

Date of Approval Letter:

## **FREEDOM OF INFORMATION SUMMARY**

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

**NADA 48-761**

Aureomycin<sup>®</sup> 50 Granular, Aureomycin<sup>®</sup> 90 Granular, and  
Aureomycin<sup>®</sup> 100 Granular (chlortetracycline)  
Type A Medicated Articles

"control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline"

Sponsored by:  
Alpharma Inc.

## I. GENERAL INFORMATION

NADA Number: 48-761

Sponsor: Alpharma Inc.  
One Executive Drive  
Fort Lee, New Jersey 07024

Established Name: chlortetracycline

Proprietary Names: Aureomycin<sup>®</sup> 50 Granular, Aureomycin<sup>®</sup> 90 Granular, and Aureomycin<sup>®</sup> 100 Granular (chlortetracycline) Type A Medicated Articles

Marketing Status: Over-the-counter (OTC)

Effect of Supplement: This supplemental application adds the claim for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.

## II. INDICATIONS FOR USE

Swine: Control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline. ✓

Treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* organisms susceptible to chlortetracycline.

Increased rate of weight gain and improved feed efficiency.

Reduction in the incidence of cervical lymphadenitis (jowl abscess) caused by Group E *Streptococci* susceptible to chlortetracycline.

Breeding Swine: Control of leptospirosis (reducing the incidence of abortion and shedding of *leptospirae*) caused by *Leptospira pomona*.

## III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE

A. Dosage Form: Type A Medicated Article

B. Route of Administration: Oral, in feed

C. Recommended Dosage: In Type C medicated feed, chlortetracycline to deliver a daily dose of 10 mg/lb body weight (approximately 400 grams per ton) for not more than 14 days.

#### **IV. EFFECTIVENESS**

The claim for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline in swine treated with 10 mg chlortetracycline per lb body weight for up to 14 days in feed was approved on July 7, 2000, for Alpharma's ChlorMax™ (65 FR 42881, July 26, 2000).

ChlorMax™ (chlortetracycline, NADA 46-699) and Aureomycin® NADA 48-761 were both found to comply with the results of NAS/NRC and DESI evaluation for effectiveness as published in the Federal Register (61 FR 35949-35958, July 9, 1996). These products approved under the DESI process were found to be equivalent at the codified levels for swine and other species.

Aureomycin® and ChlorMax™ were shown equivalent under DESI evaluation. Alpharma Inc. owns both products. As such, Alpharma Inc. may reference data found in NADA 46-699. Aureomycin® and ChlorMax™ now have identical indications. For the purposes of this supplement, no new studies were conducted to establish effectiveness associated with the use of chlortetracycline in swine.

#### **V. ANIMAL SAFETY**

The target animal information is contained in the FOI Summary for the original approval of NADA 48-761. No new data were generated for this supplement because the dosage of CTC for this indication remains within the approved dose range for swine.

#### **VI. HUMAN SAFETY**

The current tolerance established for the sum of residues of the tetracyclines, including chlortetracycline, in tissues of swine is 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney, as described in 21 CFR 556.150. Chlortetracycline has a zero-day pre-slaughter withdrawal period in swine, as described in 21 CFR 558.128.

## **VII. AGENCY CONCLUSIONS**

The information submitted in support of this NADA and in the referenced files satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The information demonstrates that Aureomycin<sup>®</sup> Type A Medicated Article when administered in swine feed is safe and effective when used as described in Section II and III .

The Agency has concluded that this product shall retain over-the-counter marketing status because adequate directions for use have been written for the layman and the conditions for use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2)(v), this is a Category II change which did not require a reevaluation of the safety or effectiveness data in the parent application.

The Agency has carefully considered the potential environmental effects of this action and has concluded that the action is categorically excluded under 21 CFR 25.33(a)(1) from the requirement to prepare an environmental assessment (EA).

Under Section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualify for marketing exclusivity because the application contains no new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant.

There are currently no U.S. patents Aureomycin<sup>®</sup> Type A Medicated Article.

## **VII. APPROVED PRODUCT LABELING**

Copies of facsimile Type A Medicated Article labeling and specimen (Blue Bird) Type B and Type C medicated feed labels are attached to this document.

- A. Aureomycin<sup>®</sup> 50 Granular
- B. Aureomycin<sup>®</sup> 90 Granular
- C. Aureomycin<sup>®</sup> 100 Granular
- D. Blue Bird CTC 40 Type B Swine Feed Medicated
- E. Blue Bird CTC Type C Swine Feed Medicated

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

Freedom of Information Staff (HFI-35)  
Food and Drug Administration, Room 12A16  
5600 Fishers Lane  
Rockville, Maryland 20857

Lot No. \_\_\_\_\_

**BLUE BIRD CTC  
TYPE C SWINE FEED  
MEDICATED**

For treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline, and for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.

