Date of Approval: August 15, 2003

FREEDOM OF INFORMATION SUMMARY

ANADA 200-354

This approval provides for the combined use of two approved Type A medicated Articles (Pennchlor™-chlortetracycline, Coban® -monensin sodium) for use in the manufacture of Type C Medicated Feeds for broiler chickens.

Sponsored by:
Pennfield Oil Company
Omaha, Nebraska 68144

I. GENERAL INFORMATION:

a. File Number:	ANADA 200-354
b. Sponsor:	PennField Oil Company 14040 Industrial Road Omaha, Nebraska 68144 Drug Labeler Code: 053389
c. Established Names:	Chlortetracycline Monesin sodium
d. Proprietary Names:	Pennchlor™ (Pennfield Oil Co.) Coban® (Elanco Animal Health, Inc.)
e. Dosage Form:	Type A Medicated Articles
f. How Supplied:	Chlortetracycline: 50-lb bags Monensin sodium: 50-lb bags
g. How Dispensed:	OTC
h. Amount of Active Ingredient(s):	Chlortetracycline- 50, 70, 90 & 100 g/lb in Type A Medicated Articles Monensin sodium- 60 g/lb in Type A Medicated Articles
i. Route of Administration:	These drugs are administered orally by adding the Type A Medicated Articles to complete broiler chicken feed (Type C Medicated Feed)
j. Species/class:	Broiler Chickens
k. Recommended Dosage:	Chlortetracycline, 500 grams per ton Monensin sodium, 90 to 110 grams per ton
l. Pharmacological Category:	Antibacterial, anticoccidial
m. Indications:	As an aid in the prevention of coccidiosis 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 treatment.

n. Pioneer Products:

Aureomycin®
Chlortetracycline
NADA 48-761
Alpharma, Inc.

Coban®
Monensin sodium
NADA 41-500
Elanco Animal Health, Inc.

Aureomycin®-Coban®
Chlortetracycline/Monensin
NADA 121-553
Alpharma, Inc.

Pennchlor™
Chlortetracycline
NADA 138-935
Pennfield Oil Company

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Pennchlor™ and Aureomycin® were both found to comply with the results of NAS/NRC/ 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(e)(1)(iv) of 500 g/ton for chickens (61 FR 35949-35958; July 9, 1996).

The Center's fourth generic 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 (Pennchlor™-Pennfield) is codified under 21 CFR § 558.128(e)(1).
Chlortetracycline (Aureomycin®-Alpharma) is codified under 21 CFR § 558.128(e)(1).

Monensin sodium is codified under 21 CFR § 558.355. The combination is codified under 21 CFR § 558.355(f)(1)(xiv) and NADA 121-553 was approved on March 5, 1982.

3. HUMAN SAFETY:

- Tolerances and Safe Concentrations of Residues

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

Tolerances for the sums of residues of the 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).). The acceptable daily intake (ADI) for total residues of tetracycline including chlortetracycline is 25 micrograms per kilogram of body weight per day.

Under NADA 121-553 a tolerance for residues of monensin was not required in broiler chickens. The acceptable daily intake (ADI) for total residues of monensin is 12.5 micrograms per kilogram of body weight per day (21 CFR 556.420).

- Withdrawal Time

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

- 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.

4. 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 sodium, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached below:

Type C Medicated Feed (Blue Bird) – Generic Labeling for ANADA 200-354

Type C Medicated Feed (Blue Bird) - Pioneer Labeling NADA 121-553