Stamp Date: Sept. 21, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION:

ANADA Number: **200-262**

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

Established Name: Chlortetracycline
Salinomycin sodium

Trade/Proprietary Name: ChlorMax™
Sacox®

Dosage Form: Type A medicated articles

Note: This ANADA provides for the combined use of two approved Type A medicated articles (ChlorMax™ chlortetracycline and Sacox® salinomycin) in Type C medicated feeds, rather than a premix incorporating both of these compounds.

How Supplied: Chlortetracycline: 50-lb bags
Salinomycin sodium: 50-lb bags

How Dispensed: OTC

Label Claim of Amount of Active Ingredient(s): Chlortetracycline-50, 65, 70, and 100 g/lb in Type A medicated articles
Salinomycin-30 and 60 g/lb lb in Type A medicated articles

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 calcium complex equivalent to chlortetracycline HCl 500 grams per ton (.055%)
Salinomycin sodium activity 40 to 60 grams per ton (.0044-.0066%)

Species: Broiler Chickens

Indications for use: For the prevention of coccidiosis in broiler chickens caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina, E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatments

Equivalent Product:	ChlorMax™ Chlortetracycline NADA 46-699 Alpharma Inc.
Pioneer Product/ Listed Product:	Aureomycin® Chlortetracycline NADA 48-761 Roche Vitamins, Inc.
	Sacox® Salinomycin sodium ANADA 200-075 Hoechst-Roussel Vet
	Aureomycin®-Sacox® Chlortetracycline/Salinomycin ANADA 200-095 Hoechst-Roussel Vet

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY:

ChlorMax™ (chlortetracycline) 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. Bioequivalency and tissue residue studies are not required for approval of the feed use combinations.

Chlortetracycline (ChlorMax™-Alpharma) is codified under 21 CFR § 558.128(d)(1). Chlortetracycline (Aureomycin®-Roche) is codified under 21 CFR § 558.128(d)(1). Salinomycin sodium is codified under 21 CFR § 558.550. The combination is codified under 21 CFR § 558.550(d)(1)(xvi).

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 chicken 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).

Under NADA 128-686 a tolerance for salinomycin was not required because residue levels in all three broiler tissues (muscle, liver, and skin/fat) were significantly below the established safe concentration.

b. Withdrawal Time

Based on the information in 21 CFR § 558.550(d)(1)(xv), a 24-hour withdrawal time is required for the combination of chlortetracycline and salinomycin.

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.

Under NADA 128-686 a regulatory method for salinomycin was not required because residue levels in all three broiler tissues (muscle, liver, and skin/fat) were significantly below the established safe concentration for total residues.

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 salinomycin, 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