Date of Approval: March 30, 2023

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-746

Tauramox™

(moxidectin)

Injectable solution

Beef and nonlactating dairy cattle

For the treatment and control of internal and external parasites of cattle.

Sponsored by:

Norbrook Laboratories Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-746

B. Sponsor

Norbrook Laboratories Ltd.
Carnbane Industrial Estate
Newry, County Down
BT35 6QQ, United Kingdom

Drug Labeler Code: 055529

U.S. Agent Name and Address:

Melanie Archer
Norbrook, Inc.
9733 Loiret Blvd
Lenexa, KS 66219

C. Proprietary Name

Tauramox™

D. Drug Product Established Name

moxidectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Injectable solution

G. Amount of Active Ingredient

10 mg moxidectin/mL

H. How Supplied

250 and 500 mL amber glass bottles

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

The recommended rate of administration for Tauramox™ Injectable is 1 mL for each 110 lb (50 kg) body weight to provide 0.2 mg moxidectin/2.2 lb (0.2 mg/kg)

body weight. Be careful not to overdose animals; estimate animal's body weight as closely as possible or weigh animals individually.

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

K. Route of Administration

Subcutaneous injection

L. Species/Classes

Beef and nonlactating dairy cattle

M. Indications

Tauramox™ Injectable, when administered at the recommended dose level of 0.2 mg/2.2 lb (0.2 mg/kg) body weight, is effective in the treatment and control of the following internal and external parasites of cattle:

Gastrointestinal Roundworms
Ostertagia ostertagi – Adults and L_4 (including inhibited Larvae)
Haemonchus placei – Adults
Trichostrongylus axei – Adults and L_4
Trichostrongylus colubriformis – Adults and L_4
Cooperia oncophora – Adults
Cooperia pectinata – Adults
Cooperia punctata – Adults and L_4
Cooperia spatulata – Adults
Cooperia surnabada – Adults and L_4
Nematodirus helvetianus – Adults
Oesophagostomum radiatum – Adults and L_4
Trichuris spp. – Adults

Lungworms
Dictyocaulus viviparus – Adults and L_4

Cattle Grubs
Hypoderma bovis
Hypoderma lineatum

Mites
Psoroptes ovis (*Psoroptes communis* var. *bovis*)

Lice
Linognathus vituli
Solenopotes capillatus

Persistent Activity: Moxidectin Injectable has been proven to effectively protect cattle from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 42 days after treatment, *Haemonchus placei* for 35 days after

treatment, and *Ostertagia ostertagi* and *Trichostrongylus axei* for 14 days after treatment.

N. Reference Listed New Animal Drug (RLNAD)

CYDECTIN™; moxidectin; NADA 141-220; Elanco US 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, Norbrook Laboratories Ltd., was granted a biowaiver for the generic product Tauramox™ (moxidectin) injectable solution. The generic drug product is an injectable 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 CYDECTIN™ (moxidectin) injectable solution, sponsored by Elanco US Inc., under NADA 141-220, and was approved for use in beef and nonlactating dairy cattle on May 20, 2005.

III. HUMAN FOOD SAFETY

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

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of moxidectin is 4 µg/kg of body weight *per* day. The tolerances established for the RLNAD apply to the generic product. A tolerance of 900 ppb is established for moxidectin (the marker residue) in cattle fat (the target tissue), 200 ppb in cattle liver, 50 ppb in cattle muscle, and 40 ppb in milk, under 21 CFR 556.426.

B. Withdrawal Period

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 moxidectin in beef and nonlactating dairy cattle treated with moxidectin injectable solution (10 mg/mL) as a single subcutaneous injection at a dose of 0.2 mg *per* kg of body weight. Because a withholding time for milk has not been established, do not use in female dairy cattle 20 months of age or older. A

withdrawal period has not been established for preruminating 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 moxidectin 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 Tauramox™:

Not For Use in Humans. Keep this and all drugs out of the reach of children.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Norbrook at 1-866-591-5777. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at 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 Tauramox™, 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 nonlactating dairy cattle treated with Tauramox™ will not represent a public health concern when the product is used according to the label.