Approval Date: December 18, 2008

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-286

B. Sponsor

IVX Animal Health, Inc.
3915 South 48th Street Ter.
St. Joseph, MO 64503

Drug Labeler Code: 059130

C. Proprietary Name

PHOENECTIN Paste 1.87%

D. Established Name

Ivermectin

E. Pharmacological Category

Antihelmintic and boticide

F. Dosage Form

Oral Paste

G. Amount of Active Ingredient

1.87% ivermectin

H. How Supplied

6.08 g and 7.30 g sizes in IVX-style and Sure-Grip style syringes

I. Dispensing Status

OTC

J. Dosage Regimen

Each syringe contains sufficient paste to treat five 1,250 lb horses or a total of 6,250 lb body weight at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) of body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.

K. Route of Administration

Oral

L. Species/Class

Horses, not for meat production

M. Indication

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. PHOENECTIN (ivermectin) Paste 1.87% provides effective treatment and control of the following parasites in horses**. Large Strongyles** (adults) – *Strongylus vulgaris* (also early forms in blood vessels), ***S. edentatus*** (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; **Small Strongyles** (adults, including those resistant to some benzimidazole class compounds) – *Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus* and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus* and *C. minutus*, and *Petrovinema poculatum*; **Small Strongyles** – Fourth-stage larvae; **Pinworms** (adults and fourth-stage larvae) – *Oxyuris equi*, **Ascarids** (adults and third-and fourth-stage larvae) – *Parascaris equorum*; **Hairworms** (adults) – *Trichostrongylus axei*; **Large-mouth Stomach Worms** (adults) – *Habronema muscae*; **Bots** (oral and gastric stages) – *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae) – *Dictyocaulus arnfieldi*; **Intestinal Threadworms** (adults) – *Strongyloides westeri*; **Summer Sores** caused by *Habronema* and *Draschia* spp. cutaneous third- stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

N. Effect of Supplement

This supplement requests the addition of labeling claims that are no longer protected by marketing exclusivity for the following parasite species: *Craterostomum acuticaudatum*, *Coronocyclus coronatus*, *Coronocyclus labratus* and *Petrovinema poculatum.*

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

Refer to the original Freedom of Information (FOI) Summary (ANADA 200-286, E-0002) dated September 20, 2000, for more detail.

III. HUMAN FOOD SAFETY

This drug is intended for use in horses, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human warnings are provided on the product label as follows: “Not for use in humans. **Keep this and all drugs out of the reach of children.** Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes.

IV. AGENCY CONCLUSIONS

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that

PHOENECTIN Paste 1.87%, when used under the proposed conditions of use, is safe and effective for its labeled indications.

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.