

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier REGINA LEDESMA

Food and Drug Administration

Notice of Approval of New Animal Drug Applications; Chlortetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that in 2001 it approved a supplemental new animal drug application (NADA) filed by Alpharma, Inc. The supplemental NADA provided for use of chlortetracycline Type A medicated articles to make Type B and Type C medicated swine feeds for the control of porcine proliferative enteropathies (ileitis). The applicable section of the regulation did not require amendment.

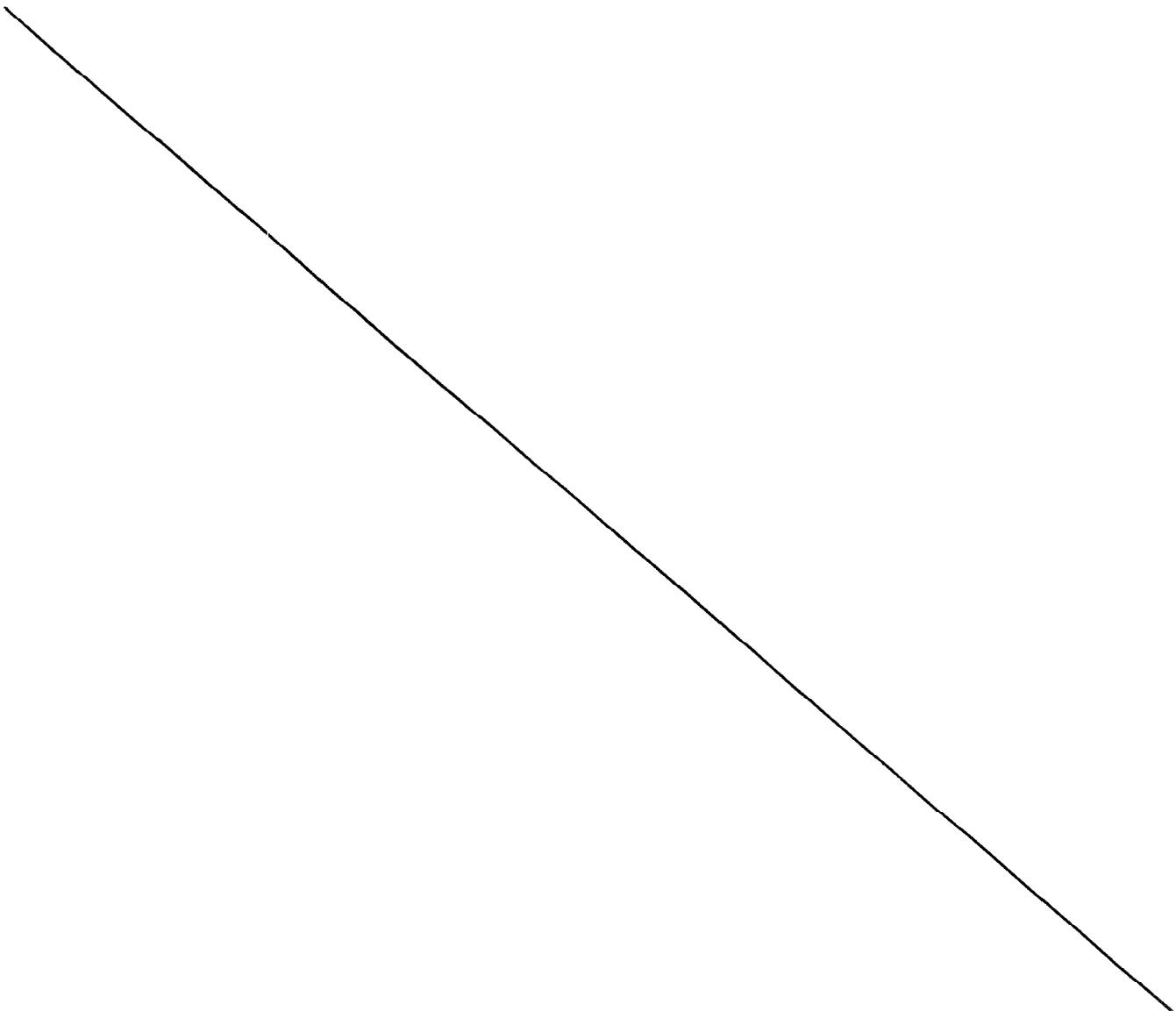
FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: jgotthar@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: In accordance with section 512(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(i)) and 21 CFR 514.105(a) and 514.106(a), FDA is providing notice that in 2001 it approved a supplemental NADA that was not the subject of a final rule. A final rule was not published because 21 CFR 558.128 did not require amendment.

On November 15, 2001, FDA approved a supplement filed by Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024 to NADA 48-761 for AUREOMYCIN (chlortetracycline) Type A medicated articles. The supplemental NADA provided for use of AUREOMYCIN Type A medicated articles to make Type B and Type C medicated swine feeds for the control

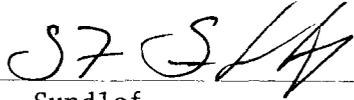
of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline. No new data were submitted. The necessary amendment to 21 CFR 558.128 was made in a final rule (65 FR 45881, July 26, 2000) for the 2000 supplemental approval of the identical claim for Alpharma, Inc.'s CHLORMAX (chlortetracycline) Type A medicated articles, approved under NADA 046-699.

A freedom of information summary containing approved product labeling 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.

Dated: 6/25/03
June 25, 2003.



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

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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