



# PENNFIELD *Oil Company*

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Lonnie W. Luther, Ph.D. P.A.S.  
Staff Chief  
Generic Animal Drug Team (HFV-104)  
Building MPN IV, Room 106  
Office of New Animal Drug Evaluation  
Center for Veterinary Medicine  
Food and Drug Administration  
Metro Park North 2  
7519 Standish Place  
Rockville, MD 20888

JAN 08 2004

12/29/03  
10:58 AM '04

Re: SUITABILITY PETITION - FILING OF AN ANADA FOR THE PIONEER PRODUCT NADA 35-805 AUREO S 700<sup>®</sup> TYPE A MEDICATED ARTICLE (CHLORTETRACYCLINE, SULFAMETHAZINE).

Dear Dr. Luther:

With reference to the provisions of Federal Food, Drug and Cosmetic Act, As Amended under Section 512(b)(2), Section 512(n)(3), and with reference to the Center of Veterinary Medicine's second policy letter (dated June 7, 1989) on the implementation of the Generic Animal Drug and Patent Term Restoration Act (GADPTR), I am hereby enclosing a suitability petition for the filing of ANADA to the pioneer product NADA 35-805 as stated above.

PennField Oil Company requests consideration of this suitability petition to file an ANADA that differs from the pioneer product (NADA 38-805) by changing the strength of each active ingredient (chlortetracycline and sulfamethazine) from 35 grams per pound to 70 grams per pound in the Type A Medicated Article. The proposed generic product is intended to deliver the same amount of active ingredients per pound of body weight. Because the change in concentration of each active ingredient will not change the dosage level from the pioneer product, no new target animal safety or efficiency studies are required. PennField has

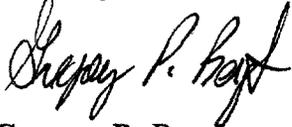
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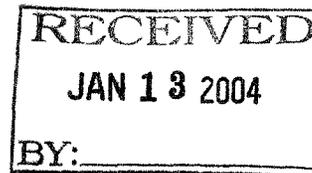
previously been granted a waiver of *in vivo* bioequivalence testing for the approval of our ANADA 200-314 which is a generic copy of Alparma Inc.'s NADA 35-805.

Please feel free to contact me at 800-832-8303 if you have any questions.

Sincerely,



Gregory P. Bergt  
Director, Research and Development



GBP:klf  
Enclosure

## SUITABILITY PETITION

### IDENTIFICATION OF PETITIONER:

This Suitability petition is submitted on behalf of PennField<sup>®</sup> Oil Company, under Section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act.

### ACTION REQUESTED:

The petitioner requests permission from the Commissioner to file an Abbreviated New Animal Drug Application (ANADA) for a change in the strength of each active ingredient from the approved pioneer product. The pioneer product is Alpharma Inc.'s Aureo S 700<sup>®</sup> (chlortetracycline and sulfamethazine) Type A Medicated Article, approved by the Food and Drug Administration under NADA 35-805. The combination of chlortetracycline and sulfamethazine is approved as an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever in beef cattle. A copy of the pioneer product labeling is included (Attachment 1).

The ANADA will provide for the concentration of both active ingredients (chlortetracycline and sulfamethazine) to be increased to 70 g/lb compared to the approved pioneer product of 35 g/lb for both active ingredients.

The product labeling will provide for indications, recommended dosages, contraindications, precautions and warnings identical to the pioneer product. Draft labeling for the proposed product is provided in Attachment 2.

The proposed product label will differ from the pioneer product specifically as follows:

1. The concentration of both active ingredients (chlortetracycline and sulfamethazine) will be increased to 70 g/lb rather than 35 g/lb for both active ingredients in the approved pioneer product.

### STATEMENT OF GROUNDS:

The proposed product contains the same active ingredient and will be labeled with the same indication, recommended dose rates, contraindications, precautions and warnings as the approved pioneer product. Because the change in concentration of each active ingredient will not change the dosage level from the pioneer product, no new target animal safety or efficacy studies are required.

