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 _____

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) 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 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 520.2220 a (e) (1) (iii)	Broiler and Replacement Chickens- 5 days before slaughter.
21 CFR 520.2220 a (e) (2) (iii)	Meat-Producing Turkeys- 5 days before slaughter
21 CFR 520. 2220 a (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