

Date of Approval: JAN 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**

FREEDOM OF INFORMATION SUMMARY

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

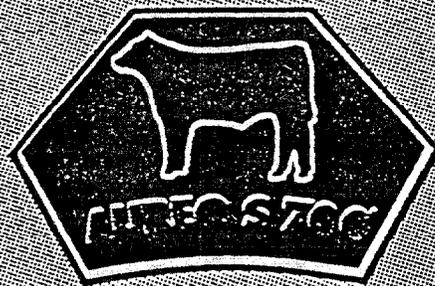
Pennchlor S 700™ Type A Medicated Article

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.

090011



AUREO S 700[®] GRANULAR

chlortetracycline, sulfamethazine

35G TYPE A MEDICATED ARTICLE

FOR USE IN THE MANUFACTURE OF CATTLE FEEDS

For INDICATIONS, MIXING DIRECTIONS and INGREDIENTS see back



Net Weight: 50 Lb. (22.7 kg)

® Registered trademark of Hoffmann-La Roche Inc.

AUREO S 700[®]
35G TYPE A MEDICATED ARTICLE



AUREO S 700[®] GRANULAR

chlortetracycline, sulfamethazine

35G TYPE A MEDICATED ARTICLE

FOR USE IN THE MANUFACTURE OF BEEF CATTLE FEEDS



AUREO S 700[®]
35G TYPE A MEDICATED ARTICLE

INDICATIONS:

AS AN AID IN THE MAINTENANCE OF WEIGHT GAINS IN THE PRESENCE OF RESPIRATORY DISEASE SUCH AS SHIPPING FEVER.

ACTIVE DRUG INGREDIENTS:

Chlortetracycline calcium complex equivalent to chlortetracycline HCl 35 g / Lb.
Sulfamethazine 7.7% (35 g / Lb.)

INGREDIENTS:

Calcium Sulfate and Dried *Streptomyces aureofaciens* Fermentation Product.

MIXING DIRECTIONS:

MIX SUFFICIENT AUREO S 700 IN THE FEED TO SUPPLY 350 MG OF AUREOMYCIN CHLORTETRACYCLINE AND 350 MG OF SULFAMETHAZINE PER HEAD PER DAY. THE FOLLOWING TABLE SHOWS THE AMOUNTS OF AUREO S 700 NEEDED FOR THE VARIOUS QUANTITIES OF SUPPLEMENT.

AUREO S 700 (G/LB. SUPPLEMENT)	SUPPLEMENT WILL CONTAIN (BY/TON)		FEED SUPPLEMENT @ (G./MILLIGRAM)
	CHLORTETRACYCLINE	SULFAMETHAZINE	
40	1400	1400	0.5
20	700	700	1
10	350	350	2
5	175	175	4
4	140	140	5
2	70	70	10
1	35	35	20

FEED FOR 28 DAYS.

WARNING:
WITHDRAW 7 DAYS PRIOR TO SLAUGHTER.

TAKE TIME OBSERVE LABEL DIRECTIONS



Manufactured for:
Roche Vitamins & Fine Chemicals
A Member of the Roche Group
Nutley, New Jersey 07110

Net Wt.: 50 Lb. (22.7 kg)
Product Code: 28927-0060
Batch No.: See bag seal
Expiration Date: See bag seal
NADA # 36-805, Approved by FDA

Made in U.S.A.

Please refer to attached overlay

*Re-certified to correct
a typo caught during
proofing.*

RE-
CERTIFIED COPY. DATE: 3/17/97
BAG CODE: 29946-0297 / PRODUCT CODE: 28927-0050
CIRCULATION DATE: 3/17/97
DATE: 3/17/97
Carol Mathews
Spencer C-3293, Republic C-3049

BAG CODE: 29946-0297
PRODUCT CODE: 28927-0050
Bag printed @ 35% of actual
size 15" x 4" x 32"

3/17/97

55-

Aureo® S-700 Premix - Label File Note:

Overlay label produced in accordance with our December 9, 1997 commitment letter, in response to CVM's letter dated June 20, 1997.

Alpharma Inc.

WARNING:

WITHDRAW 7 DAYS PRIOR TO 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.

TAKE TIME  OBSERVE LABEL DIRECTIONS



Manufactured for:

Roche Vitamins Inc.
Parsippany, New Jersey 07054

Net Wt.: 50 Lb. (22.7 kg)
Product Code: 04 84326 B12
Batch No.: See bag seal
Expiration Date: See bag seal
NADA # 35-805, Approved by FDA

079

Made in U.S.A.

CERTIFIED COPY. DATE: 7/9/99

CODE: 04 84326 B12 111

CIRCULATION DATE: 8/12/97 as bag removal

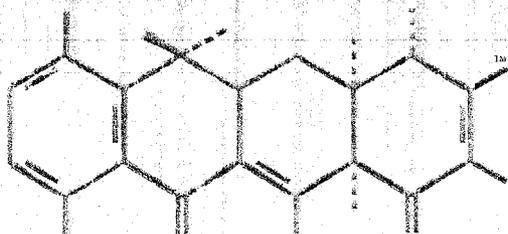
Carol R. Garcia DATE: 7/9/99

Photocopy label - No Spec. for use with bag 29946-0297.

Pennchlor S 700™

chlortetracycline, sulfamethazine

Type A Medicated Article



FOR USE IN THE MANUFACTURE OF CATTLE FEEDS

See ingredients, indications and mixing directions on back

ANADA 200-314 APPROVED BY FDA

Restricted Drug: (California) -
Use only as directed

NET WT.
50 lb (22.7 kg)

PennField®
ANIMAL HEALTH

Pennchlor S 700™

chlortetracycline, sulfamethazine
Type A Medicated Article

FOR USE IN THE MANUFACTURE OF BEEF CATTLE FEEDS

INDICATIONS:

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

ACTIVE DRUG INGREDIENTS:

Chlortetracycline calcium complex equivalent to Chlortetracycline HCl 35 g/lb
Sulfamethazine 7.7% (36 g/lb)

INGREDIENTS:

Calcium Sulfate, Dried *Streptomyces aureofaciens* Fermentation Product, Mineral Oil

MIXING DIRECTIONS:

Mix sufficient Pennchlor S 700™ in the feed to supply 350 mg of Chlortetracycline and 350 mg of Sulfamethazine per head per day. The following table shows the amounts of Pennchlor S 700™ needed for the various quantities of supplement.

Pennchlor S 700™ (Lb/Ton Supplement)	Supplement Will Contain (g/Ton)		Feed Supplement at (Lb/Head/Day)
	Chlortetracycline	Sulfamethazine	
40	1400	1400	0.5
20	700	700	1
10	350	350	2
5	175	175	4
4	140	140	5
2	70	70	10
1	35	35	20

FEED FOR 28 DAYS.

WARNING: WITHDRAW 7 DAYS PRIOR TO 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.

Text by  CIBA PHARMASIA

REV. 06/02
Bag R1

Distributed by

PennField 
ANIMAL HEALTH

14040 Industrial Rd.
Omaha, Nebraska 68144