

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 520 and 529

#### Certain Other Dosage Form New Animal Drugs; Oxytetracycline

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

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**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 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:** Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: [joan.gotthardt@fda.gov](mailto:joan.gotthardt@fda.gov).

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed a supplement to NADA 8-622 that provides for use of TERRAMYCIN-343 (oxytetracycline HCl) Soluble Powder for skeletal marking of finfish fry and fingerlings by immersion. The approval of this supplemental NADA relied on publicly available safety and effectiveness data contained in Public Master File (PMF) 5667 which were compiled under National Research Support Project-7 (NRSP-7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses. In addition, the supplemental NADA provides for the addition

of statements to product labeling warning against the use of this product in drinking water of lactating dairy cattle. The supplemental NADA is approved as of June 13, 2005, and the regulations in 21 CFR 529.1660 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has found that the regulations contain incorrect statements warning against the use of oxytetracycline soluble powder in calves intended for veal. Accordingly, the regulations in 21 CFR 520.1660d are amended to reflect appropriate warning statements for this product. This action is being taken to improve the accuracy of the regulations.

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(d)(4) 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 Parts 520 and 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 parts 520 and 529 are amended as follows:

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Section 520.1660d is amended by revising paragraph (d)(1)(iv)(C) to read as follows:

**§ 520.1660d Oxytetracycline hydrochloride soluble powder.**

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(iv) \* \* \*

(C) *Limitations.* Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Withdraw 5 days prior to slaughter. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

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**PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS**

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

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

**§ 529.1660 [Amended]**

■ 4. Section 529.1660 is amended in paragraph (b)(2) by removing “No. 059130” and by adding in its place “Nos. 000069 and 059130”.

Dated: July 1, 2005.

**Catherine P. Beck,**

*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

**BILLING CODE 4160-01-S**