Date of Approval: January 29, 2003

FREEDOM OF INFORMATION SUMMARY

ANADA 200-314

Indications for use: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

Sponsored by:
Pennfield Oil Company
Omaha, Nebraska 68144

1. GENERAL INFORMATION:

a. ANADA Number	200-314
b. Sponsor:	Pennfield Oil Company 14040 Industrial Road Omaha, Nebraska 68144 21 CFR 510.600: Labeler Code: 053389
c. Established Name:	Chlortetracycline calcium complex and sulfamethazine
d. Trade/Proprietary Name:	PENNCHLOR S 700™
e. Dosage Form:	Type A Medicated Article
f. How Supplied:	50 pound (22.7 kg) bags
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	35 grams of chlortetracycline and 35 grams sulfamethazine per pound
i. Route of Administration:	Oral
j. Species:	Beef cattle
k. Recommended Dosage:	For use in feed for beef cattle Administer at a dose rate of 350 mg of CTC and 350 mg of sulfamethazine per head per day
l. Pharmacological Category:	Antibacterial
m. Indications:	As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.

n. Pioneer Product: Aureo S 700® S manufactured by Alpharma, Inc. (NADA 35-805)

2. TARGET ANIMAL SAFETY and DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily the ANADA Sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Pennfield Oil Company was granted a waiver on April 27, 2000, from the requirement of an *in vivo* bioequivalence study for PENNCHLOR S 700. The generic and pioneer products contain the same active and inactive ingredients in the same concentration as the pioneer and are Type A Medicated Articles. The pioneer product, Aureo S 700®, the subject of Alpharma, Inc.'s NADA 35-805 was approved on October 1, 1968; (formerly Roche Vitamins).

3. HUMAN SAFETY:

WITHDRAWAL TIME

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for chlortetracycline and sulfamethazine is established under 21 CFR 558.140. There is a 7-day withdrawal period for cattle.

TOLERANCE

Under section §556.150, **Chlortetracycline:**

(a) Acceptable daily intake (ADI). The ADI for total residues of tetracyclines including chlortetracycline is 25 micrograms per kilogram of body weight per day.

(b) Tolerances. Tolerances are established for the sum of tetracycline residues in the tissues of beef cattle of 2 ppm in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.

Under section §556.670, **Sulfamethazine:**

A tolerance of 0.1 ppm is established for negligible residues of sulfamethazine in the uncooked edible tissues of cattle.

REGULATORY METHODS

The regulatory analytical methods for detection of residues of chlortetracycline are microbiological assay procedures (Antibiotic Residues in Milk, Dairy Product and Animal Tissues: Methods, Reports and Protocols, FDA, 1968). The regulatory method of detection for sulfamethazine residues is colorimetric. It is described in the USDA FSIS Analytical Chemistry Laboratory Guidebook-Residue Chemistry; Winter 1991, pp. 1-23 (Determinative method). The methods are on file at the Center for Veterinary Medicine, Food and Drug Administration, HFV-199, 7500 Standish Place, Rockville, Maryland 20855.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed 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 PENNCHLOR S 700™ is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments:

Pioneer Labeling:
50 pound bag
Aureo S 700® Type A Medicated Article

Generic Labeling:
50 pound bag
Pennchlor S 700™ Type A Medicated Article

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.