

Date of Approval: February 24, 2009

## FREEDOM OF INFORMATION SUMMARY

Supplemental Abbreviated New Animal Drug Application

ANADA 200-228

IVOMEC Injection 1%  
(ivermectin)  
Injection  
Cattle and Swine

Effect of Supplement: This supplement provides for the updating of persistent activity claims that are no longer protected by marketing exclusivity for the following parasites: *Oesophagostomum radiatum* from 14 to 28 days after treatment, and *Trichostrongylus axei* and *Cooperia punctata* from 14 to 21 days after treatment.

Sponsored by:

IVX Animal Health, Inc.

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

- a. File Number: ANADA 200-228
- b. Sponsor: IVX Animal Health, Inc.  
3915 South 48<sup>th</sup> Street Ter.  
St. Joseph, MO 64503  
  
Drug Labeler Code: 059130
- c. Established Name: Ivermectin
- d. Proprietary Name: PHOENECTIN (ivermectin) Injection
- e. Dosage Form: Sterile injectable solution
- f. How Supplied: 50 mL, 200 mL, 500 mL and 1,000 mL bottles
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 1% ivermectin
- i. Route of Administration: Subcutaneous
- j. Species/Class: Cattle, Swine, Reindeer, American Bison.
- k. 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.
- l. Pharmacological Category: Antiparasitic

m. Indications:

**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 viviparus*

**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 viviparus* 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 gastrointestinal roundworms, lungworms, lice and mange mites in swine:

**Gastrointestinal Roundworms:**

Large roundworm, *Ascaris sum*  
(adults and fourth-stage larvae)  
Red stomach worm, *Hyostrogylus 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:

IVOMEK Injection 1%; ivermectin; NADA 128-409; Merial Ltd.

o. Effect 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.

**2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:**

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.

**3. HUMAN 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.

**4. 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.

**5. ATTACHMENTS:**

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

Generic Labeling:  
Bottle label; package outsert

Pioneer Labeling:  
Bottle label; package insert; carton with labeling