

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Display Date	7-16-01
Publication Date	7-11-01
Certifier	Namoni Oliver

Animal Drugs, Feeds, and Related Products; Tylosin; Withdrawal of Approval of NADAs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions that reflect approval of two new animal drug applications (NADAs) listed below. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADAs.

DATES: This rule is effective [*insert date 10 days after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Pamela K. Esposito, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5593.

SUPPLEMENTARY INFORMATION: Heinold Feeds, Inc., P.O. Box 377, Kouts, IN 46347, has requested that FDA withdraw approval of NADA 95-628 for Tylosin® Antibiotic Premix and NADA 127-506 for Tylan® Sulfa-G Premixes because the products are no longer manufactured or marketed.

Following the withdrawal of approval of these NADAs, Heinold Feeds, Inc., is no longer the sponsor of any approved applications. Therefore, 21 CFR 510.600(c) is amended to remove entries for this sponsor.

As provided below, the animal drug regulations are amended to reflect the withdrawal of approvals.

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

21 CFR Part 510

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

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 parts 510 and 558 are 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.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for “Heinold Feeds, Inc.,” and in the table in paragraph (c)(2) by removing the entry for “043727”.
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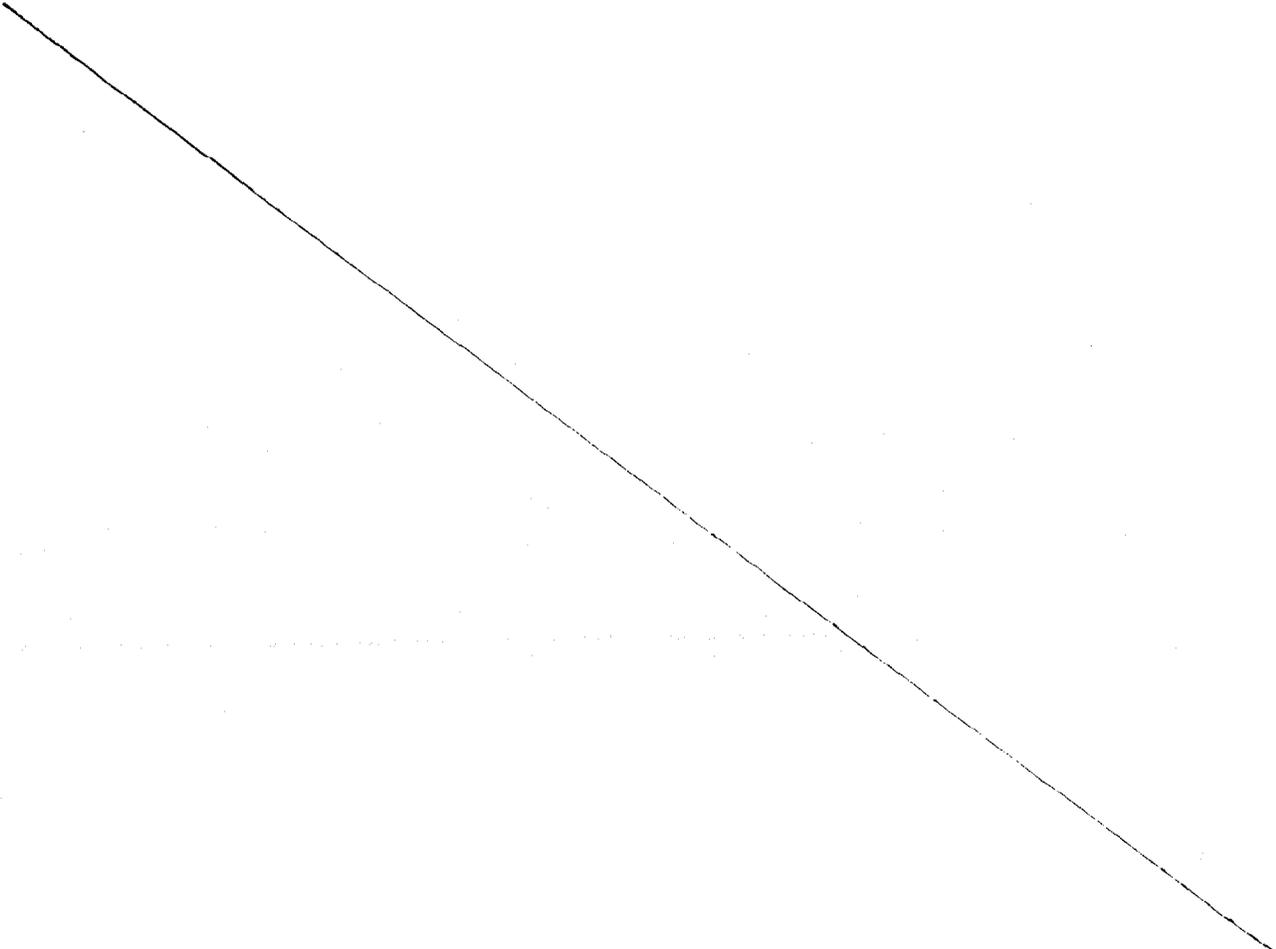
PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.625 [Amended]

4. Section 558.625 *Tylosin* is amended by removing and reserving paragraph (b)(9).



§ 558.630 [Amended]

5. Section 558.630 *Tylosin and sulfamethazine* is amended in paragraph (b)(10) by removing “043727,”; and by removing “and 051359, 053389” and by adding in its place “051359, and 053389”.

Dated: 7/2/01
July 2, 2001.

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Norman Oliver

S F Sundlof

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

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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