**ACTIVE DRUG INGREDIENTS\***

Chlortetracycline (as hydrochloride) ..... \_\_\_\_\_ g/ton\*\*

**GUARANTEED ANALYSIS**

Crude Protein, not less than.....	_____ %
Lysine, not less than.....	_____ %
Crude Fat, not less than.....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than.....	_____ %
Calcium, not more than.....	_____ %
Phosphorus, not less than.....	_____ %
Salt <sup>1</sup> , not less than.....	_____ %
Salt <sup>1</sup> , not more than.....	_____ %
Total Sodium <sup>2</sup> , not less than.....	_____ %
Total Sodium <sup>2</sup> , not more than.....	_____ %
Selenium, not less than.....	_____ ppm
Zinc, not less than.....	_____ ppm

<sup>1</sup>If added

<sup>2</sup>Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee

**INGREDIENTS**

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

**FEEDING DIRECTIONS**

Feed for not more than 14 days.

**NET WEIGHT ON BAG OR BULK**

Blue Bird Feed Mill  
Robin, IN 12345

\*Final printed label on formulated Type C medicated feed must bear single concentration.

\*\*Approximately 400 g/t; Concentration (grams per ton) must be such that feed delivers 10 mg/lb body weight daily, based on body weight and feed consumption of animals.

Lot No. \_\_\_\_\_

**BLUE BIRD CTC40  
TYPE B SWINE FEED  
MEDICATED**

For treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.

**ACTIVE DRUG INGREDIENTS**

Chlortetracycline (as hydrochloride).....40 g/lb

**GUARANTEED ANALYSIS**

Crude Protein, not less than .....	_____ %
Lysine, not less than .....	_____ %
Crude Fat, not less than .....	_____ %
Crude Fiber, not more than .....	_____ %
Calcium, not less than .....	_____ %
Calcium, not more than .....	_____ %
Phosphorus, not less than .....	_____ %
Salt <sup>1</sup> , not less than .....	_____ %
Salt <sup>1</sup> , not more than .....	_____ %
Total Sodium <sup>2</sup> , not less than .....	_____ %
Total Sodium <sup>2</sup> , not more than .....	_____ %
Selenium, not less than .....	_____ ppm
Zinc, not less than .....	_____ ppm

<sup>1</sup>added

<sup>2</sup>shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee

**INGREDIENTS**

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

**MIXING DIRECTIONS**

Mix 10 pounds of this Type B medicated feed with non-medicated feed ingredients to manufacture one ton of complete (Type C) medicated swine feed containing 400 grams<sup>3</sup> of chlortetracycline. This Type C medicated feed should be fed to swine for not more than 14 days.

**NET WEIGHT ON BAG OR BULK**

Blue Bird Feed Mill  
Robin, IN 12345

<sup>3</sup> equivalent to 10 mg/lb body weight daily

Lot No. \_\_\_\_\_

**BLUE BIRD CTC40  
TYPE B SWINE FEED  
MEDICATED**

For treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline and for control of porcine proliferative enteropathies (Ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline.

**ACTIVE DRUG INGREDIENTS**

Chlortetracycline (as hydrochloride).....40 g/lb

**GUARANTEED ANALYSIS**

Crude Protein, not less than .....	_____ %
Lysine, not less than .....	_____ %
Crude Fat, not less than .....	_____ %
Crude Fiber, not more than.....	_____ %
Calcium, not less than .....	_____ %
Calcium, not more than .....	_____ %
Phosphorus, not less than .....	_____ %
Salt <sup>1</sup> , not less than .....	_____ %
Salt <sup>1</sup> , not more than .....	_____ %
Total Sodium <sup>2</sup> , not less than .....	_____ %
Total Sodium <sup>2</sup> , not more than .....	_____ %
Selenium, not less than .....	_____ ppm
Zinc, not less than .....	_____ ppm

<sup>1</sup>If added

<sup>2</sup>Shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee

**INGREDIENTS**

Each ingredient must be named in accordance with the names and definitions adopted by the Association of American Feed Control Officials.

**MIXING DIRECTIONS**

Mix 10 pounds of this Type B medicated feed with non-medicated feed ingredients to manufacture one ton of complete (Type C) medicated swine feed containing 400 grams<sup>3</sup> of chlortetracycline. This Type C medicated feed should be fed to swine for not more than 14 days.

**NET WEIGHT ON BAG OR BULK**

Blue Bird Feed Mill  
Robin, IN 12345

<sup>3</sup> equivalent to 10 mg/lb body weight daily



# Alphacort

## 50 Granular Chlortetracycline Type A Medicated Article

<b>Indications</b>	For the treatment of bacterial infections caused by susceptible organisms in poultry.		
<b>Directions</b>	See package insert for complete directions.		
<b>Warnings</b>	Do not use in laying birds. Do not use in broilers for meat production.		
<b>Caution</b>	Use with caution in birds with known or suspected liver disease.		
<b>Adverse Reactions</b>	None reported.		
<b>How Supplied</b>	50 Granular, 100 Granular, 200 Granular.		
<b>Storage</b>	Store in a cool, dry place.		
<b>Patent</b>	Patented in the U.S. and other countries.		
<b>Manufactured by</b>	Alphacort, Inc., New York, N.Y.		

