

Date of Approval: Dec 28, 2000

FREEDOM OF INFORMATION SUMMARY

ANADA 200-299

Indication for use: Ivermectin Pour-On
applied at the recommended dose level of 500mcg/kg
is indicated for the effective control and treatment of these parasites.

Sponsored by:

Med-Pharmex, Inc.
2727 Thompson Creek Road
Pomona, CA 91767-1861

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA: 200-299

Sponsor: Med-Pharmex, Inc.
2727 Thompson Creek Road
Pomona, CA 91767-1861

Generic Name: Ivermectin Topical Liquid

Trade Name: Ivermectin Pour-On for Cattle

Dosage Form: Topical Solution

How Supplied: 8.5 fl oz/250 mL, 33.8 fl oz/1 L, 84.5 fl oz/2.5 L and 3.785 L (1 gallon) Bottles & 169 fl oz/5 L collapsible pack

How Dispensed: OTC

Amount of Active Ingredients: 5 mg/mL

Route of Administration: Topical, on the dorsal midline, withers to tailhead

Species: Cattle

Labeled Dosage: 500 mcg/kg (1 mL/22 lbs) body weight

Indications for Use: Ivermectin Pour-On applied at the recommended dose level of 500mcg/kg is indicated for the effective control and treatment 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 spp. adults and L₄)

Strongyloides papillosus (adults)

Oesophagostomum radiatum (adults and L₄)

O. venulosum (adults only)

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

It is also used to control infections of gastrointestinal roundworms: *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment.

Pioneer Product/
“Listed 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, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April, 1996).

Based upon the formulation characteristics of the generic product, Med-Pharmex, Inc. was granted a waiver on May 11, 1998, from conducting an *in vivo* bioequivalence study for Ivermectin Pour-On for Cattle. The generic and pioneer products contain the same active and inactive ingredients and are topical solutions.

3. HUMAN FOOD SAFETY:

TOLERANCE:

The tolerances established for the pioneer product apply to the generic product. The marker residue used to monitor the total residues of ivermectin and its metabolites is 22,23-dihydroavermectin B_{1a}. The target tissue is liver. A tolerance is established for 22,23-dihydroavermectin B_{1a} in liver (target tissue) as follows:

- (i) Cattle: 100 parts per billion [21 CFR 556.344(b)]

A tolerance is established for 22,23-dihydroavermectin B_{1a} (marker residue) in muscle as follows:

- (ii) Cattle: 10 parts per billion [21 CFR 556.344(b)]

WITHDRAWAL TIME

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for ivermectin pour-on is established under 21 CFR 524.1193(e)(3) - 48 days in cattle.

REGULATORY METHODS FOR RESIDUES

The official analytical method for residues is an HPLC method with fluorescence detection. [The validated regulatory analytical methods for detection of residues of ivermectin are filed in the Food Additives analytical Manual on display in FDA's Freedom of Information Public Room (Room 12A-30, 5600 Fisher's Lane, Rockville, MD 20857) and are on file at the Center for Veterinary Medicine, FDA 7500 Standish Place, Rockville, MD 20855]

HUMAN SAFETY RELATIVE TO POSSESSION, HANDLING, AND ADMINISTRATION:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This is an Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Ivermectin Pour-On for Cattle were established by demonstration of chemical equivalence to the pioneer product, Merial Limited's Ivomec[®] Pour-On for Cattle (NADA 140-841).

This generic product and the pioneer product have identical labeling indications for use in cattle. The route and method of administration of the two drugs are identical. Both drugs are administered topically. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy promulgated to implement section 512(b)(2) of FFD&C Act, no *in vivo* bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Ivermectin Pour-On for Cattle is safe and effective for its labeled indications when used under its proposed conditions of use.

Attachments:

1. Generic Labeling:

Package Insert

Bottle Label

2. Pioneer Labeling

Package Insert

Bottle Label