Date of Approval: March 8, 2004

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-341

SparMectin-E
(ivermectin)
10 mg/per mL

Anthelmintic Suspension for Horses

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

Sponsored by:

Veterinary Laboratories, Inc.
12340 Santa Fe Trail Drive
Lenexa, KS 66215

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-341
b. Sponsor:	Veterinary Laboratories, Inc. 12340 Santa Fe Trail Drive Lenexa, KS 66215 Drug Labeler Code: 000857
c. Established Name:	Ivermectin
d. Proprietary Name:	SparMectin-E
e. Dosage Form:	Liquid
f. How Supplied:	100 mL plastic bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredient:	10 milligrams of ivermectin per mL
i. Route of Administration:	Oral drench or stomach tube (nasogastric intubation)
j. Species/Class:	Horses
k. Recommended Dosage:	200 micrograms per kilogram of body weight as a single dose
l. Pharmacological Category:	Anthelmintic
m. Indications:	For the treatment and control of large strongyles, small strongyles, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, largemouth stomach worms, bots, lungworms, summer sores, and cutaneous onchocerciasis.
n. Pioneer Product:	EQVALAN; ivermectin; NADA 140-439; Merial Ltd.

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 (GADPTRA) of 1988, 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 and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Veterinary Laboratories, Inc. was granted a waiver from the requirements for an *in vivo* bioequivalence study for the generic product, SparMectin-E, on October 1, 1999. The generic product is administered as an oral liquid, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product EQVALAN, NADA 140-439, was approved on September 8, 1987.

3. HUMAN SAFETY:

This drug is indicated for use only in horses, which are non-food animals. Because this generic animal drug is not intended for food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human food safety and human exposure warning statements are provided on the product label as follows: "**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." "Do not use in horses intended for food purposes."**

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that SparMectin-E, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

<u>Generic Labeling for ANADA 200-341:</u>
SparMectin-E, 10 mg ivermectin per mL
100 mL container label with accompanying package insert.

<u>Pioneer Labeling for NADA 140-439:</u>
Merial Ltd.'s EQVALAN, 10 mg ivermectin per mL.
100 mL container label with accompanying package insert.