Date of Approval: March 26, 2010

FREEDOM OF INFORMATION (FOI) SUMMARY

SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-340

PRIVERMECTIN Pour-On for Cattle
(ivermectin)

Topical Solution

Effect of Supplement: This supplement provides for adding; Material Safety Data Sheet (MSDS) information, removing the black box around the residue warning statement, adding the statement "Restricted Drug (California)-Use Only as Directed," and adding the following under the persistent activity section: "PRIVERMECTIN Pour-On has been proved to effectively control infections and to protect cattle from reinfection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* 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:
First Priority, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-340
b. Sponsor:	First Priority, Inc. 1590 Todd Farm Dr. Elgin, IL 60123 Drug Labeler Code: 058829
c. Established Names:	Ivermectin
d. Proprietary Names:	PRIVERMECTIN Pour-On for Cattle
e. Dosage Form:	Topical solution
f. How Supplied:	250 mL, 1 liter and 1 gallon bottle for use with measuring cup; 2.5 liter, 5 liter and 5 gallon container for use with the appropriate automatic dosing applicator.
g. How Dispensed:	Over-the Counter (OTC)
h. Amount of Active Ingredients:	5 mg/mL
i. Route of Administration:	Topical; on the dorsal midline; withers to tailhead
j. Species/Class:	Cattle
k. Recommended Dosage:	500 mcg/kg (1 mL/22 lbs) body weight
l. Pharmacological Category:	Antiparasitic
m. Indications:	Privermectin® Pour-On for Cattle applied at the recommended dose level of 500 mcg/kg is indicated for the effective control and treatment of these parasites. **Gastrointestinal Roundworms** *Ostertagia ostertagi* (adults and L_4) (including inhibited stage) *Haemonchus placei* (adults and L_4) *Trichostrongylus axei* (adults and L_4)

T. colubriformis	(adults and L_4)
Cooperia oncophora.	(adults and L_4)
Cooperia punctata	(adults and L_4)
Cooperia surnabada	(adults and L_4)
Strongyloides papillosus	(adults)
Oesophagostomum radiatum	(adults and L_4)
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 irritans	

Persistent Activity
Privermectin® Pour-On for Cattle (ivermectin) has been proved to effectively control infections and to protect cattle from reinfection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* 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. Pioneer Product: IVOMEC Pour-On for Cattle; ivermectin; NADA 140-841; Merial Ltd.

o. Effect of Supplement: This supplement provides for adding the Material Safety Data Sheet (MSDS) information, removing black box around the residue warning statement, adding the statement “Restricted Drug

(California)-Use Only as Directed," and adding the following persistent activity section: "PRIVERMECTIN Pour-On has been proved to effectively control infections and to protect cattle from reinfection with: *Oesophagostomum radiatum* and *Dictyocaulus viviparus* 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."

2. TARGET ANIMAL SAFETY AND 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 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 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 Guideline, October 2000).

Based on the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product PRIVERMECTIN (ivermectin) Pour-On for Cattle. The generic product is administered as a topical solution, 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 IVOMEC (ivermectin) Pour-On for Cattle, the subject of Merial Ltd., NADA 140-841, was approved on December 4, 1990.

3. HUMAN SAFETY:

- **Tolerances for Residues:**
  The tolerances established for the pioneer product apply to the generic product. A tolerance of 100 parts per billion is established for 22,23-dihydroavermectin B_1 a. (marker residue) in the uncooked edible tissues of liver and 10 parts per billion for

22,23-dihydroavermectin $B_{1}a$ (marker residue) in uncooked edible tissues of muscle 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 Method for Residues:**
  The analytical method for detection of residues in tissues is an HPLC method with fluorescence detection. This method is found on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This supplemental ANADA filed under section 512(b) (2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that PRIVERMECTIN 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 follows:

Generic Labeling for ANADA 200-340:
Package outsert

Pioneer Labeling for NADA 140-841:
Package outsert