Date of Approval: Sept. 21, 2001

FREEDOM OF INFORMATION SUMMARY

ANADA 200-318

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

Sponsored by:

Virbac AH, Inc.
3200 Meacham Blvd.
Fort Worth, TX 76137

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA:	200-318
Sponsor:	Virbac AH, Inc. 3200 Meacham Blvd. Fort Worth, TX 76137
Generic Name:	Ivermectin Topical Liquid
Trade Name:	Virbamec™ Pour-On for Cattle
Dosage Form:	Topical Solution
How Supplied:	8.5 fl oz/250 mL, 16 fl oz/500mL, 33.8 fl oz/1 L, 84 fl oz/2.5 L, 169 fl oz/5 L collapsible pack
How Dispensed:	OTC
Amount of Active Ingredients:	5 mg of ivermectin/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:	Verbamec™ Pour-On applied at the recommended dose level of 500 mcg/kg is indicated for the effective control and treatment of these parasites in cattle.

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 viviparous	(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/	Ivomec® Pour-On for Cattle (Ivermectin)
"Listed Product:	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, October, 2000).

Based upon the formulation characteristics of the generic product, Virbac AH, Inc. was granted a waiver on February 21, 2000, from conducting an *in vivo* bioequivalence study for Virbamec™ Pour-On for Cattle. The generic and pioneer products contain the same active and inactive ingredients and are topical solutions.

3. HUMAN FOOD SAFETY:

TOLERANCES:

The tolerances established for the pioneer product apply to the generic product. The acceptable daily intake for total residues of ivermectin is 1 microgram per kilogram of body weight per day. 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 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 Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal, Food, Drug and Cosmetic (FFD&C) Act satisfies the requirements of section 512(n) of the Act and demonstrates that Virbamec™ Pour-On for Cattle is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments:

Pioneer Labeling:

Package Insert

Bottle Labels:

8.5 fl oz/250 mL, 33.8 fl oz/1 L

Generic Labeling:

Package Insert

Bottle Labels:

8.5 fl oz/250 mL, 16 fl oz/500mL, 33.8 fl oz/1 L,

84 fl oz/2.5 L, 169 fl oz/5 L collapsible pack

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.