Date of Approval: July 2, 2004

FREEDOM OF INFORMATION SUMMARY

AN ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-358

PENNCHLOR (chlortetracycline hydrochloride) and BMD (bacitracin methylene disalicylate)

Type B and Type C Medicated Feeds

This approval provides for the combined use of two approved Type A Medicated Articles PENNCHLOR, (chlortetracycline hydrochloride) and BMD (bacitracin methylene disalicylate), for use in feed-mixed Type B and Type C medicated feeds for swine.

Sponsored by:

Pennfield Oil Company
Omaha, NE 68144

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-358
b. Sponsor:	Pennfield Oil Co. 14040 Industrial Rd. Omaha, NE 68144 Drug Labeler Code: 053389
c. Established Name:	Chlortetracycline hydrochloride Bacitracin methylene disalicylate
d. Proprietary Name:	PENNCHLOR BMD
e. Dosage Form:	Type A Medicated Articles
f. How Supplied:	PENNCHLOR (chlortetracycline hydrochloride): 50-lb bags BMD (bacitracin methylene disalicylate): 50-lb bags
g. How Dispensed:	OTC
h. Amount of Active Ingredients in Type A Medicated Article:	PENNCHLOR (chlortetracycline hydrochloride): 50 to 100 g/lb. BMD (bacitracin methylene disalicylate): 25, 30, 50, 60, or 75 g/lb.
Amount of Active Ingredients in Type B Medicated Feed:	PENNCHLOR (chlortetracycline hydrochloride): 40 g/lb. BMD (bacitracin methylene disalicylate): 3 g/lb
i. Route of Administration:	Orally; by adding the Type A Medicated Articles to complete swine feeds (Type B or C medicated feeds).

j. Species/Class:	Swine
k. Recommended Dosage in Type C Medicated Feeds:	PENNCHLOR (chlortetracycline hydrochloride): approximately 400 g/ton, varying with body weight and food consumption to provide 10 mg per pound of body weight daily. BMD (bacitracin methylene disalicylate): 10 to 30 g/ton
l. Pharmacological Category:	Antibacterial
m. Indications:	For increased rate of weight gain and improved feed efficiency; for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline hydrochloride.
n. Pioneer Product:	AUREOMYCIN Chlortetracycline hydrochloride NADA 48-761 Alpharma, Inc. BMD Bacitracin methylene disalicylate NADA 46-592 Alpharma, Inc. AUREOMYCIN-BMD Chlortetracycline hydrochloride/Bacitracin methylene disalicylate NADA 141-059 Alpharma, Inc.
DESI Finalization	PENNCHLOR Chlortetracycline hydrochloride NADA 138-935 Pennfield Oil Company

2 & 3. Target Animal Safety and Drug Effectiveness*:*

PENNCHLOR and AUREOMYCIN were both found to comply with the results of the National Academy of Sciences-National Research Council/Drug Efficacy Study Group (DESI) evaluation for effectiveness as published in the FEDERAL REGISTER (61 FR 35949-35958; July 9, 1996). These products approved under the DESI finalization process were found to be equivalent at the codified level 21 CFR § 558.128(e)(3)(iv) of 10 mg/lb of body weight daily for swine.
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 a waiver from bioequivalence or tissue residue studies for any feed-use combinations approved for the pioneer. Since Alpharma's AUREOMYCIN is considered bioequivalent to Pennfield's PENNCHLOR, Pennfield is entitled to a bioequivalence waiver for the subject feed-mixed combination.

Chlortetracycline hydrochloride (PENNCHLOR-Pennfield) is codified under 21 CFR § 558.128(e)(3). Chlortetracycline hydrochloride (AUREOMYCIN-Alpharma) is codified under 21 CFR § 558.128(e)(3). Bacitracin methylene disalicylate is codified under 21 CFR § 558.76. The combination use of BMD with Chlortetracycline hydrochloride is codified under 21 CFR § 558.76(d)(1)(iv) and the pioneer NADA 141-059 was approved on September 18, 1996.

4. 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 hydrochloride in tissues of swine, 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 (ADI) under 21 CFR 556.150 for residues of chlortetracycline hydrochloride is 25 micrograms per kilogram of body weight per day.

Under NADA 141-059, a tolerance is established for residues of bacitracin from BMD (bacitracin methylene disalicylate) in uncooked edible tissues of swine is 0.5 parts per million (21 CFR 556.70). The acceptable daily intake for total residues of bacitracin is 0.05 milligrams per kilogram of body weight per day.

· Withdrawal Times:

Because a waiver of the in vivo bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

A zero-day withdrawal time is required for the combination of chlortetracycline hydrochloride and bacitracin methylene disalicylate in swine.

· **Regulatory Methods for Residues:**

The regulatory analytical method for the determination of residue of chlortetracycline hydrochloride 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 analytical method for determination of residue of bacitracin is a microbiological test using *Sarcina subflava* (ATCC 7468) or *Micrococcus subflavus* (ATCC 10240). 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.

Modified Method for the Determination of Bacitracin in Tissues, Test Procedure Code 9A, AL Laboratories, One Executive Dr., PO Box 1399, Fort Lee, NJ 07024.

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 PENNCHLOR (chlortetracycline hydrochloride) and BMD (bacitracin methylene disalicylate), 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:

Generic Labeling for ANADA 200-358
Type B and Type C Medicated Feed (Blue Bird)

Pioneer Labeling for NADA 141-059
Type B and Type C Medicated Feed (Blue Bird)