Approval Date: June 5, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-202

B. Sponsor

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

C. Proprietary Name

Phoenectin™ Liquid for Horses

D. Established Name

Ivermectin Oral Liquid

E. Dosage Form

Oral Solution

F. Amount of Active Ingredient

Each packet contains lincomycin hydrochloride equivalent to 16 g of lincomycin

G. How Supplied

100 mL bottles

H. Dispensing Status

Rx

I. Amount of Active Ingredient

10.0 mg/mL

J. Dosage

200 mcg/kg of body weight (1 mL/110 lb (50 kg) body weight)

K. Route of Administration

Orally

L. Species/Class

Horses

M. Indication

Phoenectin™ (ivermectin) Liquid is indicated for the effective treatment and control of the following parasites or parasitic conditions in horses:

1. Large Strongyles:

Strongylus vulgaris (adults and arterial larval stages), S.edentatus (adults and tissue stages), S.equinus (adults), Triodontophorus spp (adults)

2. Small Strongyles - including those resistant to some benzimidizole class compounds (adults and fourth-stage larvae):

Cyanthostomum spp, Cylicocyclus spp, Cylicostephanus spp, Cylicodontophorus spp,

3. Pinworms

(adults and fourth-stage larvae), Oxyuris equi

4. Ascarids

(adults and third- and fourth-stage larvae), Parascris equorum

5. Hairworms

(adults): Trichostrongylus axei

6. Large-mouth Stomach Worms

(adults): Habronema muscae

7. Bots

(oral and gastric stages): Gastrophilus spp

8. Lungworms

(adults and fourth-stage larvae): Dictyocaulus arnfieldi

9. Intestinal Threadworms

(adults): Strongyloides westeri

10. Summer Sores

caused by Habronema and Draschia spp cutaneous third-stage larvae.

11. Dermatitis

caused by neck threadworm microfilariae, Onchocerca spp.

N. Pioneer Product

Eqvalan® Liquid for Horses (Ivermectin), NADA 140-439 (Merial Ltd.)

II. 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 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™ Liquid. The generic and pioneer products contain the same active and inactive ingredients and are oral solutions.

III. HUMAN FOOD SAFETY

A. Human Safety Relative to Food Consumption

None required as Phoenectin™ Liquid is intended for use only in horses. The labeling includes the statement, "WARNING: Dot not use in horses intended for food purposes."

B. 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™ Liquid, were established by demonstration of chemical equivalence to the pioneer product, Eqvalan® Liquid for Horses (NADA 140-439, Merial Ltd).

This generic product and the pioneer product have identical labeling indications for use in horses. The route and method of administration of the two drugs are identical. Both drugs are administered orally. The generic and pioneer products contain the same active and inactive ingredients. Therefore, in compliance with FDA policy implementing section 512(b)(2) of FFD&C Act in vivo bioequivalency studies were not necessary nor required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Phoenectin™ Liquid, 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.