Stamp Date: September 21, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION:

ANADA Number: **200-263**

ANADA/Generic Sponsor:
Alpharma Inc.
One Executive Drive
Fort Lee, NJ 07024

Established Name: Chlortetracycline
Monensin sodium

Trade/Proprietary Name: ChlorMax™
Coban®

Dosage Form: Type A Medicated Articles

Note: This ANADA provides for the combined use of two approved Type A Medicated Articles (ChlorMax™ chlortetracycline and Coban® monensin sodium) in Type C Medicated Feeds, rather than a premix incorporating both of these compounds.

How Supplied: Chlortetracycline: 5, 10 or 50-lb bags
Monensin sodium: 50-lb bags

How Dispensed: OTC

Label Claim of Amount of Active Ingredient(s): Chlortetracycline-50, 65, and 70 g/lb in Type A Medicated Articles

Monensin-60 g/lb in Type A Medicated Article

Route of Administration: These drugs are administered orally by adding the Type A Medicated Articles to complete broiler feed (Type C Medicated Feed)

Recommended Dosage: Chlortetracycline, 500 grams per ton
Monensin, 90 to 110 grams per ton

Species: Broiler Chickens

Indications for use:	As an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments. As an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina, E. maxima*, *E. brunetti*, and *E. mivati.*
Equivalent Product:	ChlorMax™ Chlortetracycline NADA 46-699 Alpharma Inc.
Pioneer Product/ Listed Product:	Aureomycin® Chlortetracycline NADA 48-761 Roche Vitamins, Inc. Coban Monensin sodium NADA 41-500 Elanco Animal Health, a Division of Eli Lilly & Co. Aureomycin®-Coban® Chlortetracycline/Monensin NADA 121-553 Roche Vitamins, Inc.

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY:

ChlorMax and Aureomycin 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 level 21 CFR § 558.128(d)(1)(viii) of 500 g/ton for chickens (61 FR 35949-35958; July 9, 1996).

The Center's fourth policy letter dated November 2, 1989, as published in the Federal Register on January 30, 1990 (55 FR 3107), states that the approval of a new generic Type A Medicated Article entitles the sponsor to approval of all the feed combinations for which the pioneer is approved. Bioequivalence and tissue residue studies are not required for approval of the feed use combinations.

Chlortetracycline (ChlorMax-Alpharma) is codified under 21 CFR § 558.128(a)(3). Chlortetracycline (Aureomycin®-Roche) is codified under 21 CFR § 558.128(a)(1). Monensin sodium is codified under 21 CFR § 558.355. The combination is codified under 21 CFR § 558.355(f)(1)(xiv).

III. HUMAN SAFETY:

a. Tolerances and Safe Concentration of Residues

The tolerances established for the pioneer product apply to the generic product.

Tolerances for the sum of residues of tetracycline, including chlortetracycline in tissues of chickens, are as follows: (a) 2 parts per million (ppm) in muscle; (b) 6 ppm in liver; (c) 12 ppm in fat (21 CFR § 556.150).

A tolerance for monensin residues is not needed (21 CFR § 556.420).

The safe concentrations for total residues of monensin in the edible tissue of broiler chickens 1.5 ppm in muscle, 4.5 ppm in liver, and 3.0 ppm in skin with adhering fat (21 CFR § 556.420).

b. Withdrawal Time

Based on the information in 21 CFR § 558.355(f)(1)(xiv), a 24-hour withdrawal time is required for the combination of chlortetracycline and monensin.

c. Regulatory Methods for Residues

The regulatory analytical method for the determination of residue of chlortetracycline is a microbiological test using *Bacillus cereus* var. *mycoides* (ATCC 11778). The method is found in Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports and Protocols, Revised October 1968, Reprinted December 1974, National Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204.

Determination of Monensin in Tissues and Eggs. Method 5801654. Eli Lilly and Company, Box 708, Greenfield, IN 46140; on file at the Center for Veterinary Medicine, Food and Drug Administration, HFV-199, 7500 Standish Place, Rockville, Maryland 20855.

IV. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug and Cosmetic Act satisfies the requirements of section 512 (n) of the act and demonstrates that the combination of chlortetracycline and monensin, when used under its proposed conditions of use, is safe and effective for its labeled indications.

Attached labeling: Type C Medicated Feed (Blue Bird) - Generic