4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2011-N-0003]

Implantation or Injectable Dosage Form New Animal Drugs; Danofloxacin

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 of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for an additional dosage regimen for use of danofloxacin mesylate injectable solution for the treatment of bovine respiratory disease in beef cattle.

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

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141-207 for ADVOCIN (danofloxacin mesylate) Injectable Solution. The supplemental NADA provides for an additional dosage regimen for the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, and Pasteurella multocida in beef cattle. The supplemental NADA is approved as of December 16, 2011, and 21 CFR 522.522 is amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 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 § 522.522, revise paragraphs (d)(1) and (d)(2) to read as follows:

§ 522.522 Danofloxacin.

* * * * *

(d) * * *

(1) Amount: Administer by subcutaneous injection either:

(i) 6 mg per kilogram (mg/kg) of body weight, repeated in 48 hours; or

(ii) 8 mg/kg of body weight, as a single dose.

(2) Indications for use. For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica and Pasteurella multocida.

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Dated: January 23, 2012.

William T. Flynn,

Acting Director,

Center for Veterinary Medicine.

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