4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 558

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

New Animal Drugs; Ceftiofur Crystalline Free Acid; Gamithromycin; Tylosin

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 February 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 is adopting the use of a monthly Federal Register document to codify approval actions for NADAs and 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 February 2012, as listed in table 1 of this document. . FDA is also informing the public of the availability of summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA) and of environmental review documents required under the National Environmental Policy Act (NEPA), where applicable.

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

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-328	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640	ZACTRAN (gamithromycin) Injectable Solution	Supplement adding treatment of bovine respiratory disease (BRD) associated with M. bovis	522.1014	yes	CE[1]
141-209	Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017	EXCEDE (ceftiofur crystalline free acid) Sterile Suspension	Supplement adding treatment of acute bovine metritis in lactating dairy cows; and modified injection techniques	522.313a	yes	CE
200-484	Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria	TYLOVET 100 (tylosin phosphate) Type A medicated Article	Original approval as generic copy of NADA 012-491	558.625	yes	CE

[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 (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.

The basis of approval of actions requiring review of safety or effectiveness data is discussed in an FOI Summary that 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.

List of Subjects

21 CFR Part 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 522 and 558 are 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 522.313a, revise paragraphs (e)(2)(i), (e)(2)(ii), and (e)(2)(iii) to read as follows:

§ 522.313a Ceftiofur crystalline free acid**.**

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(e) * * *

(2) * * *

(i) Amount. For subcutaneous (SC) injection in the posterior aspect of the ear where it attaches to the head (base of the ear) in lactating dairy cattle. For SC injection in the middle third of the posterior aspect of the ear or in the base of the ear in beef and non-lactating dairy cattle.

(A) Single-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight as a single injection.

(B) Two-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight given as two injections in the base of the ear approximately 72 hours apart.

(ii) Indications for use--(A) Single-dose regimen: For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni in beef, non-lactating dairy, and lactating dairy cattle. For the control of respiratory disease in beef and non-lactating dairy cattle which are at high risk of developing BRD associated with M. haemolytica, P. multocida, and H. somni. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with Fusobacterium necrophorum and Porphyromonas levii in beef, non-lactating dairy, and lactating dairy cattle.

(B) Two-dose regimen: For the treatment of acute metritis (0-to 10-days postpartum) associated with bacterial organisms susceptible to ceftiofur in lactating dairy cattle.

(iii) Limitations. Following label use as either a single-dose or 2-dose regimen, a 13-day pre-slaughter withdrawal period is required after the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

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3. In 522.1014, revise paragraph (d)(1)(ii) to read as follows:

§ 522.1014 Gamithromycin.

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(d) * * *

(1) * * *

(ii) Indications for use. For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, Histophilus somni, and Mycoplasma bovis in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with M. haemolytica and P. multocida.

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

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

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

5. In § 558.625, add paragraph (b)(90) to read as follows:

§ 558.625 Tylosin.

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(b) * * *

(90) No. 016592: 100 grams per pound for use as in paragraph (f) of this section.

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Dated: April 26, 2012.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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