Date of Approval: March 26, 2010

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-429

Ivermectin Injection
(ivermectin)

1% Sterile Solution

Cattle and Swine

For the treatment and control of gastrointestinal roundworms, lungworms, lice and mange mites

Sponsored by:

Sparhawk Laboratories, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-429
b. Sponsor:	Sparhawk Laboratories, Inc. 12340 Santa Fe Trail Dr. Lenexa, KS 66215 Drug Labeler Code: 058005
c. Established Name:	Ivermectin
d. Proprietary Name:	Ivermectin Injection
e. Dosage Form:	Sterile solution
f. How Supplied:	50 mL, 200 mL and 500 mL vials
g. How Dispensed:	OTC
h. Amount of Active Ingredient:	1% ivermectin
i. Route of Administration:	Subcutaneous
j. Species/Class:	Cattle and swine
k. Recommended Dosage:	Cattle: Ivermectin should be given only by subcutaneous injection under the loose skin in front of or behind the shoulder at the recommended dose level of 200 mcg ivermectin per kilogram of body weight. Each mL of ivermectin contains 10 mg of ivermectin, sufficient to treat 110 lb (50 kg) of body weight (maximum 10 mL per injection site) Swine: Ivermectin should be given only by subcutaneous injection in the neck of swine at the recommended dose level of 300 mcg ivermectin per kilogram (2.2 lb) of body weight. Each mL of ivermectin contains 10 mg of ivermectin, sufficient to treat 75 lb of body weight.
l. Pharmacological Category:	Anthelmintic

m. Indications:

Cattle: Ivermectin injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal round worms, lung worms, grubs, suckling lice and mange mites in cattle:

Gastrointestinal Roundworms (adults and fourth-stage larvae):
Ostertagia ostertagi (including inhibited O. ostertagi)
O. lyrata
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctata
C. pectinata
Oesophagostomum radiatum
Bunostomum phlebotomum
Nematodirus helvetianus (adults only)
N. spathiger (adults only)

Lungworms (adults and fourth-stage larvae):
Dictyocaulus viviparus

Cattle Grubs (parasitic stages):
Hypoderma bovis
H. lineatum

Sucking Lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

Mites (scabies)
Psoroptes ovis (syn. *P. communis var. bovis*)
Sarcoptes scabiei var. bovis

Persistent Activity:
Ivermectin Injection has been proved to effectively control infections and to protect cattle from reinfection with: *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 28 days after treatment; *Ostertagia ostertagi*, *Trichostrongylus axei* and *Cooperia punctata* for

21 days after treatment; *Haemonchus placei*, and *Cooperia oncophora* for 14 days after treatment.

Swine: Ivermectin Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, lice, and mange mites in swine:

Gastrointestinal Roundworms:
Large roundworm, *Ascaris suum* (adults and fourth-stage larvae)
Red stomach worm, *Hyostrongylus rubidus* (adults and fourth stage larvae)
Nodular worm, *Oesophagostomum* spp. (adults and fourth stage larvae)
Threadworm, *Strongyloides ransomi* (adults)

Somatic Roundworm Larvae:
Threadworm, *Strongyloides ransomi* (somatic larvae)
Sows must be treated at least seven days before farrowing to prevent infection in piglets.

Lungworms:
Metastrongylus spp. (adults)

Lice:
Haematopinus suis

Mange Mites:
Sarcoptes scabiei var. *suis*

n. Pioneer Products: IVOMEC Injection; ivermectin; NADA 128-409; 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, 2000).

Based on the formulation characteristics of the generic product, Sparhawk Laboratories Inc., was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product Ivermectin injection. The generic product is administered by sterile solution, 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 IVOMEC (ivermectin) Injection, the subject of Merial Ltd., NADA 128-409, was approved on February 13, 1984.

3. HUMAN SAFETY:

Human Warnings are provided on the product label as follows: Not for use in humans. Keep out of reach of children.

- **Tolerances for Residues**:
  The tolerance established for the pioneer product applies to the generic product. A tolerance is established for 22,23-dihydroavermectin B1a (marker residue) in the liver at 100 parts per billion in cattle, 20 parts per billion in swine, 15 parts per billion in reindeer, 15 parts per billion in American bison and in the muscle at 10 parts per billion in cattle and 20 parts per billion in swine under 21 CFR 556.344.

- **Withdrawal Times:**
  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

  The withdrawal times are 35 days for cattle, 18 days for swine and 56 days for both reindeer and American bison.

- **Regulatory Method for Residues:**
  The official analytical methods for residues are HPLC methods with fluorescence detection. The validated regulatory analytical methods for detection and confirmation of residues of ivermectin are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. ***AGENCY CONCLUSIONS***:

This 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 Ivermectin Injection, 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 follows:

Generic Labeling for ANADA 200-429:
50 mL, 200 mL and 500 mL vial labels and label onserts

Pioneer Labeling for NADA 128-409:
50 mL bottle label & carton
200 mL, 500 mL and 1000 mL collapsible packs container label & carton
Package insert