Date of Approval: March 19, 2004

FREEDOM OF INFORMATION SUMMARY

ANADA 200-359

This approval provides for the combined use of two approved Type A Medicated Articles, PENNCHLOR (chlortetracycline) and DECCOX (decoquinate), for use in the manufacture of Type B and Type C Medicated Feeds for calves, beef and nonlactating dairy cattle.

Sponsored by:
Pennfield Oil Company
Omaha, Nebraska 68144

I. GENERAL INFORMATION:

a. File Number**:**	ANADA 200-359
b. Generic Sponsor:	Pennfield Oil Company 14040 Industrial Road Omaha, Nebraska 68144 Drug Labeler Code: 053389
c. Established Names:	Chlortetracycline Decoquinate
d. Proprietary Names:	PENNCHLOR (Pennfield Oil Co.) DECCOX (Alpharma, Inc)
e. Dosage Form:	Type A Medicated Articles
f. How Supplied:	Chlortetracycline HCl: 50-lb bags Decoquinate: 50-lb bags
g. How Dispensed:	OTC
h. Amount of Active Ingredient(s):	Decoquinate- 27.2 g/lb in Type A Medicated Articles Chlortetracycline (as hydrochloride)-50 to 100 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 cattle feed (Type B or Type C Medicated Feed)
j. Species/class:	Calves, beef and nonlactating dairy cattle

k. Recommended Dosage: Chlortetracycline, 500 to1000 grams per ton (10 mg/lb body weight/day)
Decoquinate, 13.6 to 22.7 grams per ton (22.7 mg/100 lb body weight/day

l. Pharmacological Category: Antibacterial, anticoccidial

m. Indications for use: Calves, beef and nonlactating dairy cattle: For the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* for treatment of bacterial enteritis caused by *Escherichia coli*; for bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

n. Pioneer Products:

CHLORMAX
Chlortetracycline
NADA 46-699
Alpharma, Inc.

DECCOX
Decoquinate
NADA 39-417
Alpharma, Inc.

CHLORMAX +DECCOX
Chlortetracycline/Decoquinate
NADA 141-147
Alpharma, Inc.

DESI "me-too" product

PENNCHLOR
Chlortetracycline
NADA 138-935
Pennfield Oil Company

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

PENNCHLOR and CHLORMAX 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 "me-too"

process were found to be equivalent at the codified level 21 CFR § 558.128(e)(4)(iv) of 10 mg/lb of body weight daily for cattle (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 generic Type A Medicated Article entitles the sponsor to approval of all the feed mixed 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)(4). Chlortetracycline (CHLORMAX-Alpharma) is codified under 21 CFR § 558.128(e)(4). Decoquinate (DECCOX-Alpharma)) is codified under 21 CFR § 558.195. The combination is codified under 21 CFR § 558.195(e)(2)(iii) and the NADA 141-147 was approved on September 29, 2000.

3. HUMAN SAFETY:

· Tolerances for Residues:

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

Tolerances for the sums of residues of tetracycline, including chlortetracycline in tissues of cattle, are as follows: (a) 2 parts per million (ppm) in muscle; (b) 6 ppm in liver; (c) 12 ppm in fat and kidneys (21 CFR § 556.150). The acceptable daily intake for residues of chlortetracycline is 25 micrograms per kilogram of body weight per day.

Under NADA 39-417 a tolerance for decoquinate is established for residues of decoquinate in the uncooked tissues of cattle as follows: 1 part per million (ppm) in skeletal muscle and 2 ppm in other tissues. The acceptable daily intake (ADI) for total residues of decoquinate is 75 micrograms per kilogram of body weight per day (21 CFR § 556.170).

· Withdrawal Times:

Based on the limitation in 21 CFR § 558.195(e), a 24 hour withdrawal time is required for the combination of chlortetracycline and decoquinate.

· 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.

The regulatory method for the determination of decoquinate in tissues uses a fluorometric assay procedure and is found in the *Official Methods of Analysis of AOAC International,* 16th edition.

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 decoquinate, 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 B and C Medicated Feed (Blue Bird) – Generic Labeling for ANADA 200-359

Type B and C Medicated Feed (Blue Bird) – Pioneer Labeling NADA 141-147