

HFA-305

MAR 4 1999

FREEDOM OF INFORMATION (FOI) SUMMARY

Sulfadimethoxine Soluble Powder

ANADA 200-258

Phoenix Scientific, Inc.

3915 South 48th Street Terrace

P.O. Box 6457

St. Joseph, MO 64506-0457

Date of Approval _____

ANADA 200-258

FOIS-1

FREEDOM OF INFORMATION SUMMARY

1. General Information:

ANADA Number: 200-258

Sponsor Name and Address:

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
P.O. Box 6457
St. Joseph, MO 64506-0457

Generic Name: Sulfadimethoxine Soluble Powder

Trade Name: Sulfadimethoxine Soluble Powder

Marketing Status: OTC

Indications for Use:

For Broiler and Replacement Chickens Only – Use for the treatment of disease outbreaks of **coccidiosis**, fowl cholera and infectious **coryza**.

For Meat Producing Turkeys Only – Use for the treatment of disease outbreaks of **coccidiosis** and fowl cholera.

For Dairy Calves, Dairy Heifers and Beef Cattle – Use for the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella spp.* sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.

Dosage Form(s), Route(s) of Administration and Recommended Dosages and Contraindications:

Dosage Form:

The product is available in the form of a soluble powder for oral administration.

Route(s) of Administration and Recommended Dosages:

The route of administration is as an oral solution administered to chickens at a concentration of 0.05% solution (Contents of packet diluted to 50 gallons of water) and to turkeys at a concentration of 0.025 % (contents of the packet diluted to 100 gallons of water). The treatment period is for 6 consecutive days. For Dairy Calves, Dairy Heifers and Beef Cattle the dosage is 25 mg/lb for the first day followed by 12.5 mg/lb/day for 4 days.

Contraindications: There are no known contraindications when used as directed.

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) maybe 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 approval is based on a demonstration that the generic product is bioequivalent to the pioneer product.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter: 55 FR 24645, June 18, 1990; Bioequivalence Guidance: 61 FR 26182-26186, May 24, 1996).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for Sulfadimethoxine Soluble Powder. The generic and pioneer products contain the same active and inactive ingredients and are oral solutions.

3. **HUMAN FOOD SAFETY**

Tolerance

The tolerances established for the pioneer product apply to the generic product. Tolerances are established for residues of sulfadimethoxine in uncooked edible tissues of chickens, turkeys, and cattle as follows: 0.1 part per million (negligible residue). In milk at 0.01 part per million (negligible residue)(21 CFR 556.640).

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 sulfadimethoxine soluble powder is established under:

| | |
|---------------------------------|---|
| 21 CFR 520.2220a (e) (1) (iii) | Broiler and Replacement Chickens- 5 days before slaughter. |
| 21 CFR 520.2220a (e) (2) (iii) | Meat-Producing Turkeys- 5 days before slaughter |
| 21 CFR 520. 2220a (e) (3) (iii) | Dairy Calves, Dairy Heifers and Beef Cattle- 7 days before slaughter. |

Regulatory Methods for Residues:

Sulfadimethoxine:

The regulatory analytical method for detection of residues of the drug is a thin layer densitometric procedure. This method is found in the Official Methods of Analysis of AOAC International, 16th edition.

Human Safety Relative to Possession, Handling and Administration:

Labeling contains adequate **caution/warning** statements.

4. AGENCY CONCLUSION:

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, Sulfadimethoxine Soluble Powder, were established by demonstration of chemical equivalence to the pioneer product, Pfizer's **Albon®** (NADA 046-285)

This generic product and the pioneer product have identical labeling indications for the gallon bottle for use in chickens, turkeys and cattle. The route and method of administration of the two drugs are identical. Both drugs are administered orally in the drinking water. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy

implementing section 512(b)(2) of FFD&C Act, *in vivo* bioequivalency studies were neither necessary nor required.

