Date of Approval Letter: November 15, 2002

FREEDOM OF INFORMATION SUMMARY

ANADA 200-348

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

Sponsored by:

ECO LLC
8209 Hollister Avenue
Las Vegas, NV 89131

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA:	200-348
Sponsor:	ECO LLC 8209 Hollister Avenue Las Vegas, NV 89131
Generic Name:	Ivermectin Topical Liquid
Trade Name:	ECOMECTIN Cattle Pour-On (ivermectin)
Dosage Form:	Topical Solution
How Supplied:	250 ml, 2.5 L, 5 L and 18.9L (5 gallon) containers
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 (including inhibited stage)	(adults and L_4)
Haemonchus placei	(adults and L_4)
Trichostrongylus axei	(adults and L_4)
T. colubriformis	(adults and L_4)
Cooperia spp.	adults and L_4)
Strongyloides papillosus	(adults)
Oesophagostomum radiatum	(adults and L_4)

O. venulosum	(adults only)
Trichuris spp.	(adults)
Lungworms	
Dictyocaulus viviparus	(adults and L_4)
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 irritants	

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.

Ordinarily, the ANADA Sponsor shows that the generic product is bioequivalent to the pioneer which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical end-point 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 requirement of an in vivo bioequivalence study (55 FR 24645, June 18,1990; Fifth GADPTRA Policy Letter; Bioequivalence Guidance October, 2000).

Based on the formulation characteristics of the generic product, ECO LLC was granted a waiver on April 7, 2000, 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 SAFETY:

TOLERANCES:

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 METHOD 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 ECOMECTIN Cattle Pour-On (ivermectin) is safe and effective for its labeled indications when used under it proposed conditions of use.

Attachments:

1. Generic Labeling:

   Package Insert

   Bottle Labels-250mL, 2.5L, 5L, 18.9L (5 gal.)

2. Pioneer Labeling

   Package Insert

   Bottle Label-250 mL, 1L, 2.5L, 5L