FREEDOM OF INFORMATION (FOI) SUMMARY

Primectin™ (ivermectin) Liquid for Horses

ANADA 200-321

First Priority, Inc.

1585 Todd Farm Drive

Elgin, Il 60123-1146

Date of Approval Sept. 7, 2001

1. GENERAL INFORMATION:

ANADA Number: 200-321

Sponsor Name and Address: First Priority, Inc.
1585 Todd Farm Drive
Elgin, IL 60123

Generic Name: Ivermectin Liquid for Horses

Trade Name: Primectin™ Equine Oral Liquid

Marketing Status: RX

2. INDICATIONS FOR USE:

For the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large-mouth stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis

3. DOSAGE:

a. DOSAGE FORM: 100 mL Bottles

b. ROUTE OF ADMINISTRATION: For administration by stomach tube (nasogastric intubation) or as an oral drench.

c. RECOMMENDED DOSAGES: The recommended dose is 200 mcg of ivermectin per kilogram (91 mcg/lb) of bodyweight. Each mL contains sufficient ivermectin to treat 110 lb (50 kg) of body weight: 10 mL will treat an 1100 lb (500 kg) horse.

Each mL contains 1% (10mg) Ivermectin.

4. & 5. EFFECTIVENESS & 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 (54 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 (Eqvalan® Liquid for Horses). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of and 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's 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 cannot 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 2000).

Based on the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study with Primectin™ Equine Oral Liquid. The generic and pioneer products are solutions with the same active and inactive ingredients.

6. HUMAN SAFETY:

Human Food Safety

Horses: Not for use in horses intended for food.

Human Safety Relative to Possession, Handling and Administration:

The labeling contains adequate Warning statements as described below:
Refrain from smoking and eating when handling.
Wash hands after use. Avoid contact with eyes.
Keep this and all drugs out of reach of children.

7. AGENCY CONCLUSION:

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 Primectin™ Equine Oral Liquid when used under its proposed conditions of use, is safe and effective for its labeled indications.

8. LABELING:

Attachments: Generic and pioneer labeling

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) 443-2414.