Date of Approval: December 13, 2013

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-341

SPARMECTIN-E

(ivermectin)

Liquid for Horses

Horses

This supplement provides for a change in preservative from benzyl alcohol to a combination of methylparaben and propylparaben, and a change in manufacturing process. In addition, product indications were updated to be consistent with the most recently approved labeling for the reference listed new animal drug (RLNAD).

Sponsored by:

Sparhawk Laboratories, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-341

B. Sponsor

Sparhawk Laboratories, Inc.
12340 Santa Fe Trail Dr.
Lenexa, KS 66215

Drug Labeler Code: 058005

C. Proprietary Name

SPARMECTIN-E

D. Established Name

Ivermectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form:

Liquid

G. Amount of Active Ingredient

10 mg/mL

H. How Supplied

100 mL and 200 mL plastic bottles

I. Dispensing Status

Rx

J. Dosage Regimen

200 micrograms (mcg) per kilogram (kg) of body weight as a single dose by stomach tube or as an oral drench.

K. Route of Administration

Oral

L. Species/Class

Horses

M. Indications

For the effective treatment and control of the following parasites in horses. Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels) *Strongylus edentatus* (also tissue stages) *Strongylus equinus Triodontophorus* spp. including: *Triodontophorus brevicauda Triodontophorus serratus Craterostomum acuticaudatum* Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocyclus* spp. including: *Coronocyclus coronatus, Coronocyclus labiatus Coronocyclus labratus Cyathostomum* spp. including: *Cyathostomum catinatum Cyathostomum pateratum Cylicocyclus* spp. including: *Cylicocyclus insigne Cylicocyclus leptostomum Cylicocyclus nassatus Cylicocyclus brevicapsulatus Cylicodontophorus* spp. *Cylicostephanus* spp. including: *Cyclicostephanus calicatus, Cyclicostephanus goldi Cylicostephanus longibursatus Cylicostephanus minutus Petrovinema poculatum* Small Strongyles: Fourth-stage larvae Pinworms (adults and fourth-stage larvae) - *Oxyuris equi* Roundworms or ascarids (adults and third- and fourth-stage larvae) - *Parascaris equorum* Hairworms (adults) - *Trichostrongylus axei* Large-mouth Stomach Worms (adults) - *Habronema muscae* Bots (oral and gastric stages) - *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis* Lungworms (adults and fourth-stage larvae) - *Dictyocaulus arnfieldi* Intestinal Threadworms (adults) *Strongyloides westeri* Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third- stage larvae; dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

N. Reference Listed New Animal Drug

EQVALAN; ivermectin; NADA 140-439; Merial Ltd.

O. Effect of Supplement

This supplement provides for a change in preservative from benzyl alcohol to a combination of methylparaben and propylparaben, and a change in manufacturing process. In addition, product indications were updated to be consistent with the most recently approved labeling for the RLNAD.

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 demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

The sponsor conducted an *in vitro* bioequivalence study comparing physicochemical properties to determine if the new formulation of SPARMECTIN-E is equivalent to the approved formulation of SPARMECTIN-E. The assay method used to demonstrate bioequivalence has been validated and the validation data is acceptable. The two formulations were found to be bioequivalent.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this supplemental approval.

IV. TARGET ANIMAL SAFETY:

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

V. HUMAN FOOD SAFETY:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in horses, which are not food producing animals.

VI. USER SAFETY:

CVM did not require user safety studies for this supplemental approval.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to SPARMECTIN-E:

Not for use in humans.
Keep this and all drugs out of the reach of children.
Do not use in horses intended for human consumption.
Refrain from smoking and eating when handling.
Wash hands after use.
Avoid contact with eyes.

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-E, when used according to the label, is safe and effective.