Date of Approval: August 10, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-845

MoxiSolv™ Pour-On

(moxidectin)

Topical solution

Beef and Dairy Cattle

For the treatment and control of internal [adult and fourth-stage larvae (L4)] and external parasites of cattle listed in Section I.M.

Sponsored by:

Bimeda Animal Health Ltd.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-845

B. Sponsor

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

Drug Labeler Code: 061133

U.S. Agent Name and Address:

Stephanie Batliner
Bimeda Inc.
475 N. Martingale Rd
Suite 1200
Schaumburg, IL 60173

C. Proprietary Name

MoxiSolv™ Pour-On

D. Drug Product Established Name

moxidectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Topical solution

G. Amount of Active Ingredient

5 mg moxidectin/mL

H. How Supplied

The 33.8 fl oz/1 L polyethylene bottle is intended for use with the enclosed measure-squeeze-pour system. When treating larger numbers of cattle, 84.54 fl oz/2.5 L, 169 fl oz/5 L, 338 fl oz/10 L or 676 fl oz/20 L conventional polyethylene containers are available for use with most commercially-available topical applicators.

I. Dispensing Status

Over the Counter (OTC)

J. Dosage Regimen

The recommended rate of administration is 1 mL for each 22 lb (10 kg) body weight which provides 0.5 mg moxidectin for each 2.2 lb (0.5 mg/kg) body weight.

K. Route of Administration

Topical

L. Species/Classes

Beef and dairy cattle

M. Indications

MoxiSolv™ Pour-On when applied at the recommended dose level of 0.5 mg/2.2 lb (0.5 mg/kg) body weight is effective in the treatment and control of the following internal [adult and fourth-stage larvae (L_4)] and external parasites of cattle:

Gastrointestinal Roundworms
Ostertagia ostertagi - Adult and L_4 (including inhibited larvae)
Haemonchus placei - Adult and L_4
Trichostrongylus axei - Adult and L_4
Trichostrongylus colubriformis - Adult and L_4
Cooperia oncophora - Adult and L_4
Cooperia pectinata - Adult
Cooperia punctata - Adult and L_4
Cooperia spatulata - Adult
Cooperia surnabada - Adult and L_4
Bunostomum phlebotomum - Adult
Nematodirus helvetianus - Adult and L_4
Oesophagostomum radiatum - Adult and L_4

Lungworms
Dictyocaulus viviparus - Adult and L_4

Cattle Grubs
Hypoderma bovis
Hypoderma lineatum

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

Lice
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus
Bovicola (Damalinia) bovis

Horn Flies
Haematobia irritans

Persistent Activity: Moxidectin pour-on has been proven to effectively control infections and protect from reinfection with *Haemonchus placei* for 14 days after treatment, *Oesophagostomum radiatum* and *Ostertagia ostertagi* for 28 days after treatment, and *Dictyocaulus viviparus* for 42 days after treatment. Efficacy below 90% was observed in some *Ostertagia ostertagi* persistent activity studies at 21 and 28 days posttreatment.

N. Reference Listed New Animal Drug (RLNAD)

CYDECTIN™: moxidectin; NADA 141-099; 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 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, Bimeda Animal Health Ltd. was granted a biowaiver for the generic product MoxiSolv™ Pour-On (moxidectin). 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 CYDECTIN™ (moxidectin) pour-on, sponsored by Elanco US Inc., under NADA 141-099, and was approved for use in cattle on January 28, 1998.

III. HUMAN FOOD SAFETY

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

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residue of moxidectin is 4 µg moxidectin/kg of body weight per day. The tolerances established for the RLNAD apply to the generic product. Tolerances for moxidectin (the marker residue) are 900 parts per billion in fat, 200 parts per billion in liver, 50 parts per billion in muscle and 40 parts per billion in milk under 21 CFR 556.426.

B. Withdrawal Period and Milk Discard Time

Based on a biowaiver being granted and an evaluation of the product formulation and relevant physicochemical properties with respect to residue chemistry, the withdrawal period and milk discard time are those previously assigned to the RLNAD product. A withdrawal period of zero days and a milk discard time of zero days has been established for moxidectin in beef and dairy cattle.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of moxidectin is on file at the Center for Veterinary Medicine, CPK1, 5001 Campus Drive, College Park, MD 20740. 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 MoxiSolv™ Pour-On:

Warning: Not For Use In Humans. Keep this and all drugs out of the reach of children. This product can cause irritation to skin, eyes, or mucous membranes. In case of accidental skin contact and/or clothing contamination, wash skin thoroughly with soap and water and launder clothing with detergent. In case of accidental eye contact, flush eyes with copious amounts of water. When direct inhalation occurs, cleanse lungs and respiratory passages with fresh air. In case of ingestion do not induce vomiting and seek medical attention immediately. If irritation or any other symptom attributable to exposure to this product persists, consult your physician.

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 MoxiSolv™ Pour-On, when used according to the label, is safe and effective for the conditions of use in the General Information Section above.

Additionally, data demonstrate that residues in food products derived from beef and dairy cattle treated with MoxiSolv™ Pour-On will not represent a public health concern when the product is used according to the label.