Date of Approval: December 18, 2008

FREEDOM OF INFORMATION SUMMARY

Supplemental Abbreviated New Animal Drug Application

ANADA 200-286

PHOENECTIN Paste 1.87%
(ivermectin)
Oral Paste
Horses

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

Sponsored by:

IVX Animal Health, Inc.

FREEDOM OF INFORMATION SUMMARY

1. 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. Established Name:	Ivermectin
d. Proprietary Name:	PHOENECTIN Paste 1.87%
e. Dosage Form:	Oral Paste
f. How Supplied:	6.08 g and 7.30 g sizes in IVX-style and Sure-Grip style syringes
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	1.87% ivermectin
i. Route of Administration:	Oral
j. Species/Class:	Horses, not for meat production
k. Recommended Dosage:	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.
l. Pharmacological Category:	Antihelmintic and boticide
m. Indications:	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. Pioneer Product: EQVALAN Paste 1.87%; ivermectin; NADA 134-314; Merial Ltd.

o. 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.*

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

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

3. HUMAN 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.**"**

4. 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.

5. ATTACHMENTS:

Facsimile Generic Labeling and Currently Approved Pioneer Labeling are attached as indicated below:

Generic Labeling:
Syringe label; package insert; carton label; display tray

Pioneer Labeling:
Syringe label; package insert; carton label