FREEDOM OF INFORMATION (FOI) SUMMARY

Iversol (ivermectin) Liquid for Horses

ANADA 200-292

Med-Pharmex, Inc.

2727 Thompson Creek Road

Pomona, CA 91767-1861

Date of Approval _____

FREEDOM OF INFORMATION SUMMARY:

1. GENERAL INFORMATION:

ANADA Number: 200-292

Sponsor Name and Address:
Med-Pharmex, Inc.
2727 Thompson Creek Rd
Pomona, CA 91767-1861

Generic Name:
Ivermectin.

Trade Name:
Iversol (Ivermectin) Liquid for Horses.

Dosage Form:
Solution.

How Supplied: 50 mL, 100 mL and 250 mL bottles.

Marketing Status: Rx

Amount of Active Ingredients: Each mL contains 10 mg of ivermectin.

Route of Administration:
By stomach tube (nasogastric intubation) or as an oral drench.

Species: Horses.

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

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 onchocerclasis.

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'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 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, April, 1996).

Based on the formulation characteristics of the generic product, Med-Pharmex, Inc was granted a waiver from conducting an *in-vivo* bioequivalence study with Iversol (Ivermectin) Liquid for Horses. The generic and pioneer products are solutions with the same active and inactive ingredients.

3. HUMAN SAFETY

Human Food Safety

Horses: Not for use in horses intended for food purposes.

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 the reach of children.

4. 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

Iversol (ivermectin) oral solution when used under the proposed conditions of use, is safe and effective for its labeled indications.

Attachments: Generic an pioneer labeling.