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

Attachment: Generic and pioneer labeling

| | |
|---------------------------|-------------|
| Generic – 3.77 oz packet: | Front panel |
| | Back panel |

| | |
|---------------------------|-------------|
| Pioneer – 3.77 oz packet: | Front panel |
| | Back panel |

NDC 59130-706-28

SULFADIMETHOXINE SOLUBLE POWDER ANTIBACTERIAL

Each packet contains 94.6 g (3.34 oz) sulfadimethoxine as sodium sulfadimethoxine.

Restricted Drug (California)-Use Only as Directed
Not for Human Use

For Broiler and Replacement Chickens Only- Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

For Meat-producing Turkeys Only-Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers, and Beef Cattle-Use for the treatment of shipping fever complex and bacterial pneumonia associated with Pasteurella spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with Sphaerophorus necrophorus sensitive to sulfadimethoxine.

Dosage and Administration

| Species | Concentration | Use Directions |
|----------|---------------|--|
| Chickens | 0.05% | Contents of packet to 50 gal of water |
| Turkeys | 0.025% | Contents of packet to 100 gal of water |

Automatic Proportioners-To make stock solution, add contents of 5 packets to 2 gal of water for chickens and to 4 gal of water for turkeys. Set proportioner to feed at rate of 1 fl oz stock solution per gal of water. Treatment Period: 6 consecutive days.

Dairy Calves, Dairy Heifers, and Beef Cattle
Dose: 25 mg/lb first day followed by 12.5 mg/lb/day for 4 days

Sulfadimethoxine in Water

| Amount of Stock Solution for Cattle* | Water Consumption | |
|--------------------------------------|------------------------------------|-----------------------------------|
| | [Summer] 1 gal/100 lb body wt** | Winter) 1 gal/150 lb body wt** |
| First Day Add | 1 qt | 10 gal |
| | 2 qt | 20 gal |
| | 1 gal | 40 gal |
| Next 4 Days Add | 1 qt | 20 gal |
| | 2 qt | 40 gal |
| | 1 gal | 80 gal |

*Note: Make a cattle stock solution by adding 1 packet of Sulfadimethoxine Soluble Powder to 1 gal of water. Twenty fl oz of cattle stock solution will medicate 1 600-lb animal initially or 2 600-lb animals on maintenance dose. Contents of packet will medicate 6 100-lb animals initially or 12 600-lb animals on maintenance dose.

**This dosage recommendation is based on a water consumption of 1 gal per 100 lb of body weight per day, the expected water consumption rate for summer. Water consumption during cold months (winter) may drop markedly (30-40%). Accordingly, adjustments must be made in the dilution rates to compensate for this and insure proper drug intake.

For treatment of individual cattle, Sulfadimethoxine Soluble Powder stock solution for cattle may be given as a drench. Administer using same mg/lb dosage as outlined above.

Treatment Period: 5 consecutive days

Caution: Chickens and Turkeys-If animals show no improvement within 5 days, discontinue treatment and reevaluate diagnosis. Prepare a fresh stock solution daily. Handle the recommended dilutions (chickens 0.05% and turkeys 0.025%) as regular drinking water. Administer as sole source of drinking water and sulfonamide medication.

Chickens and turkeys that have survived fowl cholera outbreaks should not be kept for replacements or breeders. Cattle- During treatment period, make certain that animals maintain adequate water intake. If animals show no improvement within 2 or 3 days, reevaluate diagnosis. Treatment should not be continued beyond 5 days.

Warning: Chickens and Turkeys-Withdraw 5 days before slaughter. Do not administer to chickens over 16 weeks (112 days) of age or to turkeys over 24 weeks (168 days) of age. Cattle-Withdraw 7 days before slaughter. For dairy calves, dairy heifers, and beef cattle rely. A withdrawal period has not been established for this product in pre-ruminating calves. Do Not Use in Calves to be Processed for Veal.

800508

Lot No.:

Exp. Date:

TAKE TIME



OBSERVE LABEL DIRECTIONS

Iss. 8-98
Manufactured By:
Phoenix Scientific, Inc.
St. Joseph, MO 64503

NET WEIGHT: 25 x 107 g (3.77 OZ)

ANADA 200-258, Approved By FDA

AmTech®

Group, Inc.

