Approval Date: April 30, 1997

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-185

B. Sponsor

Agri Laboratories, Ltd.
P. O. Box 3103
St. Joseph, MO 64503

C. Proprietary Name

Gen-gard™ Soluble Powder

D. Established Name

gentamicin sulfate soluble powder

E. Dosage Form

Soluble powder

F. Dispensing Status

OTC

G. Dosage Regimen

Administer GEN-GARD™ Soluble Powder in drinking water at the following recommended levels, *ad libitum*:

Colibacillosis - 25 mg/gallon for 3 consecutive days (0.5 mg/lb BW/day)

Swine dysentery - 50 mg/gallon for 3 consecutive days (1.0 mg/lb BW/day)

H. Route of Administration

GEN-GARD™ Soluble Powder is recommended for oral use via drinking water in swine only.

I. Species/Class

Weanling swine

J. Indication

GEN-GARD™ Soluble Powder is recommended for the control and treatment of colibacillosis in weanling swine caused by strains of E. coli sensitive to gentamicin, and the control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.

II. 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 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 and conducts a tissue residue study to establish the withdrawal time for the generic product. For certain dosage forms, the agency will grant a waiver from conducting an in vivo bioequivalence study (61 FR 26182, May 24, 1996, Bioequivalence Guidance).

Based upon the formulation characteristics of the generic product, Agri Labs Ltd. was granted a waiver from conducting an in vivo bioequivalence study for GEN-GARD™ (gentamicin sulfate) soluble powder. The generic and pioneer products are administered as oral solutions and contain the same active and inactive ingredients.

III. HUMAN FOOD SAFETY

A. Tolerance

The tolerances established for the pioneer product apply to the generic product. Tolerances of 0.1 ppm in muscle, 0.3 ppm in liver, and 0.4 ppm in kidney and fat are established for gentamicin residues in the edible tissues of swine under 21 CFR 556.300.

B. Withdrawal Time

When a waiver of in vivo bioequivalence testing is granted, the withdrawal time established for the pioneer product is also assigned to the generic product. The withdrawal time for gentamicin sulfate soluble powder is 10 days for swine.

C. Regulatory Method for Residues

The analytical method for the determination of gentamicin in tissues uses a microbiological procedure. This method is on file in the

Dockets Management Branch, HFA-305
12420 Parklawn Drive
Rockville, MD 20857

IV. AGENCY CONCLUSIONS

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Gentamicin Sulfate Soluble Powder when used under the 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.