Date of Approval: Jan 31, 2019

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-450

Bimectin® Plus

ivermectin and clorsulon

Injectable solution

Cattle

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

Sponsored by:

Bimeda Animal Health Ltd.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-450

B. Sponsor

Bimeda Animal Health Ltd.,
1B The Herbert Building, The Park,
Carrickmines, Dublin, 18, IE

Drug Labeler Code: 061133

US Agent Name and Address:
Ms. Deb Ann Voss
Post Approval US Regulatory Affairs
Bimeda Inc.
291 Forest Prairie Road
Le Sueur, MN 56058

C. Proprietary Name

Bimectin® Plus

D. Product Established Name

ivermectin and clorsulon

E. Pharmacological Category

Endectocide

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

10 mg (1%) ivermectin and 100 mg (10%) clorsulon per mL

H. How Supplied

250 mL, 500 mL, and 1000 mL bottles

I. Dispensing Status

OTC

J. Dosage Regimen

1 mL for each 110 lbs (50 kg) body weight. This volume will deliver 10 mg ivermectin and 100 mg clorsulon.

K. Route of Administration

Subcutaneous

L. Species/Class

Cattle

M. Indications

Bimectin® Plus is indicated for the effective treatment and control of the following parasites in cattle:
Gastrointestinal Roundworms (adults and fourth-stage larve):
Ostertagia ostertagi (including inhibited *O. ostertagi*)
O. lyrata
Haemonchus placei
Trichostrongylus axei
T. colubriformis
Cooperia oncophora
C. punctate
C. pectinate
Bunostomum phlebotomum
Nematodirus helvetianus (adults only)
N .spathiger (adults only)
Oesophagostomum radiatum
Lungworms (adults and fourth-stage larvae):
Dictyocaulus viviparous
Liver Flukes:
Fasciola hepatica (adults only)
Cattle Grubs (parasitic stages):
Hypoderma bovis
H. lineatum
Sucking Lice:
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
Manage Mites (Cattle Scab):
Psoroptes ovis (syn. *P. communis* var. *bovis*)

Persistent Activity
Ivermectin and clorsulon injection has been proven to effectively control infections and to protect cattle from reinfection with *Dictyocaulus viviparous* and *Oesophagostomum radiatum* for 28 days after treatment; *Ostertagia ostertagi*, *Trichostronglyus 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; NADA 140-833; Merial, Inc.

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 (GADPTRA) 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 (RLNAD)). 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 period for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement to perform *in vivo* bioequivalence studies (biowaiver) (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Bimeda Animal Health Ltd., was granted a biowaiver for the generic product Bimectin® Plus (ivermectin and clorsulon) Injection for Cattle. The generic drug product is a sterile 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 bioavailability of the active ingredient. The RLNAD is Ivomec® Plus (ivermectin and clorsulon) Injection for Cattle, sponsored by Merial, Inc., under NADA 140-833 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:

A. Acceptable Daily Intake and Tolerances for Residues:

The acceptable daily intake (ADI) for total residues of ivermectin is 5 micrograms *per* kilogram of body weight per day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 1.6 parts per million is established for 22,23-dihydroavermectin $B_{1}a$ (the marker residue) in bovine liver (the target tissue), and 650 parts per billion in bovine muscle, under 21 CFR 556.344.

The ADI for total residues of clorsulon is 8 micrograms *per* kilogram of body weight per day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 1.0 part per million is established for parent clorsulon (the marker residue) in kidney (the target tissue), and 0.1 parts per million in muscle, under 21 CFR 556.163.

B. Withdrawal Period:

Because a waiver from the requirement to demonstrate bioequivalence was granted, the withdrawal period is that previously assigned to the RLNAD product. A withdrawal period of 21 days has been established for ivermectin and clorsulon in cattle.

C. Analytical Method for Residues:

The validated analytical methods for analysis of residues of ivermectin and clorsulon are 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 Summary request to: https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

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

WARNING: NOT FOR USE IN HUMANS.
Keep this and all drugs out of reach of children.
The Safety Data Sheet (SDS) contains more detailed occupational safety information.
To report adverse effects, obtain an SDS or for assistance, contact Bimeda, Inc. at 1-888-524-6332

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 Bimectin® Plus, when used according to the label, is safe and effective.

Additionally, data demonstrates that residues in food products derived from species treated with Bimectin® Plus will not represent a public health concern when the product is used according to the label.