

Date of Approval: September 13, 2004

FREEDOM OF INFORMATION SUMMARY

AN ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-272

NOROMECTIN (ivermectin) Pour-On for Cattle

NOROMECTIN (ivermectin) Pour-On for Cattle when applied at the recommended dose of 500 mcg/kg is indicated for the effective control and treatment of gastrointestinal roundworms (including *Ostertagia ostertagi*) lungworms, grubs, hornflies, sucking and biting lice, and sarcoptic mange mites in cattle.

Sponsored by:

**Norbrook Laboratories, Ltd.
Station Works
Newry BT35 6JP
Northern Ireland**

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-272
- b. Sponsor: Norbrook Laboratories, Ltd.
Station Works
Newry BT35 6JP
Northern Ireland
- Drug Labeler Code: 055529
- c. Established Name: Ivermectin
- d. Proprietary Name: NOROMECTIN Pour-On for Cattle
- e. Dosage Form: Pour-On
- f. How Supplied: 33.8 fl oz / 1L, 84.5 fl oz / 2.5 L and 169 fl oz / 5L collapsible pack with pour-on applicator gun or as a replacement pack and 676 fl oz / 20 L container with draw-off device and applicator gun.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each milliliter (mL) of solution contains 5 milligrams (mg) of ivermectin
- i. Route of Administration: Topical, on the dorsal midline, withers to tail head.
- j. Species/Class: Cattle
- k. Recommended Dosage: 500 mcg/kg (1 mL for each 22 lb of bodyweight)
- l. Pharmacological Category: Parasiticide
- m. Indications: NOROMECTIN Pour-On for Cattle applied at the recommended dose level of 500 mcg/kg is indicated for the effective control of these parasites.

Gastrointestinal Roundworms

Ostertagia ostertagi (adults and L₄) (including inhibited stage)

Haemonchus placei (adults and L₄)

Trichostrongylus axei (adults and L₄)

Trichostrongylus colubriformis (adults and L₄)

Cooperia spp. (adults and L₄)

Oesophagostomum radiatum (adults and L₄)

Strongyloides papillosus (adults)

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:

NOROMECTIN Pour-On for Cattle has proven to effectively control infections and protect cattle from reinfection with *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata*, and *Cooperia oncophora* for 14 days after treatment.

n. Pioneer Product:

IVOMEC Pour-on for Cattle; ivermectin;

NADA 140-841; Merial Ltd.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

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

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, 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 Guidance, revised October 9, 2003).

Based on the formulation characteristics of the generic product, Norbrook Laboratories Ltd. was granted a waiver from the requirement for an *in vivo* bioequivalence study for NOROMECTIN (ivermectin) Pour-On for Cattle. The generic product is administered as pour-on (topical) contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product IVOMEK (ivermectin) Pour-on for Cattle, the subject of Merial Ltd's NADA 140-841, was approved on December 4, 1990.

3. HUMAN SAFETY:

- **Tolerance:**

The tolerance established for the pioneer product applies to the generic product. A tolerance is established for 22, 23-dihydroavermectin B_{1a} (marker residue) in tissues of liver (target tissue) in cattle at 100 parts per billion under 21 CFR 556.344. Muscle residues are not indicative of the safety of other edible tissues. A tolerance is established for 22, 23-dihydroavermectin B_{1a} (marker residue) in tissues of muscle in cattle at 10 parts per billion under 21 CFR 556.344.

- **Withdrawal Times:**

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

The withdrawal time is 48-days.

- **Regulatory Methods for Residues:**

The analytical method for the detection of residues in tissues is the HPLC method with fluorescence detection. This method is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855. An analytical method was developed for determination of the marker residue in bovine tissues by the Analytical Laboratory, PPD Development. A bridging study was conducted comparing the PPD method to the regulatory method and both methods were demonstrated to be comparable.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that NOROMECTIN (ivermectin) Pour-On for Cattle when used under its proposed conditions of use, is safe and effective for its labeled indications

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Pioneer Labeling for NADA 140-841

IVOMEK pour-on for cattle (ivermectin), Package Insert
IVOMEK pour-on for cattle (ivermectin), 250 mL Bottle Label
IVOMEK pour-on for cattle (ivermectin), 250 mL Carton Label
IVOMEK pour-on for cattle (ivermectin), 1 Liter Container Label
IVOMEK pour-on for cattle (ivermectin), 1 Liter Package insert
IVOMEK pour-on for cattle (ivermectin), 2.5 Liter Container Label
IVOMEK pour-on for cattle (ivermectin), 2.5 Liter Container Carton Label
IVOMEK pour-on for cattle (ivermectin), 2.5 Liter Container Package Insert
IVOMEK pour-on for cattle (ivermectin), 5 Liter Container Label
IVOMEK pour-on for cattle (ivermectin), 5 Liter Carton Label
IVOMEK pour-on for cattle (ivermectin), 5 Liter Container Package Insert

Generic Labeling for ANADA 200-272

NOROMECTIN (ivermectin) Pour-On for Cattle, Package Insert
NOROMECTIN (ivermectin) Pour-On for Cattle, 33.8 fl oz (1 L), Label
NOROMECTIN (ivermectin) Pour-On for Cattle, 33.8 fl oz (1L), Carton Label
NOROMECTIN (ivermectin) Pour-On for Cattle, 33.8 fl oz (1L), Carton Label with applicator gun
NOROMECTIN (ivermectin) Pour-On for Cattle, 84.5 fl oz (2.5 L) Label
NOROMECTIN (ivermectin) Pour-On for Cattle, 84.5 fl oz (2.5 L) Carton Label
NOROMECTIN (ivermectin) Pour-On for Cattle, 84.5 fl oz (2.5 L) Carton Label with applicator gun
NOROMECTIN (ivermectin) Pour-On for Cattle, 169 fl oz (5 L) Label
NOROMECTIN (ivermectin) Pour-On for Cattle, 169 fl oz (5L) Carton Label
NOROMECTIN (ivermectin) Pour-On for Cattle, 169 fl oz (5L) Carton Label with applicator gun
NOROMECTIN (ivermectin) Pour-On for Cattle, 680 fl oz (20 L) Label
Simcro Applicator Pour-on/Drencher (30 mL) instructions