

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2008-N-0038]

Implantation or Injectable Dosage Form New Animal Drugs; Tulathromycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

DOM
Display Date 10 - 7 - 08
Publication Date 10 - 8 - 08
Case # SL 1122

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 veterinarian prescription use of tulathromycin injectable solution for the treatment of bovine foot rot (interdigital necrobacillosis) in beef and non-lactating dairy cattle.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8343, e-mail: *donald.prater@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141-244 for DRAXXIN (tulathromycin) Injectable Solution. The supplemental NADA provides for treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii* in beef and non-lactating dairy cattle. The application is approved as of August 28, 2008, and the regulations are amended in 21 CFR 522.2630 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 3 years of marketing exclusivity apply only to the bovine foot rot indication for which this supplement is approved.

The agency has determined under 21 CFR 25.33(d)(5) 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 re delegated 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 § 522.2630, revise paragraph (d)(1)(ii) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(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*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, *H. somni*, and *M. bovis*. For the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis*. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii*.

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Dated: 9/29/08
September 29, 2008.



Bernadette Dunham,
Director,
Center for Veterinary Medicine.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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