

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

DMB

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**Tolerances for Residues of New Animal Drugs in Food; Oxytetracycline; Technical Amendment**

**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 the tolerance for the sum of residues of the tetracyclines in milk previously established but inadvertently removed in a subsequent amendment and to reflect the correct tolerance of 0.3 part per million oxytetracycline in milk. This action is being taken to improve the accuracy of the agency's regulations.

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

**FOR FURTHER INFORMATION CONTACT:** Lynn G. Friedlander, Center for Veterinary Medicine (HFV-151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6985.

**SUPPLEMENTARY INFORMATION:** FDA is amending the animal drug regulations in § 556.500 (21 CFR 556.500) to reflect the tolerance for the sum of residues of the tetracyclines in milk, which had been established in a final rule published in the **Federal Register** of September 30, 1998 (63 FR 52157 at 52158), but removed in a subsequent amendment to § 556.500 in a final rule published in the **Federal Register** of October 27, 1998 (63 FR 57245 at 57246). At this time, § 556.500 is being amended to reflect the correct tolerance of 0.3 part per million for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline in milk.

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. Publication of this document constitutes final action on this changes under the Administrative Procedure Act (5 U.S.C. 553).

### List of Subjects in 21 CFR Part 556

Animal drugs, Foods.

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 556 is amended as follows:

### PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

2. Section 556.500 is amended by revising paragraph (b) to read as follows:

#### § 556.500 Oxytetracycline.

\* \* \* \* \*

(b) *Beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobster, and salmonids.* Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk as follows:

(1) 2 parts per million (ppm) in muscle.

(2) 6 ppm in liver.

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(3) 12 ppm in fat and kidney.

(4) 0.3 ppm in milk.

Dated: 8/20/01

August 20, 2001.

Claire M. Lathers

Claire M. Lathers,  
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