Date of Approval: February 24, 2023

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-741

EpriGard™

(eprinomectin)

Topical solution

Beef and Dairy Cattle, including Lactating Dairy Cattle

EpriGard™ (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.

Sponsored by:

Aurora Pharmaceutical, Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-741

B. Sponsor

Aurora Pharmaceutical, Inc.
1196 Highway 3 South
Northfield, MN 55057-3009

Drug Labeler Code: 051072

C. Proprietary Name

EpriGard™

D. Drug Product Established Name

eprinomectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

topical solution

G. Amount of Active Ingredient

5 mg/mL

H. How Supplied

250 mL in a bottle with a measure-squeeze-pour system and 1 L, 2.5 L, and 5 L backpack containers

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

The dose rate is 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

EpriGard™ (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, EpriGard™ Pour-On is indicated for the effective treatment and control of the following parasites.

Gastrointestinal Roundworms

Haemonchus placei	(adults and L4)
Ostertagia ostertagi (including inhibited L4)	(adults and L4)
Trichostrongylus axei	(adults and L4)
Trichostrongylus colubriformis	(adults and L4)
Trichostrongylus longispicularis	(adults only)
Cooperia oncophora	(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

Persistent Activity

EpriGard™ (eprinomectin) Pour-On for Beef and Dairy Cattle has been proved to effectively control infections and to protect cattle from re-infection with *Dictyocaulus viviparus* for 21 days after treatment and *Haematobia irritans* for 7 days after treatment.

N. Reference Listed New Animal Drug (RLNAD)

Eprinex®; eprinomectin; NADA 141-079; Boehringer Ingelheim Animal Health USA, Inc.

II. BIOEQUIVALENCE

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, allows for an abbreviated new animal drug application (ANADA) to be submitted for a generic version of an approved new animal drug (RLNAD). 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. Effectiveness, target animal safety and human food safety data (other than tissue residue data) are not required for approval of an ANADA. If bioequivalence is demonstrated through a clinical endpoint study in a food-producing animal, then a tissue residue study to establish the withdrawal period for the generic product is also required. 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, Aurora Pharmaceutical, Inc., was granted a biowaiver for the generic product EpriGard™ (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 Boehringer Ingelheim Animal Health USA, Inc., under NADA 141-079, and was approved for use in beef and dairy cattle, including lactating dairy cattle, on April 16, 1997.

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 eprinomectin is 10 µg/kg of body weight *per* 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), 100 parts *per* billion (ppb) in muscle, and 12 ppb in milk, under 21 CFR 556.227.

B. Withdrawal Periods

Because a biowaiver was granted, the withdrawal periods are those previously assigned to the RLNAD product. A withdrawal period of zero days has been established for eprinomectin 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 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 EpriGard™:

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 Safety Data Sheet (SDS) contains more detailed occupational safety information.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the SDS, contact Aurora Pharmaceutical at 1-888-215-1256 or www.aurorapharmaceutical.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov.reportanimalae

V. AGENCY CONCLUSIONS

The data submitted in support of this ANADA satisfy the requirements of section 512(c)(2) of the FD&C Act. The data demonstrate that EpriGard™, 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 beef and dairy cattle, including lactating dairy cattle, treated with EpriGard™ will not represent a public health concern when the product is used according to the label.