Approval Date: June 17, 1992

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-031

B. Sponsor

AgriLabs, Ltd.
P. O. Box 3103
St. Joseph, MO 64503

C. Proprietary Name

Sulfadimethoxine Antibacterial Soluble Powder

D. Established Name

sulfadimethoxine

E. Dosage Form

Soluble Powder

F. Dispensing Status

Over the Counter (OTC)

G. Dosage Regimen

Dairy Calves and Heifers and Beef Cattle: 25 mg/lb first day followed by 12.5 mg/lb/day for 4 days. Treatment period is 5 consecutive days.

Chickens and Turkeys: 0.05% and 0.025% respectively for 6 consecutive days.

Note: For Dosage and Administration details see following chart.

DOSAGE AND ADMINISTRATION

Species	Concentration	Use Direction
CHICKENS	0.05%	Contents of packet to 50 gallons of water
TURKEYS	0.025%	Contents of packet to 100 gallons of water

Automatic proportioners - To make a stock solution, add contents of 5 packets to 2 gallons of water for chickens and to 4 gallons of water for turkeys. Set proportioner to feed at a rate of 1 fl oz of stock solution per gallon of water.

TREATMENT PERIOD - 6 consecutive days

DAIRY CALVES, DAIRY HEIFERS AND BEEF CATTLE

	SULFADIMETHOXINE IN WATER **WATER CONSUMPTION**		
Dosage 25 mg/lb first day followed by 12.5 mg/lb/day for 4 days	**Amount of Stock Solution for Cattle***	**(Summer) 1 gallon/** 100 lb b.w.**	**(Winter) 1 gallon/** 100 lb b.w.**
FIRST DAY ADD:	1 quart	10 gallons	7 gallons
	2 quarts	20 gallons	14 gallons
	1 gallon	40 gallons	28 gallons
NEXT 4 DAYS ADD:	1 quart	20 gallons	14 gallons
	2 quarts	40 gallons	28 gallons
	1 gallon	80 gallons	56 gallons

*NOTE: Make a cattle stock solution by adding 1 packet of SULFADIMETHOXINE Soluble Powder to 1 gallon of water

** This dosage recommendation is based on a water consumption of 1 gallon 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.

Twenty fluid ounces of cattle stock solution will medicate one 600 lb animal initially or two 600 lb animals on maintenance dose. Contents of packet will medicate six 600 lb animals initially or twelve 600 lb animals on maintenance dose.

TREATMENT PERIOD - 5 consecutive days

H. Route of Administration

Oral--either in the drinking water or solubilized and given as an individual drench.

I. Indication

Broiler and Replacement Chickens:

Indicated for the treatment of disease outbreaks of coccidiosis, fowl cholera, and infectious coryza.

Meat Producing Turkeys:

Indicated for the treatment of disease outbreaks of coccidiosis and fowl cholera.

For Dairy Calves, Dairy Heifers and Beef:

Indicated for the treatment of shipping fever complex, bacterial pneumonia, calf diphtheria, and foot rot.

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

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 relies on the target animal safety, drug effectiveness and human food safety data in the pioneer's new animal drug application. 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 (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990).

Based upon the formulation characteristics of the generic product, AgriLabs Ltd. was granted a waiver from conducting an in vivo bioequivalence study for sulfadimethoxine soluble powder. The generic product is administered as an oral solution. It contains the same active ingredient and drug concentration as the pioneer product. It is the same dosage form as the pioneer and contains no inactive ingredients that may significantly affect absorption of the active ingredient.

III. HUMAN FOOD SAFETY

Tolerance

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.1 ppm (negligible residue) is established for sulfadimethoxine residues in the uncooked edible tissues of chickens, turkeys and cattle under 21 CFR 556.640.

Withdrawal Time

When a waiver of the in vivo bioequivalence study is granted, the withdrawal times are those previously assigned to the generic product.

The withdrawal times are 5 days for chickens and turkeys, and 7 days for cattle (21 CFR 520.2220a).

Regulatory Method for Residues

The analytical method for detection of residues in tissue is the thin layer densitometric procedure. This method is found in the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 15th edition, 1990.

IV. AGENCY CONCLUSIONS

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that sulfadimethoxine soluble powder, when used under its proposed conditions of use, is safe and effective for its labeled indication.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.