

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
21 CFR Parts 510 and 558

DMB

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Certifier	<i>J. DeLeon</i>

Animal Drugs, Feeds, and Related Products; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to reflect changes to previously approved new animal drug applications (NADAs). Several sponsors currently listed as sponsors of approved applications and specified in the animal drug approval regulations are incorrect. 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.

SUPPLEMENTARY INFORMATION: FDA has found several errors in the agency's regulations concerning sponsors of approved applications of medicated animal feeds. To correct those errors, FDA is amending 21 CFR 510.600(c)(1) and (c)(2) to remove names and corresponding drug labeler codes for Carnation Co., Illini Feeds, and Tevcon Ind., Inc., because these firms are no longer the holders of any approved NADAs. The agency is also amending the animal drug approval regulations by removing the entry associated with Carnation Co.'s NADA 104-424 in 21 CFR 558.58, which is no longer an approved NADA.

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 correcting nonsubstantive errors.

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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 entries for “Carnation Co.”, “Illini Feeds”, and “Tevcon Ind., Inc.” and in the table in paragraph (c)(2) by removing the entries for “047019 and 037310”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

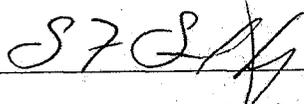
3. The authority citation for 21 CFR part 558 continues to read as follows:

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

§ 558.58 [Amended]

4. Section 558.58 *Amprolium and ethopabate* is amended in the table in paragraph (d)(1) by removing paragraph (d)(1)(v).

Dated: 8/29/01
August 29, 2001.



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

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

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