

**HFA-305 DOCKET
MANAGEMENT
BRANCH**

Date of Approval APR 27 2001

FREEDOM OF INFORMATION SUMMARY

ANADA 200-295

Sponsored by:

PennField Oil Company
14040 Industrial Road
Omaha, Nebraska 68144

ANADA 200-295

FOIS-1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA: 200-295

Sponsor: PennField Oil Company
14040 Industrial Road
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
Swine-10 mg/Lb b.w. in divided doses
Chickens-200-1000 mg per gallon
Turkeys-400 mg per gallon, 25 mg/Lb b.w.

Indications for Use: Calves, beef cattle and nonlactating dairy cattle and swine:
Bacterial Pneumonia (*Pasteurella* spp., *Hemophilus* spp., *Klebsiella* spp.) and
Bacterial Enteritis (*Escherichia coli*, *Salmonella* spp.)

Turkeys:

Control of complicating bacterial organisms associated with Bluecomb (transmissible enteritis or Coronavirus enteritis) susceptible to chlortetracycline.
Infectious Synovitis (*Mycoplasma synoviae*)

Chickens:
Chronic Respiratory Disease (CRD) and Air-sac infection (*Mycoplasma gallisepticum*, *Escherichia coli*) For the control of mortality due to fowl cholera (*Pasteurella multocida*) in growing chickens.

Pioneer Product/
"Listed Product:

American Cyanamid Company, AHP Corporation
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

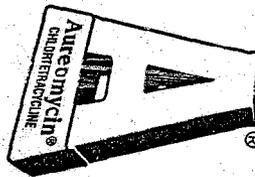
TURKEYS	DOSE
Control of complicating bacterial organisms associated with Bluecomb (transmissible enteritis or Coronavirus enteritis) susceptible to chlortetracycline	25 mg/lb body weight/day. Administer 1 packet for every 4,096 lbs of turkeys in the total water consumed over a full, 24-hour period.
Infectious Synovitis (<i>Mycoplasma synoviae</i>)	2 packets per 512 gallons (400 mg/gallon). Administer at this rate in the total water consumed over a full, 24-hour period.

Medicate chickens and turkeys continuously at the first clinical signs of disease and continue for 7 to 14 consecutive days. The dosage ranges permitted provide for different levels based on the severity of the infection. If improvement is not noted in 24-48 hours, consult a veterinarian or a diagnostic laboratory to determine diagnosis and for advice regarding the optimal level of the drug where ranges are permitted.

Manufactured for
Fort Dodge Animal Health
Fort Dodge, Iowa 50501 USA
by PM Resources, Inc.
Bridgeton, MO 63044

TO OPEN CUT HERE

Aureomycin®
CHLORTETRACYCLINE
Soluble Powder
CONCENTRATE
Antibiotic



INDICATIONS AND DIRECTIONS FOR USE (cont'd)

CALVES	DOSE - 10 mg/lb body weight/day
Bacterial Pneumonia (<i>Pasteurella</i> spp., <i>Hemophilus</i> spp., <i>Klebsiella</i> spp.)	One standard measuring teaspoonful of powder contains 500 mg. Administer 4 such teaspoonfuls in solution to a 200-lb calf daily in divided doses
Bacterial Enteritis (<i>Escherichia coli</i> , <i>Salmonella</i> spp.)	Administer at this rate in the total water consumed over a full, 24-hour period, or as a drench in divided doses. Do not administer for more than 5 days.
CHICKENS	DOSE
Chronic Respiratory Disease (CRD) and Air-sac infection (<i>Mycoplasma gallisepticum</i> , <i>Escherichia coli</i>)	2-4 packets per 512 gallons (400-800 mg/gallon)
Infectious Synovitis (<i>Mycoplasma synoviae</i>)	1-2 packets per 512 gallons (200-400 mg/gallon)
For the control of mortality due to fowl cholera (<i>Pasteurella multocida</i>) in growing chickens.	5 packets per 512 gallons (1000 mg/gallon)

Administer at the indicated rates in the total water consumed over a full, 24-hour period.

Chlortetracycline hydrochloride - 102.4 g per packet (64 g/lb)

INDICATIONS AND DIRECTIONS FOR USE

For the control or treatment of the following diseases caused by organisms susceptible to chlortetracycline

SWINE	DOSE - 10 mg/lb body weight/day
Bacterial Enteritis (Scours) (<i>Escherichia coli</i> , <i>Salmonella</i> spp.)	5 packets per 512 gallons. (This will treat 51,200 lbs of pigs for 5 days; that is five hundred twelve 100-lb pigs; providing 10 mg/lb body weight.)
Bacterial Pneumonia (<i>Pasteurella</i> spp., <i>Hemophilus</i> spp., <i>Klebsiella</i> spp.)	Administer at this rate in the total water consumed over a full, 24-hour period; do not administer for more than 5 days.



Lot
Exp. Date

X

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For Veterinary Use in Drinking Water

Chlortetracycline hydrochloride 64 g per pound

This packet contains 102.4 g chlortetracycline HCl and will make:

1024 gallons containing 100 mg Aureomycin chlortetracycline HCl per gallon

512 gallons containing 200 mg Aureomycin chlortetracycline HCl per gallon

256 gallons containing 400 mg Aureomycin chlortetracycline HCl per gallon

102.4 gallons containing 1000 mg Aureomycin chlortetracycline HCl per gallon

Store at controlled room temperature

15° to 30°C (59° to 86°F).

Net Wt: 25.6 Oz (725.7 g)

NADA 65-440, Approved by FDA

WARNING

Use as the sole source of chlortetracycline. Not to be used for more than 14 consecutive days in chickens and turkeys, 5 days in calves, or 5 days in swine. Do not use in laying chickens. For growing turkeys only. Do not administer this product with milk or milk replacers. Administer one hour before or two hours after feeding milk or milk replacers. Do not administer to swine within 24 hours of slaughter. Do not administer to calves within 1 day of slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not administer to chickens at 1000 mg/gallon of water (one packet per 102.4 gallons) within 24 hours of slaughter.

GENERAL INFORMATION ON DOSAGE

Dosages in terms of packets per 512 gallons are based on stated dosages per unit of body weight and age water consumption of the species. Weather conditions, ambient temperature, humidity, age, class of livestock and other factors may affect consumption and, except where calves are drenched, the unit of dosage should be used as a guide to effective use in drinking water. Animal must actually consume enough water to provide the desired therapeutic dose under the conditions that prevail.

CAUTION

When used in plastic or stainless steel waterers or automatic waterers, prepare fresh solutions every 24 hours. When used in galvanized waterers, prepare fresh solutions every 12 hours. When feeding milk or milk replacers, administration one hour before or two hours after feed is recommended.