**ENVIRONMENTAL IMPACT:**

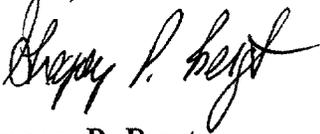
The action of submitting this Suitability Petition and its review by the FDA – Center for Veterinary Medicine is not expected to have an environmental impact. The action requested qualifies for categorical exclusion under 21 CFR Part 25.33(a)(I) from the requirement for an environmental assessment.

**ECONOMIC IMPACT:**

An “Economic Impact” analysis of this action will be provided if requested by the Commissioner.

**CERTIFICATION:**

PennField® Oil Company certifies that this Suitability Petition contains all information known to them, which is unfavorable to the petition.



Gregory P. Bergt  
Director, Research and Development

GPB:klf

Enclosures: Attachment 1 – Pioneer Product Label  
Attachment 2 – Proposed Product Label

**ATTACHMENT 1**

**Labeling for Alpharma Inc.'s Aureo S 700®**

 ALPHARMA

# Aureo S 700<sup>®</sup>

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## Granular

Aureo S 700<sup>®</sup>  
Granular



Chlortetracycline,  
sulfamethazine  
35 G Type A Medicated Article

For indications, mixing directions  
and ingredients see back

Net wt 50 LB (22.68 kg)

 ALPHARMA<sup>®</sup>

Aureo S 700<sup>®</sup>  
Granular

ALPHARMA<sup>®</sup>

# Aureo S 700<sup>®</sup>

## Granular

### Chlortetracycline, sulfamethazine 35 G Type A Medicated Article

**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.

**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. Feed for 28 days.

**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 (lb/ton of 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

#### 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.

NADA #35-805, Approved by FDA

Marketed by  
 **ALPHARMA.**

AlphaPharma Inc.  
One Executive Drive  
Fort Lee, New Jersey 07024

Take Time



**Observe Label Directions**

Aureo S 700 is a registered trademark of AlphaPharma Inc.

**Net wt 50 LB (22.68 kg)**

**Made in USA**

**700338 0211**

**ATTACHMENT 2**

**Labeling for PennField®'s ANADA**

# TRADENAME™

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 70 g/lb  
Sulfamethazine 15.4% (70 g/lb)

### INGREDIENTS:

Calcium Sulfate, Dried Streptomyces aureofaciens Fermentation Product, Mineral Oil

### MIXING DIRECTIONS:

Mix sufficient Tradename™ 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 Tradename™ needed for the various quantities of supplement.

Tradename™ (Lb/Ton Supplement)	Supplement Will Contain (g/ton)		Feed Supplement at (Lb/Head/Day)
	Chlortetracycline	Sulfamethazine	
20	1400	1400	0.5
10	700	700	1
5	350	350	2
2.5	175	175	4
2	140	140	5
1	70	70	10
5	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.

TAKE TIME  OBSERVE DIRECTIONS

REV.  
Bag

*Distributed by*

**Pennfield**   
ANIMAL HEALTH®

14040 Industrial Rd.  
Omaha, Nebraska 68144

# TRADENAME™

chlortetracycline, sulfamethazine  
**Type A Medicated Article**

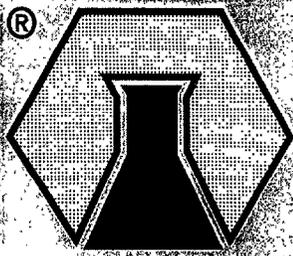
**FOR USE IN THE MANUFACTURE OF CATTLE FEEDS**

*See ingredients, indications and mixing directions on back*

ANADA APPROVED BY FDA

Restricted Drug: (California)–  
Use only as directed

**NET WT.  
50 lb (22.7 kg)**

**PennField®**   
**ANIMAL HEALTH®**