Approval Date: February 24, 2009

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-228

B. Sponsor

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

Drug Labeler Code: 059130

C. Proprietary Name

PHOENECTIN (ivermectin) Injection

D. Established Name

Ivermectin

E. Pharmacological Category

Antiparasitic

F. Dosage Form

Sterile injectable solution

G. Amount of Active Ingredient

1% ivermectin

H. How Supplied

50 mL, 200 mL, 500 mL and 1,000 mL bottles

I. Dispensing Status

OTC

J. Route of Administration

Subcutaneous

K. Species/Class

Cattle, Swine, Reindeer, American Bison.

L. Recommended Dosage

Cattle: PHOENECTIN Injection should be given only by subcutaneous injection under the loose skin in front of or behind the shoulder at the recommended dose

level of 200 mcg ivermectin per kilogram of body weight. Each mL of PHOENECTIN contains 10 mg of ivermectin, sufficient to treat 110 lb (50 kg) of body weight (maximum 10 mL per injection site.)

Swine: PHOENECTIN should be given only by subcutaneous injection in the neck of swine at the recommended dose level of 300 mcg ivermectin per kilogram (2.2 lb) of body weight. Each mL of PHOENECTIN contains 10 mg of ivermectin, sufficient to treat 75 lb of body weight.

M. Indication

Cattle: PHOENECTIN Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinal roundworms, lungworms, grubs, sucking lice and mange mites in cattle:

Gastrointestinal Roundworms(adults and fourth-stage larvae): Ostertagia ostertagi (including inhibited O. ostertagi), O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. pectinata, Oesophagostomum radiatum, Bunostomum phlebotomum, Nematodirus helvetianus (adults only), N. spathiger (adults only)

Lungworms (adults and fourth-stage larvae): *Dictyocaulus viviparous*

Cattle grubs (parasitic stages): *Hypoderma bovis, H. lineatum*

Sucking Lice: *Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus*

Mites (Scabies): *Psoroptes ovis* (syn. *P. communis var. bovis*), *Sarcoptes scabiei var. bovis*

Persistent Activity: PHOENECTIN Injection has been proved to effectively control infections and to protect cattle from reinfection with Dictyocaulus viviparous and Oesophagostomum radiatum for 28 days after treatment; Ostertagia ostertagi, Trichostrongylus axei and Cooperia punctata for 21 days after treatment; Haemonchus placei and Cooperia oncophora for 14 days after treatment.

Swine: PHOENECTIN Injection is indicated for the effective treatment and control of the following harmful species of gastrointestinalroundworms, lungworms, lice and mange mites in swine:

Gastrointestinal Roundworms: Large roundworm, *Ascaris sum*, (adults and fourth-stage larvae), Red stomach worm, *Hyostrongylus rubidus*, (adults and fourth-stage larvae), Nodular worm, *Oesophagostomum spp*., (adults and fourth-stage larvae), Threadworm, *Strongyloides ransomi* (adults)

Somatic Roundworm Larvae: Threadworm, *Strongyloides ransomi* (somatic larvae)

Sows must be treated at least seven days before farrowing to prevent infection in piglets.

Lungworms: *Metastrongylus spp*. (adults)

Lice: *Haematopinus suis*

Mange Mites: *Sarcoptes scabei var. suis*

N. Pioneer Product

Lincomix Soluble Powder, The Upjohn Company, NADA 111-636.

O. Effective of Supplement

This supplement provides for the extension of persistent activity claims against the following parasites that are no longer protected by marketing exclusivity: *Oesophagostomum radiatum* from 14 to 28 days after treatment, and persistent activity against *Trichostrongylus axei* and *Cooperia punctata* from 14 to 21 days after treatment. The Environmental Safety section has been updated by the addition of the sentences, "As with other avermectins, ivermectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects." The following has been added to the residue information section of the labeling: "A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal". All revisions are consistent with the information that appears on the reference product labeling.

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

Refer to the original Freedom of Information (FOI) Summary dated December 27, 2000, for more detail. No additional bioequivalence information is required for this supplemental approval.

III. HUMAN FOOD SAFETY

Refer to the original Freedom of Information (FOI) Summary dated December 27, 2000, for more detail. No additional human safety information is required for this supplemental approval.

IV. AGENCY CONCLUSIONS

This supplemental 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 Injection, 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.