

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160, has informed FDA of a change of name and mailing address to Abraxis Pharmaceutical Products, a Div. of Abraxis Bioscience, 6133 River Rd., suite 500, Rosemont, IL 60018. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes.

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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ 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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for “American Pharmaceuticals Partners, Inc.” and alphabetically adding a new entry for “Abraxis Pharmaceutical Products”; and in the table in paragraph (c)(2) by revising the entry for “063323” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
Abraxis Pharmaceutical Products, a Div. of Abraxis Bioscience, 6133 River Rd., suite 500, Rosemont, IL 60018.	063323
* * * * *	* * * * *

(2) * * *

Drug labeler code	Firm name and address
063323	Abraxis Pharmaceutical Products, a Div. of Abraxis Bioscience, 6133 River Rd., suite 500, Rosemont, IL 60018
* * * * *	* * * * *

Dated: May 1, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7-8870 Filed 5-8-07; 8:45 am]

BILLING CODE 4160-01-S

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 May 9, 2007.

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 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.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7-8869 Filed 5-8-07; 8:45 am]

BILLING CODE 4160-01-S