Date of Approval: January 16, 2018

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-563

Eprizero™

eprinomectin

Topical Solution

Beef and Dairy Cattle, including Lactating Dairy Cattle

Eprizero™ is indicated for the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, sucking and biting lice, chorioptic and sarcoptic mange mites, and horn flies in beef and dairy cattle of all ages, including lactating dairy cattle.

Sponsored by:

Norbrook Laboratories Limited

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-563

B. Sponsor

Norbrook Laboratories Limited
Station Works, Newry BT35 6JP
Northern Ireland

Drug Labeler Code: 055529

US Agent Name and Address:
Bill Zollers, PhD
Norbrook, Inc.
9401 Indian Creek Parkway, Suite 680
Overland Park, KS 66210

C. Proprietary Name

Eprizero™

D. Product Established Name

Eprinomectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Topical Solution

G. Amount of Active Ingredient

5 mg/mL

H. How Supplied

1, 2.5, 5, and 20 L containers

I. Dispensing Status

OTC

J. Dosage Regimen

1 mL/10 kg (22 lb) of body weight. The product should be applied topically along the backline in a narrow strip extending from the withers to the tailhead.

K. Route of Administration

Topical

L. Species/Class

Beef and Dairy Cattle, including Lactating Dairy Cattle

M. Indications

Eprizero™ (eprinomectin) Pour-On is indicated for the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, sucking and biting lice, chorioptic and sarcoptic mange mites, and horn flies in beef and dairy cattle of all ages, including lactating dairy cattle. Applied at the recommended dose volume of 1 mL/10 kg (22 lb) body weight, to achieve a dose level of 500 mcg eprinomectin/kg body weight, Eprizero™ Pour-On is indicated for the effective treatment and control of the following parasites.

Gastrointestinal Roundworms

Haemonchus placei	(adults and L4)
Ostertagia ostertagi	(adults and L4)
(including inhibited L4)	
Trichostrongylus axei	(adults and L4)
Trichostrongylus colubriformis	(adults and L4)
Trichostrongylus longispicularis	(adults only)
Cooperia onchophora	(adults and L4)
Cooperia punctata	(adults and L4)
Cooperia surnabada	(adults and L4)
Nematodirus helvetianus	(adults and L4)
Oesophagostomum radiatum	(adults and L4)
Bunostomum phlebotomum	(adults and L4)
Strongyloides papillosus	(adults only)
Trichuris spp.	(adults only)

Lungworms

Dictyocaulus viviparus	(adults and L4)

Cattle Grubs (all parasitic stages)

Hypoderma lineatum
Hypoderma bovis

Lice

Damalinia bovis
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

Mange Mites

Chorioptes bovis
Sarcoptes scabiei

Horn Flies

Haematobia irritans

Not for use in calves to be processed for veal.

N. Reference Listed New Animal Drug

Eprinex®; eprinomectin; NADA 141-079; 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.

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 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 of performing 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, Norbrook Laboratories Limited, was granted a waiver from the requirement to perform an *in vivo* bioequivalence study for the generic product Eprizero™ (eprinomectin) Pour-On for Beef and Dairy Cattle. The generic drug product is a topical 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 Eprinex® (eprinomectin) Pour-On for Beef and Dairy Cattle, sponsored by Merial, Inc., under NADA 141-079 and, was approved for use in beef and dairy cattle, including lactating dairy cattle on November 11, 1996.

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 eprinomectin is 10 µg/kg of bodyweight/day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 1.5 parts *per* million is established for eprinomectin B_{1a} (the marker residue) in liver (the target tissue). A tolerance of 12 parts *per* billion (ppb) is established for eprinomectin B_{1a} (the marker residue) in milk. A tolerance of 100 ppb also is established for eprinomectin B_{1a} (the marker residue) in muscle (21 CFR §556.227).

B. Withdrawal Period:

Because a waiver from the requirement to perform an *in vivo* bioequivalence study was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of zero days has been established for Eprizero™ (eprinomectin) Pour-on for Beef and Dairy in beef and dairy cattle. A milk discard time of zero days has been established for eprinomectin in lactating dairy cows. A withdrawal period has not been established for pre-ruminating calves.

C. Analytical Method for Residues:

The validated analytical method for analysis of residues of eprinomectin 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 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 Eprizero™:

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

As with any topical medication intended for treatment of animals, skin contact should be avoided. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water. The material safety data sheet (MSDS) contains more detailed occupational safety information. To report adverse effects, obtain an MSDS or for assistance, contact Norbrook at 1-866-591-5777.

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 Eprizero™, when used according to the label, is safe and effective.

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