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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Oxytetracycline

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 an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for use of oxytetracycline hydrochloride soluble powder for skeletal marking of finfish fry and fingerlings by immersion.

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

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–460 that provides for use of TETROXY Aquatic (oxytetracycline hydrochloride) Soluble Powder for skeletal marking of finfish fry and fingerlings by immersion. The application is approved as of April 20, 2007, and the regulations are amended in 21 CFR 529.1660 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

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NFR1

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.

FDA 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 529

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 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 2. In § 529.1660, revise paragraph (b)(1) to read as follows:

§ 529.1660 Oxytetracycline.

* * * * *

(b) * * *

(1) Nos. 046573 and 061623 for use of product in paragraph (a)(1) of this section.

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Dated: May 1, 2007

May 1, 2007.

Bernadette Dunham DVM, PhD.

Bernadette Dunham,
Deputy Director,
Center for Veterinary Medicine.

[FR Doc. 07–????? Filed ??–??–07; 8:45 am]

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