

Date of Approval: April 29, 2026

FREEDOM OF INFORMATION (FOI) SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-852

Moxidectin Oral Drench for Sheep

(moxidectin)

Solution

Sheep

Moxidectin Oral Drench for Sheep, when administered at the recommended dose level of 0.2 mg moxidectin/2.2 lb (0.2 mg/kg) body weight, is effective in the treatment and control of adult and larval (L₄) stages of the following internal parasites of sheep: *Haemonchus contortus*, *Teladorsagia circumcincta*, *Teladorsagia trifurcata*, *Trichostrongylus axei*, *Trichostrongylus colubriformis*, *Trichostrongylus vitrinus*, *Cooperia curticei*, *Cooperia oncophora*, *Oesophagostomum columbianum*, *Oesophagostomum venulosum*, *Nematodirus battus*, *Nematodirus filicollis*, and *Nematodirus spathiger*.

Sponsored by:

First Priority, Inc.

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I. GENERAL INFORMATION

A. File Number

ANADA 200-852

B. Sponsor

First Priority, Inc.
1590 Todd Farm Dr.
Elgin, IL 60123

Drug Labeler Code: 058829

C. Proprietary Name

Moxidectin Oral Drench for Sheep

D. Drug Product Established Name

moxidectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Solution

G. Amount of Active Ingredient

1 mg moxidectin/mL

H. How Supplied

1 L and 4 L containers

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

The recommended rate of administration for Moxidectin Oral Drench for Sheep is 1 mL per 11 lb (1 mL per 5 kg) body weight into the mouth of sheep, using any standard drenching equipment.

K. Route of Administration

Oral

L. Species/Class

Sheep

M. Indications

Moxidectin Oral Drench for Sheep, when administered at the recommended dose level of 0.2 mg moxidectin/2.2 lb (0.2 mg/kg) body weight, is effective in the treatment and control of adult and larval (L₄) stages of the following internal parasites of sheep:

Parasites

Haemonchus contortus - Adult and L₄

Teladorsagia circumcincta - Adult and L₄

Teladorsagia trifurcata - Adult and L₄

Trichostrongylus axei - Adult and L₄

Trichostrongylus colubriformis - Adult and L₄

Trichostrongylus vitrinus - Adult and L₄

Cooperia curticei - Adult and L₄

Cooperia oncophora - Adult and L₄

Oesophagostomum columbianum - Adult and L₄

Oesophagostomum venulosum - Adult and L₄

Nematodirus battus - Adult and L₄

Nematodirus filicollis - Adult and L₄

Nematodirus spathiger - Adult and L₄

N. Reference Listed New Animal Drug (RLNAD)

CYDECTIN™; moxidectin; NADA 141-247; 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, First Priority, Inc., was granted a biowaiver for the generic product Moxidectin Oral Drench for Sheep (moxidectin). The generic drug product is a 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) oral drench for sheep, sponsored by Elanco US Inc., under NADA 141-247, and was approved for use in sheep on November 30, 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 sheep:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residue 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 parts *per billion* (ppb) is established for moxidectin (the marker residue) in sheep fat (the target tissue), 200 ppb in sheep liver, and 50 ppb in sheep muscle, under 21 CFR 556.426.

B. Withdrawal Period

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 is that previously assigned to the RLNAD product. A withdrawal period of 7 days has been established for moxidectin drench for sheep in sheep.

C. Analytical Method for Residues

The validated analytical methods for analysis of residues of moxidectin are 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 Moxidectin Oral Drench for Sheep:

Not for use in humans. Keep this and all drugs out of the reach of children.

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 Moxidectin Oral Drench for Sheep, 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 sheep treated with Moxidectin Oral Drench for Sheep will not represent a public health concern when the product is used according to the label.