Date of Approval: December 13, 2023

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-348

ECOMECTIN CATTLE POUR-ON

(ivermectin topical solution)

Topical solution

Beef cattle and dairy cattle (except dairy cows)

Provides for updates to the persistent activity statement: ECOMECTIN CATTLE POUR-ON (ivermectin topical solution) has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia surnabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

Sponsored by:

Huvepharma EOOD

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I. GENERAL INFORMATION

A. File Number

ANADA 200-348

B. Sponsor

Huvepharma EOOD
5th Floor
3A Nikolay Haytov Str.
1113 Sofia, Bulgaria

Drug Labeler Code: 016592

C. Proprietary Name

ECOMECTIN CATTLE POUR-ON

D. Drug Product Established Name

ivermectin topical solution

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Topical solution

G. Amount of Active Ingredient

5 mg/mL

H. How Supplied

1 L, 4 L, 10 L, and 20 L containers

I. Dispensing Status

Over the counter (OTC)

J. Dosage Regimen

There were no changes to the dosage regimen as a result of this supplemental approval.

K. Route of Administration

Topical

L. Species/Class

Beef cattle and dairy cattle (except dairy cows)

M. Indications

PERSISTENT ACTIVITY
ECOMECTIN CATTLE POUR-ON (ivermectin topical solution) has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for 28 days after treatment; *Cooperia punctata* and *Trichostrongylus axei* for 21 days after treatment; *Ostertagia ostertagi*, *Haemonchus placei*, *Cooperia oncophora* and *Cooperia surnabada* for 14 days after treatment; *Damalinia bovis* for 56 days after treatment.

N. Reference Listed New Animal Drug (RLNAD)

ivomec®; ivermectin topical solution; NADA 140-841; Boehringer Ingelheim Animal Health USA, Inc.

O. Effect of Supplement

This supplement provides for updates to the labeling including revisions of trade dress to reflect a change in ownership, as well as revisions to the adverse event statement, manufactured for statement and applicator gun language. The supplement also provides multiple changes to the labeling to align with the RLNAD labeling, including presentation of the established name, addition of the Office of Surveillance and Compliance requested antiparasitic language, and updating the persistent activity indications.

II. BIOEQUIVALENCE

CVM did not require additional bioequivalence information for this supplemental approval. The FOI Summary for the original approval of ANADA 200-348, dated November 15, 2002, contains a summary of the basis for granting a biowaiver for ECOMECTIN CATTLE POUR-ON (ivermectin topical solution) for cattle.

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 cattle:

A. Acceptable Daily Intake and Tolerances for Residues

The acceptable daily intake (ADI) for total residues of ivermectin is 5 µg/kg of body weight per day. The tolerances established for the RLNAD apply to the generic product. The tolerance for 22,23-dihydroavermectin B_{1a} (the marker residue) is 1.6 parts per million in liver (the target tissue), and 650 parts per billion in muscle under 21 CFR 556.344.

B. Withdrawal Period

Because a biowaiver was granted, the withdrawal period is that previously assigned to the RLNAD product. A withdrawal period of 48 days has been established for ivermectin topical solution in cattle.

C. Analytical Method for Residues

The validated analytical method for analysis of residues of ivermectin topical solution 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 ECOMECTIN CATTLE POUR-ON:

WARNING
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 Huvepharma, Inc. at 1-877-994-4883 or www.huvepharma.us. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

WARNING! FLAMMABLE!
KEEP AWAY FROM HEAT, SPARKS, OPEN FLAME,
AND OTHER SOURCES OF IGNITION.

This product should not be applied to self or others because it may be irritating to human skin and eyes and absorbed through the skin. To minimize accidental skin contact, the user should wear a long-sleeved shirt and rubber gloves. If accidental skin contact occurs, wash immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water and seek medical attention.

V. AGENCY CONCLUSIONS

The information submitted in support of this supplemental ANADA satisfy the requirements of section 512(c)(2) of the Federal Food, Drug, and Cosmetic Act. The data demonstrate that ECOMECTIN CATTLE POUR-ON, when used according to the label, is safe and effective for the effect of supplement in the General Information Section above.

Additionally, data demonstrate that residues in food products derived from beef cattle and dairy cattle (except dairy cows) treated with ECOMECTIN CATTLE POUR-ON will not represent a public health concern when the product is used according to the label.