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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

0604 '03 FEB 19 110:03

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for the administration of an oxytetracycline injectable solution to lactating dairy cattle.

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

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terr., St. Joseph, MO 64506-0457, filed a supplement to approved ANADA 200-123 that provides for the use of MAXIM-200 (oxytetracycline) Injection as a treatment for various bacterial diseases in cattle and swine. The supplemental ANADA provides for the administration of this oxytetracycline injectable solution to lactating dairy cattle. The supplemental ANADA is approved as of November 19, 2002, and the regulations are amended in 21

cv0259

ANADA 200-123

NFR 1

CFR 522.1660 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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 supplemental application may be seen in the Dockets Management Branch (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.

The agency has determined under 21 CFR 25.33(a)(1) 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.

§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (d)(1)(iii) in the eighth sentence by removing “sponsors 059130 and 061623”; and adding in its place “sponsor 061623”; and in the ninth sentence by removing “and 055529” and adding in its place “055529, and 059130”.

ms, Karl Gibler / JS
2/11/03

sentence by removing "000069 and 011722" and adding in its place "000069,
011722,
01172, and 059130"

settled
1-12-2003
JD

Dated: January 21, 2003
January 21, 2003.

Steve F. Vaughn

Steve F. Vaughn,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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CERTIFIED TO BE TRUE
COPY OF THE ORIGINAL.

Glenn Farley