Date of Approval Letter: November 15, 2001

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 48-761

Aureomycin® 50 Granular, Aureomycin® 90 Granular, and
Aureomycin® 100 Granular (chlortetracycline)
Type A Medicated Articles

"control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline"

Sponsored by:
Alpharma Inc.

I. GENERAL INFORMATION

NADA Number:	48-761
Sponsor:	Alpharma Inc. One Executive Drive Fort Lee, New Jersey 07024
Established Name:	chlortetracycline
Proprietary Names:	Aureomycin® 50 Granular, Aureomycin® 90 Granular, and Aureomycin® 100 Granular (chlortetracycline) Type A Medicated Articles
Marketing Status:	Over-the-counter (OTC)
Effect of Supplement:	This supplemental application adds the claim for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.

II. INDICATIONS FOR USE

Swine:	Control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline. Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline. Increased rate of weight gain and improved feed efficiency. Reduction in the incidence of cervical lymphadenitis (jowl abscess) caused by Group E *Streptococci* susceptible to chlortetracycline.
Breeding Swine:	Control of leptospirosis (reducing the incidence of abortion and shedding of *leptospirae*) caused by *Leptospira pomona.*

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE

A. Dosage Form: Type A Medicated Article

B. Route of Administration: Oral, in feed

C. Recommended Dosage: In Type C medicated feed, chlortetracycline to deliver a daily dose of 10 mg/lb body weight (approximately 400 grams per ton) for not more than 14 days.

IV. EFFECTIVENESS

The claim for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline in swine treated with 10 mg chlortetracycline per lb body weight for up to 14 days in feed was approved on July 7, 2000, for Alpharma's ChlorMax™ (65 FR 42881, July 26, 2000).

ChlorMax™ (chlortetracycline, NADA 46-699) and Aureomycin® NADA 48-761 were both found to comply with the results of NAS/NRC and DESI evaluation for effectiveness as published in the Federal Register (61 FR 35949-35958, July 9, 1996). These products approved under the DESI process were found to be equivalent at the codified levels for swine and other species.

Aureomycin® and ChlorMax™ were shown equivalent under DESI evaluation. Alpharma Inc. owns both products. As such, Alpharma Inc. may reference data found in NADA 46-699. Aureomycin® and ChlorMax™ now have identical indications. For the purposes of this supplement, no new studies were conducted to establish effectiveness associated with the use of chlortetracycline in swine.

V. ANIMAL SAFETY

The target animal information is contained in the FOI Summary for the original approval of NADA 48-761. No new data were generated for this supplement because the dosage of CTC for this indication remains within the approved dose range for swine.

VI. HUMAN SAFETY

The current tolerance established for the sum of residues of the tetracyclines, including chlortetracycline, in tissues of swine is 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney, as described in 21 CFR 556.150. Chlortetracycline has a zero-day pre-slaughter withdrawal period in swine, as described in 21 CFR 558.128.

VII. AGENCY CONCLUSIONS

The information submitted in support of this NADA and in the referenced files satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The information demonstrates that Aureomycin® Type A Medicated Article when administered in swine feed is safe and effective when used as described in Section II and III .

The Agency has concluded that this product shall retain over-the-counter marketing status because adequate directions for use have been written for the layman and the conditions for use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2)(v), this is a Category II change which did not require a reevaluation of the safety or effectiveness data in the parent application.

The Agency has carefully considered the potential environmental effects of this action and has concluded that the action is categorically excluded under 21 CFR 25.33(a)(1) from the requirement to prepare an environmental assessment (EA).

Under Section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualify for marketing exclusivity because the application contains no new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant.

There are currently no U.S. patents Aureomycin® Type A Medicated Article.

VII. APPROVED PRODUCT LABELING

Copies of facsimile Type A Medicated Article labeling and specimen (Blue Bird) Type B and Type C medicated feed labels are attached to this document.

A. Aureomycin® 50 Granular

B. Aureomycin® 90 Granular

C. Aureomycin® 100 Granular

D. Blue Bird CTC 40 Type B Swine Feed Medicated

E. Blue Bird CTC Type C Swine Feed Medicated

Copies of applicable labels may be obtained by writing to the following:

Freedom of Information Staff (HFI-35)
Food and Drug Administration, Room 12A16
5600 Fishers Lane
Rockville, Maryland 20857