Approval Date: December 31, 1992

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-030

B. Sponsor

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

C. Proprietary Name

Sulfadimethoxine 12.5% Oral Solution

D. Established Name

sulfadimethoxine 12.5% oral solution

E. Dosage Form

oral solution for drinking water or as a drench

F. Dispensing Status

Over the Counter (OTC)

G. Dosage Regimen

Species	Concentration	Use Directions
CHICKENS	0.05%	Add 1 fl oz* to 2 gallons of drinking water or 25 fl oz to 50 gallons of drinking water
TURKEYS	0.025%	Add 1 fl oz* to 4 gallons of drinking water or 25 fl oz to 100 gallons of drinking water

Automatic Proportioners

** Stock Solution-To make 2 gallons of Stock Solution use:

CHICKENS

1 gal Sulfadimethoxine 12.5% Drinking Water Solution Concentrate - plus - 1 gal of water

TURKEYS

2 qts Sulfadimethoxine 12.5% Drinking Water Solution Concentrate - plus - 6 qts of water

TREATMENT PERIOD -- 5 consecutive days

SULFADIMETHOXINE IN WATER

	DOSAGE	**WATER CONSUMPTION (SUMMER)**	**WATER CONSUMPTION (WINTER)**
DAIRY CALVES DAIRY HEIFERS AND BEEF CATTLE	25 mg/lb first day followed by 12.5 mg/lb/day for 4 days.	1 gallon/***100 lb.b.w.	1 gallon/***150 lb.b.w.
FIRST DAY ADD:	1 pint (16 fl oz) to:	25 gallons	16 gallons
	1 quart (32 fl oz) to:	50 gallons	33 gallons
	1 gallon (128 fl oz) to:	200 gallons	127 gallons
NEXT 4 DAYS ADD:	1 pint (16 fl oz) to:	50 gallons	33 gallons
	1 quart (32 fl oz) to:	100 gallons	66 gallons
	1 gallon (128 fl oz) to:	400 gallons	266 gallons

***** This dosage recommendation is based on 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 in drug concentration in drinking water must be made to ensure proper drug intake. For individual treatment of cattle, Sulfadimethoxine 12.5% Drinking Water Solution may be given as a drench. Administer using same mg/lb dosage as outlined above. Four fluid ounces will medicate one-600 lb animal initially or two-600 lb animals on maintenance dose.**

TREATMENT PERIOD -- 5 consecutive days

* 1 fl oz Sulfadimethoxine 12.5% Drinking Water Solution = 30 mL or 2 tablespoonfuls.

** Set proportioner to a feed rate of 1 fl oz of Sulfadimethoxine Stock Solution per gallon of water.

H. Route of Administration

oral

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 Cattle:

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

II. EFFECTIVENESS and ANIMAL TARGET

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, 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 oral solution. The generic and pioneer products are oral solutions with the same active and inactive ingredients. The generic and pioneer products also contain the same concentration of active ingredient.

III. HUMAN FOOD SAFETY

Tolerance for the marker residue:
The tolerance established for the pioneer product applies to the generic product.

A tolerance of 0.1 ppm is established for sulfadimethoxine residues in the edible tissues of chickens, turkeys and cattle under 21 CFR 556.640.

Withdrawal Period:
When a waiver of the in *vivo* bioequivalence study is granted, the withdrawal times are the same as those previously assigned to the pioneer product.

For sulfadimethoxine 12.5% drinking water solution, a withdrawal period of five days has been established for chickens and turkeys, and a withdrawal period of seven days has been established for cattle.

Regulatory Method:
The analytical method for the determination of sulfadimethoxine in tissue uses a 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 oral solution, when used under its proposed conditions of use, is safe and effective for its labeled indications.

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.