Date of Approval:September 4, 2012

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-466

SparMectin Plus Clorsulon
(ivermectin and clorsulon)

Injection

Cattle

Indications: For the treatment and control of internal parasites, including adult liver flukes and external parasites

Sponsored by:

Sparhawk Laboratories, Inc.

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I. GENERAL INFORMATION:

A. File Number:	ANADA 200-466
B. Sponsor:	Sparhawk Laboratories, Inc. 12340 Santa Fe Trail Dr. Lenexa, KS 66215 Drug Labeler Code: 058005
C. Proprietary Name:	SparMectin Plus Clorsulon
D. Established Names:	Ivermectin and clorsulon
E. Pharmacological Category:	Antiparasitic
F. Dosage Form:	Injection
G. Amount of Active Ingredients:	Each milliliter (mL) of solution contains 1% (10 mg) w/v ivermectin and 10% (100 mg) w/v clorsulon
H. How Supplied:	50 mL, 200 mL, and 500 mL multiple-dose, amber glass bottles
I. How Dispensed:	OTC
J. Dosage:	1 mL per 110 lb (50 kg) body weight. This delivers 10 mg ivermectin and 100 mg clorsulon.
K. Route of Administration:	Subcutaneously
L. Species/Class:	Cattle
M. Indications:	SparMectin Plus Clorsulon is indicated for the effective treatment and control of the following parasites of 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* *Bunostomum phlebotomum*

Nematodirus helvetianus (adults only)
N. spathiger (adults only)
Oesophagostomum radiatum
Lungworms (adults and fourth-stage larvae):
Dictyocaulus viviparus
Liver Flukes:
Fasciola hepatica (adults only)
Cattle Grubs (parasitic stages):
Hypoderma bovis
H. lineatum
Sucking Lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
Mange Mites: (cattle scab*):
Psoroptes ovis (syn. P. *communis* var. *bovis*)
Sarcoptes scabiei var. *bovis*

SparMectin Plus Clorsulon 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.

N. Reference listed new animal drug: IVOMEC Plus; ivermectin and clorsulon; 140-833; Merial Ltd.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). 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 RLNAD, 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, Sparhawk Laboratories, Inc. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product SparMectin Plus Clorsulon (ivermectin and clorsulon) Injection. The generic product is administered as an injectable solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The RLNAD is IVOMEC Plus (ivermectin and clorsulon) Injection and was approved for use in cattle on September 17, 1990.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

The following are assigned to this product for cattle:

- Tolerances for Residues:
  The tolerances established for the pioneer product apply to the generic product. A tolerance of 100 parts per billion (ppb) is established for 22, 23-dihydroavermectin B_1 a (the marker residue) of ivermectin in liver (the target tissue), and 10 ppb in the muscle, under 21 CFR 556.344. A tolerance of 1 part per million (ppm) is established for parent clorsulon (the marker residue) in the kidney (the target tissue), and 0.1 ppm in the muscle, under 21 CFR 556.163. The acceptable daily intake (ADI) for total residues of ivermectin is 1 microgram per kilogram of body weight per day and clorsulon is 8 micrograms per kilogram of body weight per day.

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

  A withdrawal period of 49 days has been established for ivermectin and clorsulon in cattle. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

- Regulatory Method for Residues:
  The official analytical methods for residues of ivermectin are HPLC methods with fluorescence detection and the analytical method for detection of clorsulon in tissues is UV-LC Finish or Determinative Assay. The validated regulatory method for the determination and confirmation of residues of ivermectin and clorsulon is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

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VI. USER SAFETY:

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to SparMectin Plus Clorsulon Injection:

- WARNING: Not for Use in Humans. Keep this and all drugs out of the reach of children.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that SparMectin Plus Clorsulon, when used according to the label, is safe and effective.