Date of Approval 4/27/01

# FREEDOM OF INFORMATION SUMMARY

# ANADA 200-295

Sponsored by:

PennField Oil Company
14040 Industrial Road
Omaha, Nebraska 68144

# FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

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| ANADA: | 200-295 |
| Sponsor: | PennField Oil Company<br>14040 Industrial Road<br>Omaha, Nebraska, 68144 |
| Generic Name: | chlortetracycline HCL powder |
| Trade Name: | Pennchlor 64 |
| Dosage Form: | powder |
| How Supplied: | 25.6 ounce packets |
| How Dispensed: | OTC |
| Amount of Active Ingredients: | 102.4 g of chlortetracycline per packet |
| Route of Administration: | Oral |
| Species: | Calves, swine, chickens and turkeys |
| Labeled Dosage: | Calves-10 mg/Lb b.w. in divided doses<br>Swine-10 mg/Lb b.w. in divided doses<br>Chickens-200-1000 mg per gallon<br>Turkeys-400 mg per gallon, 25 mg/Lb b.w. |
| Indications for Use: | Calves, beef cattle and nonlactating dairy cattle and swine:<br>Bacterial Pneumonia (*Pasteurella* spp*., Hemophilus* spp., *Klebsiella* spp.) and<br>Bacterial Enteritis (*Escherichia coli, Salmonella spp.*)<br><br>Turkeys: |

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| | Control of complicating bacterial organisms associated with Bluecomb (transmissible enteritis or Coronavirus enteritis) susceptible to chlortetracycline.<br>Infectious Synovitis (*Mycoplasma synoviae*)<br><br>Chickens:<br>Chronic Respiratory Disease (CRD) and Air-sac infection (*Mycoplasma gallisepticum, Escherichia coli*) For the control of mortality due to fowl cholera (*Pasteurella multocia*) in growing chickens. |
| Pioneer Product/<br>"Listed Product: | American Cyanamid Company, AHP Corporation<br>NADA 65-440, Aureomycin® soluble powder. |

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, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April, 1996).

Based upon the formulation characteristics of the generic product, Pennchlor 64 was granted a waiver on July 22, 1996, from conducting an *in vivo* bioequivalence study. The generic and pioneer products contain the same active but different inactive ingredients and are soluble powders.

3. HUMAN FOOD SAFETY:

TOLERANCE:

Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, non-lactating dairy cows, calves, swine, sheep, chickens, turkeys, and ducks, of 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.

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 pioneer chlortetracycline soluble powder (Aureomycin®) is established under 21 CFR 520.445b:

Swine-24 hour withdrawal period,
Calves-1day withdrawal period
Chickens-24 hour withdrawal period
Turkeys-24 hour withdrawal period

The withdrawal period for this generic product (Pennchlor 64) is the same as the pioneer with the exception of the withdrawal period in swine. Pennchlor will be approved with a different withdrawal period in swine, zero day instead of the 24 hours for swine on the pioneer label. The generic sponsor was allowed this different withdrawal period from the pioneer under the Center for Veterinary Medicine's Hybrid ANADA approval process. Pennfield Oil Company owns another chlortetracycline soluble powder product (NADA 65-480) which is identical in formulation to this generic product. Pennfield Oil Company received an approval of a supplement (December 22, 1999) for a shortened withdrawal period in swine (zero day). The Agency is allowing Pennfield Oil Company to reference their residue data for the zero day withdrawal period for swine for this generic chlortetracycline soluble powder, Pennchlor 64 under the Hybrid ANADA policy.

REGULATORY METHODS FOR RESIDUES:

The regulatory analytical method for detection of residues of the drug 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, Nation Center for Antibiotic and Insulin Analysis, FDA, Washington, DC 20204.

4. AGENCY CONCLUSIONS:

This is an Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Pennchlor 64 were established by demonstration of chemical equivalence to the pioneer product, American Cyanamid's Aureomycin® (NADA 65-440).

The route and method of administration of the two drugs are identical. Both drugs are administered orally. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy promulgated to implement section 512(b)(2) of FFD&C Act, no *in vivo* bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Pennchlor 64 is safe and effective for its labeled indications when used under its proposed conditions of use.

Attachments:

1. Generic Labeling:

2. Pioneer Labeling