.

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 part 522 is amended as follows:

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

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

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

2. In 522.313c, revise paragraph (d) to read as follows:

§ 522.313c Ceftiofur sodium.

* * * * *

(d) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle, swine, chickens, and turkeys for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

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§ 522.1044 [Amended]

3. In § 522.1044, in paragraph (b)(4), remove "No. 000859" and in its place add "Nos. 000859 and 061623".

§ 522.2662 [Amended]

4. In § 522.2662, in paragraph (b)(2), remove "No. 000010" and in its place add " Nos. 000010 and 061623".

Dated: April 9, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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