Date of Approval: February 8, 2021

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-466

SparMectin Plus Clorsulon

(ivermectin and clorsulon)

Injectable solution

Cattle

Provides for a decrease in the residue withdrawal period for cattle from 49 days to 21 days prior to slaughter.

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. Drug Product Established Name

Ivermectin and clorsulon

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

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, 500 mL and 1000 mL bottles

I. Dispensing Status

Over-the-counter (OTC)

J. Dosage Regimen

There were no changes to the dosage regimen as a result of this supplemental approval.

K. Route of Administration

Subcutaneous

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*

Persistent Activity
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 (RLNAD)

Ivomec® Plus; ivermectin and clorsulon; NADA 140-833; Boehringer Ingelheim Animal Health USA, Inc.

O. Effect of Supplement

This supplement provides for a decrease in the residue withdrawal period for cattle from 49 days to 21 days prior to slaughter.

II. BIOEQUIVALENCE

CVM did not require additional bioequivalence information for this supplemental approval. The FOI Summary for the original approval of ANADA 200-466, dated September 4, 2012, contains a summary of data that demonstrates bioequivalence of the drug for cattle.

III. HUMAN FOOD SAFETY

The tolerances for residues and withdrawal periods established for the RLNAD apply to the generic product. The following are assigned to this product for cattle:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of ivermectin is 5 [micro]g/kg of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. The tolerances for 22,23-dihydroavermectin B_1a (marker residue) are 1.6 parts *per* million (ppm) in liver (target tissue) and 650 parts *per* billion (ppb) in muscle under 21 CFR 556.344.

The ADI for total residues of clorsulon is 8 [micro]g/kg of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. The tolerances for clorsulon (marker residue) are 1.0 ppm in kidney (target tissue) and 0.1 ppm in muscle under 21 CFR 556.163.

B. Withdrawal Periods

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of 21 days has been established for ivermectin and clorsulon in cattle. Because a discard time for 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.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of ivermectin and clorsulon is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. To obtain a copy of the analytical method, please submit a Freedom of Information request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

IV. USER SAFETY

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

No special handling or protective clothing is necessary.

NOT FOR USE IN HUMANS. Keep this and all drugs out of the reach of children.

V. AGENCY CONCLUSIONS

The information submitted in support of this supplemental ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that SparMectin Plus Clorsulon, when used according to the label, is safe and effective for the indications listed in Section I.M. above.

Additionally, data demonstrate that residues in food products derived from cattle treated with SparMectin Plus Clorsulon will not represent a public health concern when the product is used according to the label.