Date of Approval Letter: May 16, 2001

Supplemental ANADA 200-219

FREEDOM OF INFORMATION SUMMARY

The supplement provides for the addition of the persistent activity claims.

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
P.O. Box 8039
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA:	200-219
Sponsor:	Phoenix Scientific, Inc. 3915 South 48th Street Terrace P.O. Box 6457 St. Joseph, MO 64506-0457
Generic Name:	Ivermectin Topical Liquid
Trade Name:	Phoenectin™ Pour-On for Cattle
Dosage Form:	Topical Solution
How Supplied:	250 mL, 500 mL, 1 L, 3.785 L (1 gallon) Bottles 5 L & 25 L
How Dispensed:	OTC
Amount of Active Ingredients:	5 mg/mL ivermectin
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)

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	

Phoenectin™ Pour-On has been proved to effectively control infections and to protect cattle from re-infection with *Ostertagia 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). Phoenix Scientific, Inc. is supplementing their ANADA for the addition of the persistent activity claims. Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on from conducting an *in vivo* bioequivalence study with Ivermectin® Pour-On for Cattle. The generic product was approved on July 6, 1998. The three-year exclusivity period for the additional claims granted to the pioneer product ended on June 4, 2000. No new data was required for the additional new claims.

3. HUMAN FOOD SAFETY:

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(d)(3) - 48 days in cattle. Therefore, no human food safety information is required for the approval of the supplement.

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.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change providing for the addition of new claims to the previous approved label. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

Attachments:

1. Generic Labeling:

   Package Insert

   Bottle Label

2. Pioneer Labeling

   Package Insert

   Bottle Label