

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Ractopamine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

ADM

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Certifier Shea

SUMMARY: The Food and Drug Administration (FDA) is revising the animal drug regulations for medicated feeds to reflect the approved maximum concentration of ractopamine in Type B medicated feeds. 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: Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: *eric.dubbin@fda.gov*.

SUPPLEMENTARY INFORMATION: FDA has found that parts 500 to 599 (21 CFR parts 500 to 599) of the Code of Federal Regulations does not reflect the approved maximum concentration of ractopamine in Type B medicated feeds. Higher levels of ractopamine in Type B medicated feeds were approved when this drug was approved for use in cattle on September 18, 2003 (68 FR 54658). At this time, FDA is amending the regulations in 21 CFR 558.4 to reflect the new maximum concentration of ractopamine in Type B medicated feeds.

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 558

Animal drugs, Animal feeds.

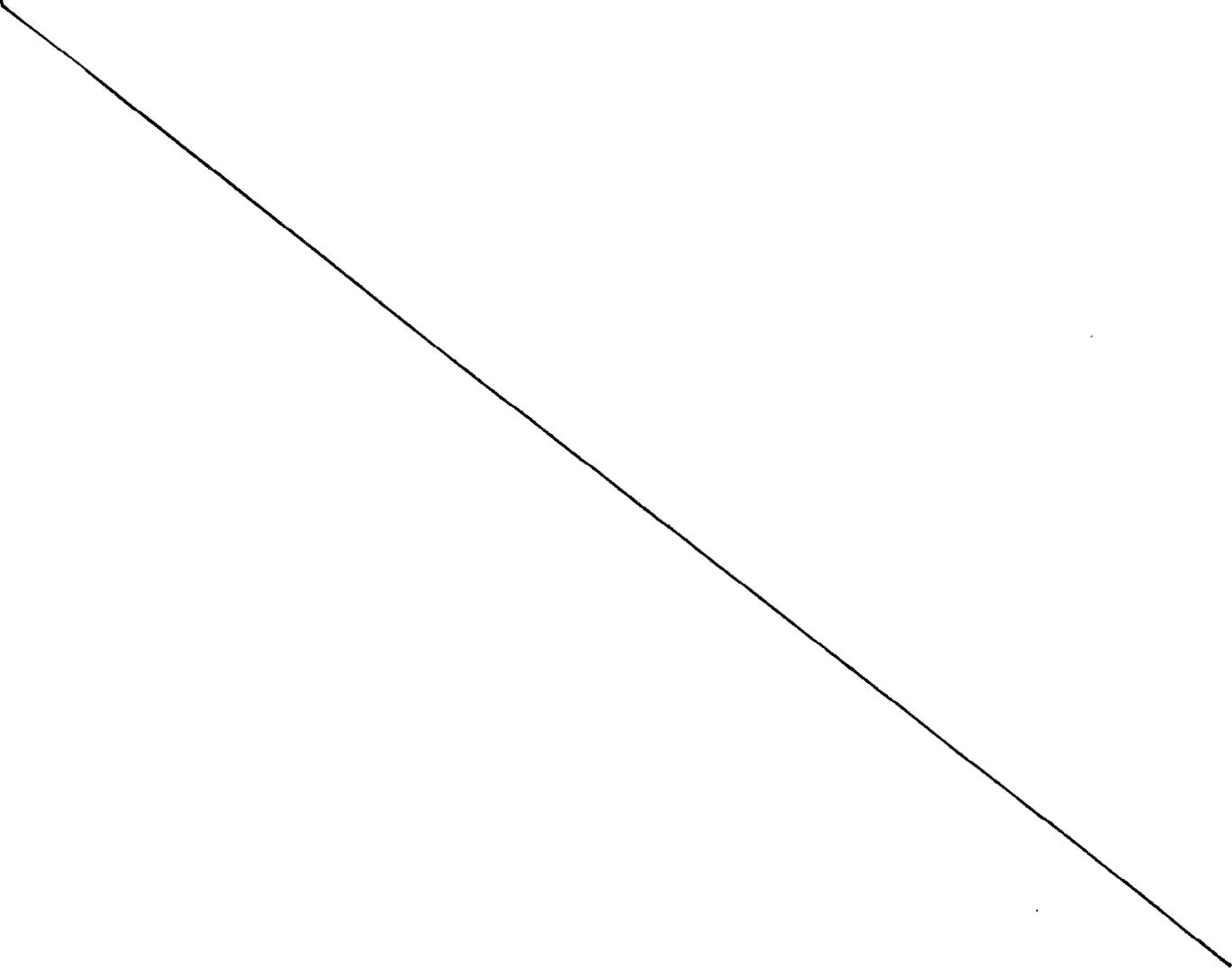
■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

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 "Ractopamine" in the "Type B maximum (200x)" column by removing "1.8 g/lb (0.4%)" and adding in its place "2.46 g/lb (0.54%)".

Dated: 4/23/04

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