

DHB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

Display Date 8.27.04
Publication Date 8.30.04
Certifier J. P. [Signature]

New Animal Drugs For Use in Animal Feeds; Decoquinatate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Alpharma Inc. The supplemental NADA provides for the use of single-ingredient decoquinatate and monensin Type A medicated articles to make two-way Type B and Type C medicated feeds for cattle at a broader range of concentrations.

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

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: janis.messenheimer@fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Drive, P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 141-148 for use of DECCOX (decoquinatate) and RUMENSIN (monensin sodium) Type A medicated articles to make two-way Type B and Type C medicated feeds for cattle at the broader range of concentrations. The supplemental application is approved as of July 30, 2004, and the regulations are amended in 21 CFR 558.195 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor environmental impact statement is required.

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 the 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

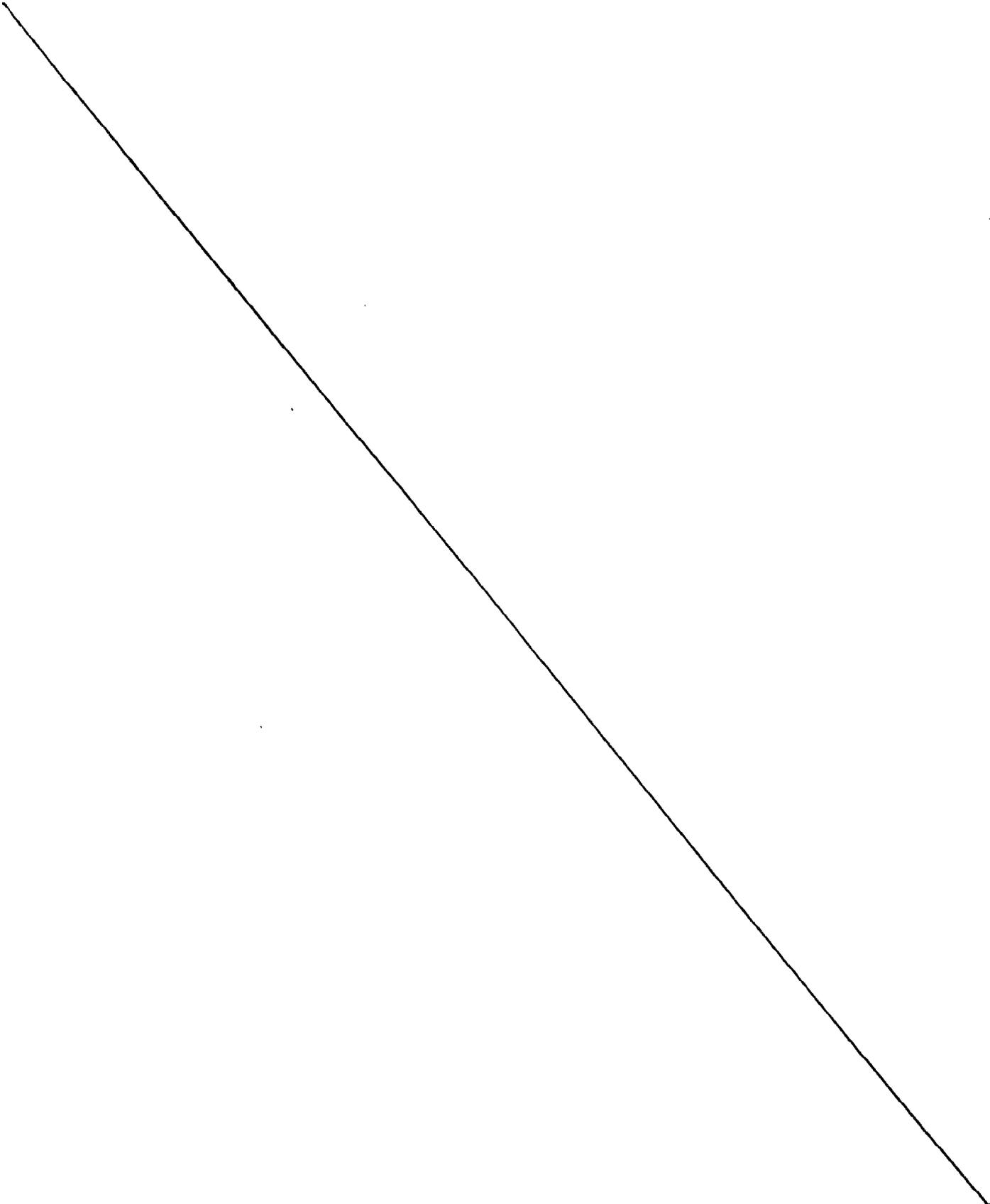
■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

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

§ 558.195 [Amended]

■ 2. Section 558.195 *Decoquinat*e is amended in paragraph (e)(2)(iv) in the table in the “Decoquinate in grams/ton” column by removing “13.6 to 27.2” and by

adding in its place "12.9 to 90.8"; and in the "Limitations" column after the fourth sentence by adding "Do not feed to lactating dairy cattle."



Dated: August 18, 2004
August 18, 2004.

Steven D. Vaughn DVM

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Booke