CUSTOMER PROOF • CHECK CAREFULLY!

Customer: Phoenix Scientific
CYREI #: 24260 (sh) Date: 2/17/98
P.O. #: Lisa
8/4/98 8/13/98

UNWIND #:

LABEL: AmTech Sulfadimethoxine 25 x 107 grams

SIZE: 5.5 x 9 inches

PATTERN VARNISH: none

COLORS: 1797red black

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks. Every effort has been taken to insure the accuracy and conformance to applicable regulations on this proof. However, please check carefully as the final liability rests with the customer.

Approved by: _____ Date approved: _____

Dec 8/15/98
Oct 8/19/98
Aug 15 98
2 8/15/98

CUSTOMER PROOF • CHECK CAREFULLY!

Fax Proofs are intended for proofing of content and placement only, not for exact size or color breaks.

Customer: 23663 (sh) Phoenix Scientific
P.O. #: proof
Date: 8/13/98
Sent:

Approved by:

Date approved:

| Dosage and Administration | | |
|--|---------------|--|
| Species | Concentration | Use Directions |
| Chickens | 0.05% | Contents of packet to 50 gal of water |
| Turkeys | 0.025% | Contents of packet to 100 gal of water |
| Automatic Proportioners-To make stock solution, add contents of 5 packets to 2 gal of water for chickens and to 4 gal of water for turkeys. Set proportioner to feed at rate of 1 fl oz stock solution per gal of water. | | |
| Treatment Period: 6 consecutive days. | | |
| 2 qt | 40 gal | 28 gal |
| 1 gal | 80 gal | 56 gal |

*Note: Make a cattle stock solution by adding 1 packet of Sulfadimethoxine Soluble Powder to 1 gal of water.

*Twenty fl oz of cattle stock solution will medicate 1 600-lb animal initially or 2 600-lb animals on maintenance dose. Contents of packet will medicate 6 600-lb animals initially or 12 600-lb animals on maintenance dose.

**This dosage recommendation is based on a water consumption of 1 gal per 100 lb of body weight per day, the expected water consumption rate for summer. Water consumption during cold months (winter) may drop markedly (30-40%). Accordingly, adjustments must be made in the dilution rates to compensate for this and insure proper drug intake.

For treatment of individual cattle, Sulfadimethoxine Soluble Powder stock solution for cattle may be given as a drench. Administer using same mg/lb dosage as outlined above.

Treatment Period: 5 consecutive days

Caution: Chickens and Turkeys-If animals show no improvement within 5 days, discontinue treatment and reevaluate diagnosis. Prepare a fresh stock solution daily. Handle the recommended dilutions (chickens 0.05% and turkeys 0.025%) as regular drinking water. Administer as sole source of drinking water and sulfonamide medication. Chickens and turkeys that have survived fowl cholera outbreaks should not be kept for replacements or breeders. **Cattle**-During treatment period, make certain that animals maintain adequate water intake. If animals show no improvement within 2 or 3 days, reevaluate diagnosis. Treatment should not be continued beyond 5 days.

Warning: Chickens and Turkeys-Withdraw 5 days before slaughter. Do not administer to chickens over 16 weeks (112 days) of age or to turkeys over 24 weeks (168 days) of age. **Cattle**-Withdraw 7 days before slaughter. For dairy calves, dairy heifers, and beef cattle only. A withdrawal period has not been established for this product in pre-ruminating calves. **Do Not Use in Calves to be Processed for Veal.**

300508

Iss. 8-98



Manufactured By:
Phoenix Scientific, Inc.
St. Joseph, MO 64502

Dec 8/18/98
CW 8/18/98
RYS-16 88
7/8/98

NDC 59130-706-28

SULFADIMETHOXINE SOLUBLE POWDER

ANTIBACTERIAL

Each packet contains 94.6 g (3.34 oz) sulfadimethoxine as sodium sulfadimethoxine.

