

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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Certifier	Moni Oliver

New Animal Drugs for Use in Animal Feeds; Monensin, Sulfadimethoxine, and Ormetoprim; 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 for medicated feeds to correctly reflect previously approved assay limits for Type A medicated articles containing monensin, or sulfadimethoxine and ormetoprim in combination. 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: Mary G. Leadbetter, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6964.

SUPPLEMENTARY INFORMATION: FDA has found that the April 1, 2000, edition of Title 21, Parts 500 to 599 of the Code of Federal Regulations (CFR) does not reflect revised assay limits for Type A medicated articles containing monensin, or sulfadimethoxine and ormetoprim in combination, that were approved in the new animal drug applications for these drugs. At this time, FDA is amending the regulations to correct these errors in 21 CFR 558.4.

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:

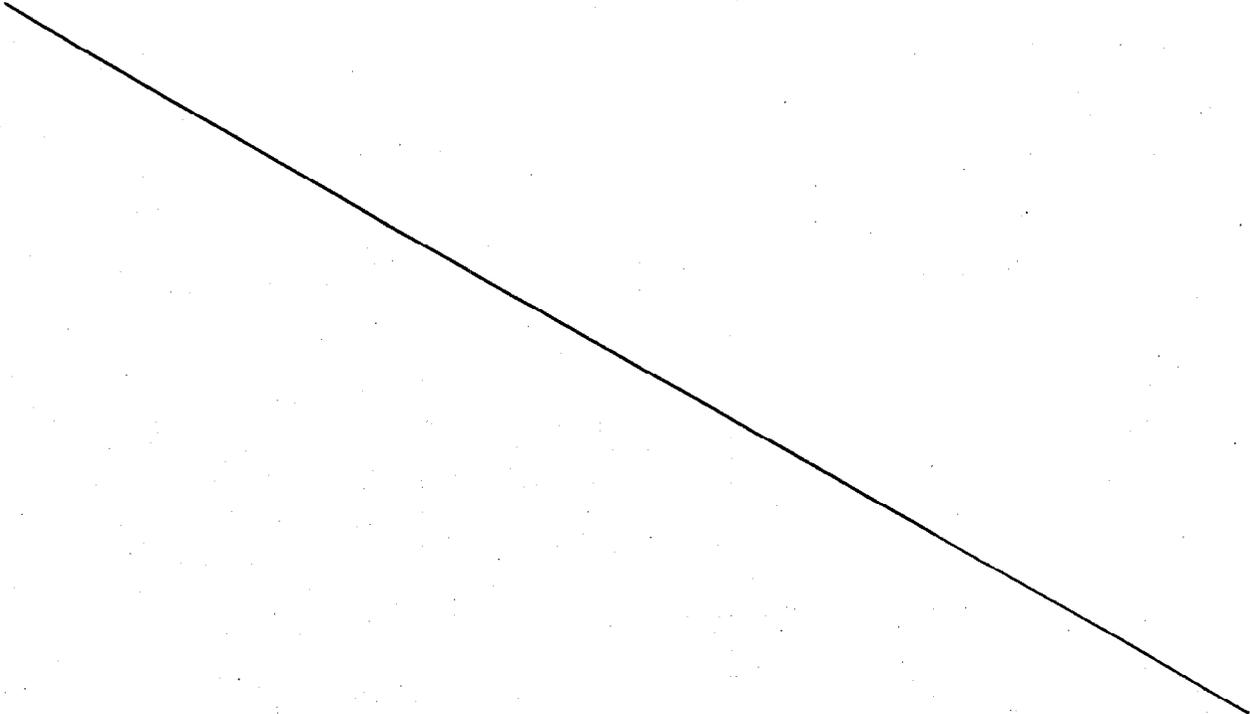
PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.4 [Amended]

2. Section 558.4 *Requirement of a medicated feed mill license* is amended in paragraph (d) in the “Category I” table in the entry for “Monensin” in the “Assay limits percent type A” column by removing “90–110” and adding in its place “85–115”; and in the “Category II” table in both paired entries for “Sulfadimethoxine” and “Ormetoprim” in the “Assay limits percent type A” column by removing “95–115” and in its place adding “90–110”.



Dated: 4/20/01
April 20, 2001.

cv0120

Claire M. Lathers

Claire M. Lathers,
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Center for Veterinary Medicine.

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

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Ramona Oliver