

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DMB

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**New Animal Drugs for Use in Animal Feeds; Nequinatate; 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 that reflect approval of two new animal drug applications (NADAs) for combination drug Type C feeds containing nequinatate. In a notice published in the **Federal Register** of February 28, 1978 (43 FR 8182), FDA withdrew approval of these NADAs. This action is being taken to improve the accuracy of the regulations.

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

**FOR FURTHER INFORMATION CONTACT:** George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567, e-mail: ghaibel@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of February 28, 1978 (43 FR 8182), the agency published a notice that it was withdrawing approval of NADA 42-919 for combination use of nequinatate and roxarsone, and NADA 48-205 for combination use of nequinatate and oxytetracycline, both in chicken feed. These actions were requested by the sponsor, Ayerst Laboratories, because the products were no longer manufactured or marketed. However, a final rule published in the same issue of the **Federal Register** (43 FR 8134) did not amend all applicable portions of the regulations. At this time, the agency is amending the animal drug regulations in 21 CFR 558.365 and 558.450 to remove portions reflecting approval of these NADA's.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely making nonsubstantive 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 558**

Animal drugs, Animal feeds.

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 558 is amended as follows:

### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

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

#### **§ 558.365 [Amended]**

2. Section 558.365 *Nequinat* is amended by removing paragraphs (d)(1)(ii) and (d)(1)(iii), and by redesignating paragraphs (d)(1)(i)(a) and (d)(1)(i)(b) as paragraphs (d)(1)(ii) and (d)(1)(iii).

#### **§ 558.450 [Amended]**

3. Section 558.450 *Oxytetracycline* is amended in table 1 in paragraphs (d)(1)(iv) and (d)(1)(vi) by removing the entries for “Nequinat 18.16 g/ton (0.002%)”.

Dated: 8/20/01  
August 20, 2001.

SF S/M

Stephen F. Sundzof,  
Director,  
Center for Veterinary Medicine.

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