

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Notice of Approval of New Animal Drug Applications; Clindamycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that it has approved three new animal drug applications (NADAs) or abbreviated new animal drug applications (ANADAs) in 2002 for feed combinations including a generic bacitracin zinc Type A medicated article that were not the subject of final rules. Final rules were not published because the applicable sections of the regulation did not require amendment.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600, e-mail: candres@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 it has approved three NADAs or ANADAs in 2002 that were not the subject of final rules. Final rules were not published because the applicable sections of part 558 (21 CFR part 558) did not require amendment.

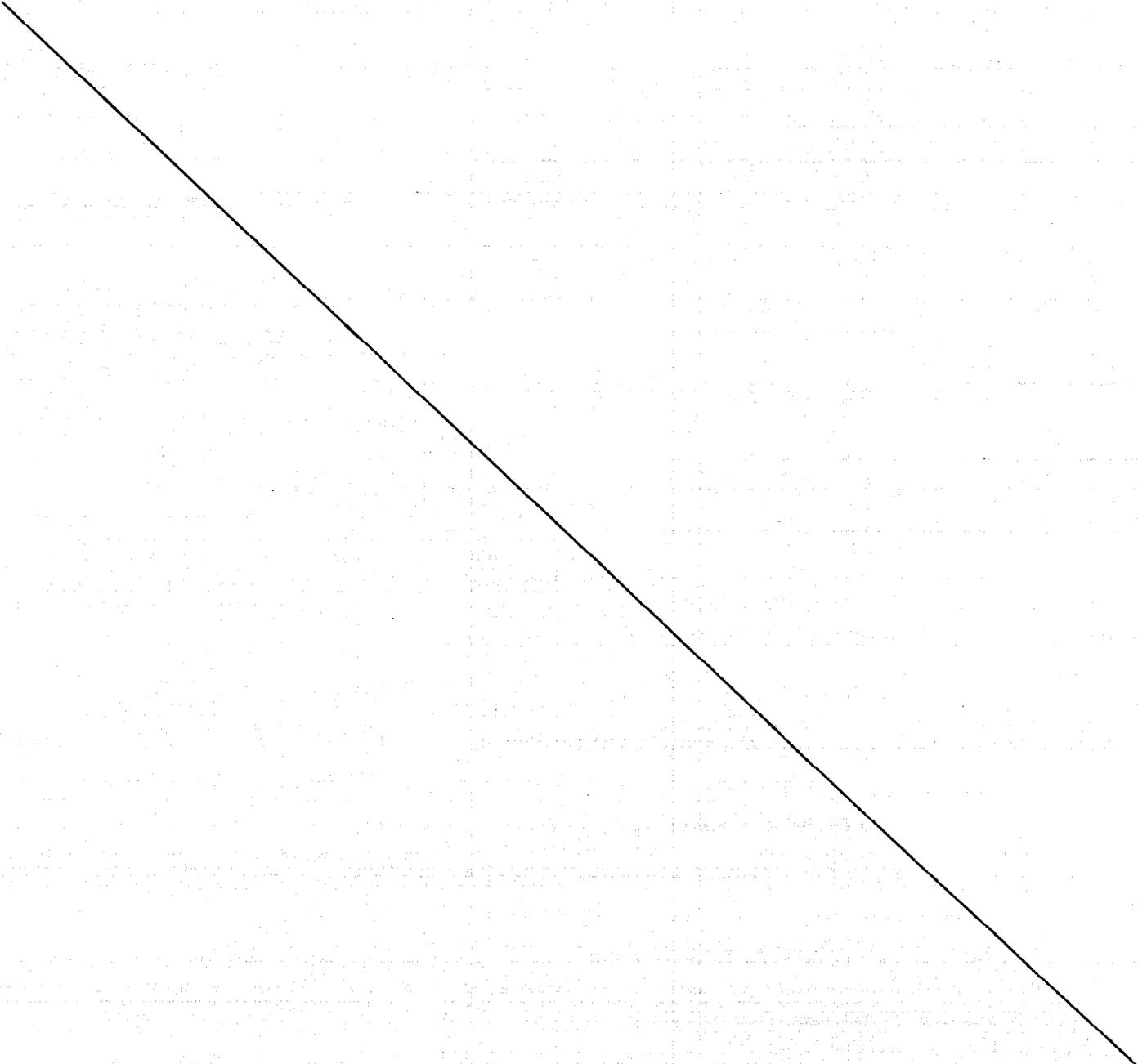
On April 29, 2002, FDA approved a supplement filed by Alpharma, Inc., to NADA 140-865 for use of single-ingredient MONTEBAN (narasin) and BACIFERM (bacitracin zinc) Type A medicated articles to make two-way combination drug Type B and Type C medicated feeds used for prevention

of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; and for increased rate of weight gain and improved feed efficiency in broiler chickens. The supplemental NADA provided for use of Alparma, Inc.'s ALBAC (bacitracin zinc) 50 Type A medicated article, approved under ANADA 200–223 as a generic copy of BACIFERM, in these two-way combination chicken feeds. No new data were submitted. The necessary amendment to §§ 558.78 and 558.363 were made in a final rule (65 FR 55893, September 15, 2000) for the 2000 approval of this combination for MONTEBAN and BACIFERM Type A medicated articles.

On May 15, 2002, FDA approved original NADA 141–181 filed by Alparma, Inc., for use of single-ingredient AVATEC (lasalocid) and ALBAC (bacitracin zinc) Type A medicated articles to make two-way combination drug Type B and Type C medicated feeds for the prevention of coccidiosis caused by *E. meleagrimitis*, *E. gallopavonis*, and *E. adenoides*, and for increased rate of weight gain and improved feed efficiency in growing turkeys. No new data were submitted. The necessary amendments to §§ 558.78 and 558.311 were made in a final rule (64 FR 26844, May 18, 1999) for the 1999 approval of Alparma, Inc.'s NADA 141–109 for use of AVATEC and BACIFERM Type A medicated articles in two-way combination turkey feeds for identical conditions of use.

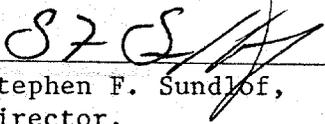
On June 24, 2002, FDA approved original ANADA 200–208 filed by Alparma, Inc., for use of single-ingredient AVATEC (lasalocid), 3 NITRO (roxarsone), and ALBAC (bacitracin zinc) Type A medicated articles to make three-way combination drug Type B and Type C medicated feeds used for prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; as an aid in the reduction of lesions due

to *E. tenella*; and for increased rate of weight gain or improved feed efficiency in broiler chickens. ANADA 200-208 was approved as a generic copy of Alpharma, Inc.'s NADA 126-052, for use of AVATEC, 3 NITRO, and BACIFERM (bacitracin zinc) Type A medicated articles for identical conditions of combination use. No new data were submitted. The necessary amendments to §§ 558.78, 558.311, and 558.530 were made in a final rule (47 FR 46496, October 19, 1982) for the 1982 approval of the pioneer combination.



Freedom of information summaries containing approved product labeling may be seen in the Dockets Management Branch (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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