Date of Approval: September 21, 2011

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-318

BIMECTIN Pour-On

(ivermectin)

Pour-on

Cattle

Effects of Supplement is to approve the proprietary name BIMECTIN Pour-On and updates to the persistent activity statement as follows: BIMECTIN (ivermectin) Pour-On has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparous* 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:

Cross Vetpharm Group Ltd.

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I. GENERAL INFORMATION:

A. File Number:	ANADA 200-318
B. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Rd., Tallaght, Dublin 24, Ireland Drug Labeler Code: 061623 U.S. Agent: Ms. Linda Duple Bimeda, Inc. 2836 Dolliver Park Avenue Lehigh, IA 50557
C. Proprietary Name(s):	BIMECTIN Pour-On
D. Established Name(s):	Ivermectin
E. Pharmacological Category:	Antiparasitic
F. Dosage Form(s):	Solution
G. Amount of Active Ingredient(s):	5 mg/mL
H. How Supplied:	Squeeze-Measure-Pour System: 33.8 fl. oz/1 liter with a measure-pour system BackPack: 84.5 fl. oz/2.5 liter pack, 169 fl. oz/5 liter pack intended for use with appropriate automatic dosing equipment Free Standing Bottle: 338 fl. oz/10 liter bottle intended for use with appropriate automatic dosing equipment
I. How Dispensed:	OTC
J. Dosage(s):	1 mL/22 lb of body weight
K. Route(s) of Administration:	Topical
L. Species/Class(es):	Cattle
M. Indication(s):	BIMECTIN (ivermectin) Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective treatment and

control of these parasites.

Gastrointestinal Roundworms
Ostertagia ostertagi (adults and L4) (including inhibited stage)
Haemonchus placei (adults and L4)
Trichostrongylus axei (adults and L4)
T. colubriformis (adults and L4)
Cooperia oncophora (adults and L4)
Cooperia punctata (adults and L4)
Cooperia surnabada (adults and L4)
Strongyloides papillosus (adults)
Oesophagostomum radiatum (adults and L4)
Trichuris spp. (adults)

Lungworms
Dictyocaulus viviparus (adults and L4)

Cattle Grubs (parasitic stages)
Hypoderma bovis
H. lineatum

Mites
Sarcoptes scabiei var. *bovis*

Lice
Linognathus vituli
Haematopinus eurysternus
Damalinia bovis
Solenopotes capillatus

Horn Flies
Haematobia irritans

Persistent Activity:
BIMECTIN (ivermectin) Pour-On has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparous* 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 Pour-On; ivermectin; NADA 140-841; Merial Ltd.

O. Effect(s) of Supplement: This supplement provides for approval of the proprietary name BIMECTIN Pour-On and updates to the persistent activity statement to be consistent with the RLNAD as follows: BIMECTIN (ivermectin) Pour-On has been proved to effectively control infections and to protect cattle from re-infection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparous* 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.

II. BIOEQUIVALENCE:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act of 1988, an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (reference listed new animal drug). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, 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. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Cross Vetpharm Group Ltd., was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product BIMECTIN (ivermectin) Pour-On. The generic product is administered as 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 absorption of the active ingredient. The RLNAD is IVOMEC Pour-On, sponsored by Merial Ltd., NADA 140-841, and was approved for use in cattle on December 4, 1990.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this supplemental approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this supplemental approval.

V. HUMAN FOOD SAFETY:

The following are assigned to this product for cattle:

- **Tolerances for Residues:**
  The tolerance established for the pioneer product applies to the generic product. A tolerance of 100 parts per billion (ppb) and 10 ppb is established for 22, 23-dihydroavermectin B_1a (marker residue) residues in the liver and muscle, respectively, of cattle under 21 CFR 556.344. The acceptable daily intake (ADI) for total residues of ivermectin is 1 microgram per kilogram of body weight per day.

- **Withdrawal Times:**
  Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

  A withdrawal period of 48 days has been established for ivermectin in cattle.

- **Regulatory Method for Residues:**
  The validated regulatory method for the determination and confirmation of residues of ivermectin is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

VI. USER SAFETY:

CVM did not require user safety studies for this supplemental approval.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfy the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that BIMECTIN Pour-On, when used according to the label, is safe and effective for the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi)*, lungworms, grubs, horn flies, sucking and biting lice and sarcoptic mange mites in cattle.