Date of Approval: May 15, 2002

FREEDOM OF INFORMATION SUMMARY

ANADA 200-327

Privermectin™ (ivermectin) Drench for Sheep

Sponsored by:
First Priority, Inc.
Elgin, IL 60123

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number	200-327
Sponsor:	First Priority, Inc. 1585 Todd Drive Elgin, IL 60123 21 CFR 510.600: Labeler Code 058829
Established Name:	Ivermectin liquid
Trade/Proprietary Name:	Privermectin™ Drench for Sheep
Dosage Form:	Drench
How Supplied:	32.46 fl. oz (1 quart) 960 mL size bottle
How Dispensed:	OTC
Amount of Active Ingredients:	200 mcg/kg of body weight as a single dose oral drench
Route of Administration:	Oral
Species:	Sheep
Labeled Dosage	3 mL per 26 lbs. b.w.
Indications for Use:	Treatment and control of gastrointestinal roundworms, lungworms, and nasal bots.
Pharmacological Category:	Antiparasitic

Pioneer Product: Ivomec® Drench for Sheep manufactured by Merial Limited (NADA 131-392)

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 relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. 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, October 10, 2000).

Based upon the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver on January 28, 2000, from conducting an *in vivo* bioequivalence study for Privermectin Drench for Sheep. The generic and pioneer products contain the same active in the same concentration as the pioneer, and nearly the same inactive ingredients and are oral solutions.

3. HUMAN FOOD SAFETY:

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 Ivermectin liquid is established under 21 CFR 520.1194- 11 days in sheep.

TOLERANCE:

Under section §556.344, **Ivermectin,** the tolerances for ivermectin (1) Liver: A tolerance is established for 22,23-dihydroavermectin B^1a (marker residue) in liver of sheep at 30 parts per billion. The ADI for total residues of ivermectin is 1 microgram per kilogram of body weight per day.

HUMAN SAFETY RELATIVE TO POSSESSION, HANDLING, AND ADMINISTRATION:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed 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 Privermectin™ Drench for Sheep is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments: Pioneer Labeling:

Package Insert

32.46 fl. oz (1 quart) 960 mL pack

Generic Labeling:

Package Insert

32.46 fl. oz (1quart) 960 mL pack

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.