Approval Date: August 27, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-225

B. Sponsor

Agri Laboratories, Ltd.
P. O. Box 3103
St. Joseph, MO 64503-0103

C. Proprietary Name

Prohibit™ Soluble Drench Powder

D. Established Name

Levamisole hydrochloride

E. Dosage Form

Soluble Drench Powder

F. Dispensing Status

OTC

G. Dosage Regimen

Add water to contents of container (544.5 g of Levamisole HCl) to the 3 Liter mark and dissolve. This provides approximately 180 mg/mL of Levamisole HCl activity. Administer as a single drench as follows:

CATTLE - 2 mL per 100 lb. body weight

Weight	Drench Dosage	Bottle will Treat
100 lb.	2 mL	1,500 head
300 lb.	6 mL	500 head
500 lb.	10 mL	300 head
700 lb.	14 mL	214 head
1,000 lb.	20 mL	150 head

SHEEP - 1 mL per 50 lb. body weight

Weight	Drench Dosage	Bottle will Treat
50 lb.	1 mL	3,000 head
100 lb.	2 mL	1,500 head
150 lb.	3 mL	1,000 head
200 lb.	4 mL	750 head

NOTE: Careful weight estimates are essential for proper performance of this product.

Cattle and sheep maintained under conditions of constant helminth exposure may require retreatment within two to four weeks after the first treatment.

H. Route of Administration

PROHIBIT™ Soluble Drench Powder is recommended as an oral drench in cattle and sheep.

I. Indication

PROHIBIT™ Soluble Drench Powder is indicated as an anthelmintic effective against Stomach Worms (*Haemonchus, Trichostrongylus, Ostertagia*), Intestinal Worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*) (*Chabertia*, sheep only), Lung worms (*Dictyocaulus*) in cattle and sheep.

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. Approval of an ANADA requires that the sponsor show 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, June18,1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Based on the formulation characteristics of the generic product, Agri Laboratories Ltd was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product PROHIBIT™ (levamisole HCL) Soluble Drench Powder. The generic product is administered as an oral solution and contains the same active and inactive ingredients in the same concentration as the pioneer product.

III. HUMAN FOOD SAFETY

Tolerance

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.1 ppm is established for Levamisole residues in the uncooked edible tissues of cattle and sheep under 21 CFR 556.350.

Withdrawal Time

Under the CVM Bioequivalence Guidelines, when a generic product is granted a waiver of in vivo bioequivalence testing, the withdrawal period established for the pioneer product is also assigned to the generic product.

For PROHIBIT™ Soluble Drench Powder, a withdrawal period of 2 days has been established for cattle and 3 days for sheep (21 CFR 520.1242a).

Regulatory Method for Residues

The analytical method for the determination of Levamisole HCl tissues uses a chemical procedure.

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 PROHIBIT™ (levamisole HCL) Soluble Drench Powder when used under its proposed conditions of use, is safe and effective for the 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.