**Warning**

Do not use in laying birds. Do not use in broilers for meat production.

**Caution**

Use with caution in birds with known or suspected liver disease.

**Directions**

See package insert for complete directions.



**ALPHACORT**  
Chlortetracycline

**Observe Label Directions**

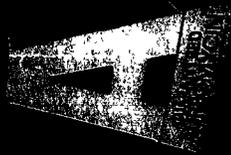
Net Weight: 13 (22.68 kg)



# Aureomycin<sup>®</sup>

## 90 Granular

**Aureomycin**  
90 Granular



Chlortetracycline  
Type A Medicated Article  
Net wt 50 LB (22.68 kg)



Aureomycin<sup>®</sup>  
90 Granular

**Aureomycin**  
90 Granular  
Chlortetracycline  
Type A Medicated Article

Active Drug Ingredient	
See description on separate sheet for each active ingredient.	
<b>Supplements</b>	
See use in the description of medicated animal feeds.	
<b>For Use in</b>	
See description of medicated animal feeds.	
<b>Use Directions</b>	
See description of medicated animal feeds.	
<b>Warnings</b>	
See description of medicated animal feeds.	
<b>Directions</b>	
See description of medicated animal feeds.	
<b>Caution</b>	
See description of medicated animal feeds.	
<b>Contraindications</b>	
See description of medicated animal feeds.	
<b>Adverse Reactions</b>	
See description of medicated animal feeds.	
<b>How Supplied</b>	
See description of medicated animal feeds.	
<b>Storage</b>	
See description of medicated animal feeds.	
<b>Other Information</b>	
See description of medicated animal feeds.	
<b>Patent Information</b>	
See description of medicated animal feeds.	
<b>Manufacturing Information</b>	
See description of medicated animal feeds.	
<b>Other</b>	
See description of medicated animal feeds.	

ALPHARMA  
10000  
Net wt 50 LB (22.68 kg)  
20010510





Amphillyn

100 Granular

# Chlortetracycline Type A Medicated Article

Item No.	Description	Quantity	Unit
1	Amphillyn 100 Granular	1	Box
2	Chlortetracycline Type A Medicated Article	1	Box
3	Amphillyn 100 Granular	1	Box
4	Chlortetracycline Type A Medicated Article	1	Box
5	Amphillyn 100 Granular	1	Box
6	Chlortetracycline Type A Medicated Article	1	Box
7	Amphillyn 100 Granular	1	Box
8	Chlortetracycline Type A Medicated Article	1	Box
9	Amphillyn 100 Granular	1	Box
10	Chlortetracycline Type A Medicated Article	1	Box
11	Amphillyn 100 Granular	1	Box
12	Chlortetracycline Type A Medicated Article	1	Box
13	Amphillyn 100 Granular	1	Box
14	Chlortetracycline Type A Medicated Article	1	Box
15	Amphillyn 100 Granular	1	Box
16	Chlortetracycline Type A Medicated Article	1	Box
17	Amphillyn 100 Granular	1	Box
18	Chlortetracycline Type A Medicated Article	1	Box
19	Amphillyn 100 Granular	1	Box
20	Chlortetracycline Type A Medicated Article	1	Box
21	Amphillyn 100 Granular	1	Box
22	Chlortetracycline Type A Medicated Article	1	Box
23	Amphillyn 100 Granular	1	Box
24	Chlortetracycline Type A Medicated Article	1	Box
25	Amphillyn 100 Granular	1	Box
26	Chlortetracycline Type A Medicated Article	1	Box
27	Amphillyn 100 Granular	1	Box
28	Chlortetracycline Type A Medicated Article	1	Box
29	Amphillyn 100 Granular	1	Box
30	Chlortetracycline Type A Medicated Article	1	Box
31	Amphillyn 100 Granular	1	Box
32	Chlortetracycline Type A Medicated Article	1	Box
33	Amphillyn 100 Granular	1	Box
34	Chlortetracycline Type A Medicated Article	1	Box
35	Amphillyn 100 Granular	1	Box
36	Chlortetracycline Type A Medicated Article	1	Box
37	Amphillyn 100 Granular	1	Box
38	Chlortetracycline Type A Medicated Article	1	Box
39	Amphillyn 100 Granular	1	Box
40	Chlortetracycline Type A Medicated Article	1	Box
41	Amphillyn 100 Granular	1	Box
42	Chlortetracycline Type A Medicated Article	1	Box
43	Amphillyn 100 Granular	1	Box
44	Chlortetracycline Type A Medicated Article	1	Box
45	Amphillyn 100 Granular	1	Box
46	Chlortetracycline Type A Medicated Article	1	Box
47	Amphillyn 100 Granular	1	Box
48	Chlortetracycline Type A Medicated Article	1	Box
49	Amphillyn 100 Granular	1	Box
50	Chlortetracycline Type A Medicated Article	1	Box

Amphillyn 100 Granular  
Chlortetracycline Type A Medicated Article