**Restricted Drug (California)-Use Only as Directed
Not for Human Use**

For Broiler and Replacement Chickens Only- Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

For Meat-producing Turkeys Only-Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers, and Beef Cattle-Use for the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.

NET WEIGHT: 107 g (3.77 oz)

ANADA 200-258, Approved By FDA

AmTech®
Group, Inc.

Note
Pfizer
cont. units to
use this
label

ALBON[®]

(Brand of Sulfadimethoxine)

ANTIBACTERIAL SOLUBLE POWDER

Each packet contains 3.34 oz (94.6 g) sulfadimethoxine in the form of the soluble sodium salt and disodium edetate.

Restricted Drug (California)—Use Only as Directed

Not for Human Use

For Broiler and Replacement Chickens Only—Use for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

For Meat-producing Turkeys Only—Use for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers, and Beef Cattle—Use for the treatment of shipping fever complex and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; and calf diphtheria and foot rot associated with *Sphaerophorus necrophorus* sensitive to sulfadimethoxine.



Net wt 3.77 oz (107 g)

NADA #046-285, Approved by FDA

SK SmithKline Beecham

Dosage and Administration

| Species | Concentration | Use Directions |
|----------|---------------|--|
| Chickens | 0.05% | Contents of packet to 50 gal of water |
| Turkeys | 0.025% | Contents of packet to 100 gal of water |

Automatic Proportioners—To make stock solution, add contents of 5 packets to 2 gal of water for chickens and to 4 gal of water for turkeys. Set proportioner to feed at rate of 1 fl oz stock solution per gal of water.
Treatment Period: 6 consecutive days

Dairy Calves, Dairy Heifers, and Beef Cattle
Dosage: 25 mg/lb first day followed by 12.5 mg/lb/day for 4 days

| | 'mount of Stock Solution for Cattle | Albon (sulfadimethoxine) In Water | |
|-----------------|-------------------------------------|-----------------------------------|---------------------------------|
| | | (Summed 1 gal/100 lb body wt**) | (Winter) 1 gal/150 lb body wt** |
| First Day Add | 1 qt 2 qt 1 gal | 10 gal 20 gal 40 gal | 7 gal 14 gal 28 gal |
| Nest 4 Days Add | 1 qt 2 qt 1 gal | 20 gal 40 gal 80 gal | 14 gal 28 gal 56 gal |

*Note: Make a cattle stock solution by adding 1 packet of Albon Soluble Powder to 1 gal of water.
 *Twenty fl oz of cattle stock solution will medicate 1 600-lb animal initially or 2 600-lb animals on maintenance dose.
 Contents of packet will medicate 6 600-lb animals initially or 12 600-lb animals on maintenance dose.
 **This dosage recommendation is based on a water consumption of 1 gal per 100 lb of body weight per day, expected water consumption rate for summer. Water consumption during cold months (winter) may drop markedly (30-40%). Accordingly, adjustments must be made in the dilution rates to compensate for this and insure proper drug intake.
 For treatment of individual cattle, Albon (sulfadimethoxine) Soluble Powder stock solution for cattle may be given as a drench. Administer using same mg/lb dosage as outlined above.
Treatment Period: 5 consecutive days

Caution: Chickens and Turkeys—If animals show no improvement within 5 days, discontinue treatment and reevaluate diagnosis. Prepare a fresh stock solution daily. Handle the recommended dilutions (chickens 0.05% and turkeys 0.025%) as regular drinking water. Administer as sole source of drinking water and sulfonamide medication.
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Warning: Chickens and Turkeys—Withdraw 5 days before slaughter. Do not administer to chickens over 16 weeks (112 days) of age or to turkeys over 24 weeks (168 days) of age.

Cattle—Withdraw 7 days before slaughter. For dairy calves, dairy heifers, and beef cattle only.
 A withdrawal period has not been established for this product in pre-ruminating calves.

Do Not Use in Calves to be Processed for Veal

Distributed by:
 SmithKline Beecham Animal Health
 West Chester, PA 19380, USA

942 0-8446