

DMB

Display Date	7-25-00
Publication Date	7-26-00
Certifier	JN Reese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Penicillin; Technical Amendment

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 correctly reflect a previously approved 227 grams per pound (g/lb) strength of penicillin G Type A medicated article for use in the feed of several domestic species which was omitted from the regulation in the 1998 notice of approval.

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

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0212.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, is sponsor of NADA 046-668 that provides for use of Penicillin 100 (100 g/lb penicillin G procaine) and Penicillin 50 (227 g/lb penicillin G procaine) Type A medicated articles to make Type C medicated feeds used for increased rate of weight gain and improved feed efficiency in poultry and swine. In its approval letter of April 10, 1998, to Pfizer, Inc., the Center for Veterinary Medicine approved the use of these products to make Type C medicated feeds, but did not codify the approval of the 227 g/lb strength of Type A medicated article for this sponsor (63 FR 36179, July 2, 1998). At this time, 21 CFR 558.460(b) is amended by adding the 227 g/lb strength of Type A medicated article to reflect the 1998 approval.

NFR 2

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

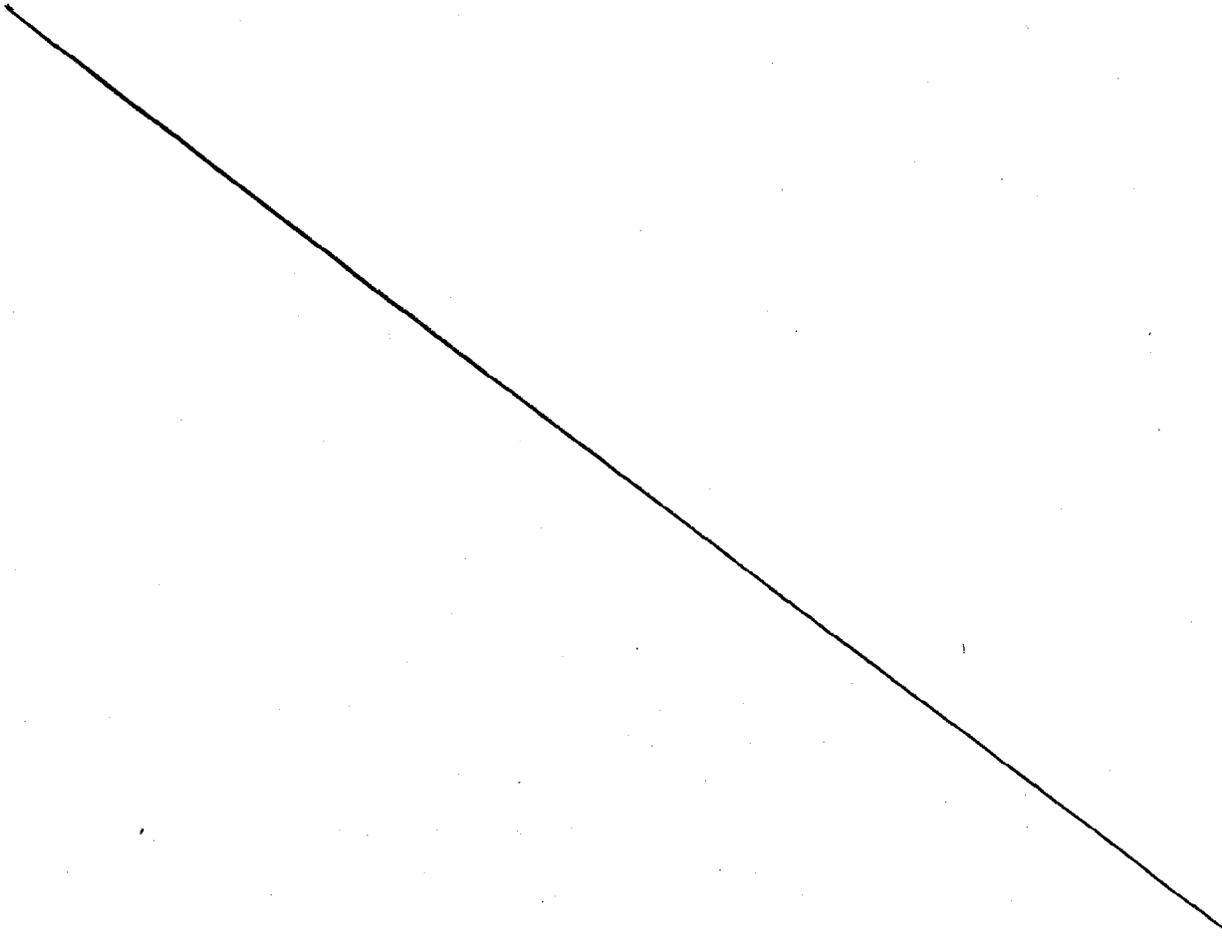
Animal drugs, Animal feeds.

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.



§ 558.460 [Amended]

2. Section 558.460 *Penicillin* is amended in the first sentence in paragraph (b) by adding “and 227” after “To 000069, 100”.

Dated: July 18, 2000
July 18, 2000

Claire M. Lathers

Claire M. Lathers,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Suzette N. Reese