Approval Date: July 6, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-219

B. Sponsor

I Phoenix Scientific, Inc.
3915 South 48th Street Terrace
P.O. Box 6457
St. Joseph, MO 64506-0457

C. Proprietary Name

Phoenectin™ Pour-On for Cattle

D. Established Name

Ivermectin Topical Liquid

E. Reference Listed New Animal Drug

Merial's Ivomec® Pour-On for Cattle (NADA 140-841)

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

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 approval is based on a demonstration that the generic product is bioequivalent to the pioneer product.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter: 55 FR 24645, June 18, 1990; Bioequivalence Guidance: 61 FR 26182 - 26186, May 24, 1996).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for Phoenectin™ Pour-On. The generic and pioneer products contain the same active and inactive ingredients and are topical solutions.

III. HUMAN FOOD SAFETY

A. 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 as follows: Cattle: 100 parts per billion [21 CFR 556.344(a)]

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(d)(3) - 48 days in cattle.

C. REGULATORY METHODS FOR RESIDUES

The official analytical methods 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 Manual on display in FDA's Freedom of Information Public Room (Room 12A-30, 5600 Fisher's Lane, Rockville, MD 20857).]

D. HUMAN SAFETY RELATIVE TO POSSESSION, HANDLING, AND ADMINISTRATION

Labeling contains adequate caution/warning statements.

IV. 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, Phoenectin™ Pour-On, were established by demonstration of chemical equivalence to the pioneer product, Merial'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 Phoenectin TM Pour-On, is safe and effective for its labeled indications when used under it proposed conditions of use.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.