Date of Approval: December 17, 2004

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-386

Levamisole Hydrochloride Soluble Drench Powder

Anthelmintic for cattle and sheep

Levamisole Hydrochloride Soluble Drench Powder used to make a drench solution for oral administration to cattle and sheep which is effective against various internal parasites.

Sponsored by:

Phoenix Scientific, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-386
b. Sponsor:	Phoenix Scientific, Inc. 3915 South 48th St. Terrace St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Name:	Levamisole hydrochloride
d. Proprietary Name:	Levamisole Hydrochloride Soluble Drench Powder
e. Dosage Form:	Soluble powder
f. How Supplied:	1.8 oz (52 g) preprinted pouch 14.21 oz (403 g) bottle, water fill line indicated on label 21.34 oz (605 g) bottle, water fill line indicated on label
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	1.8 oz (52 g) preprinted pouch contains 46.8 grams of Levamisole hydrochloride activity 14.21 oz (403 g) bottle contains 362.7 grams of Levamisole hydrochloride activity 21.34 oz (605 g) bottle contains 544.5 grams of Levamisole hydrochloride activity
i. Route of Administration:	Oral
j. Species/Class:	Cattle and sheep
k. Recommended Dosage:	8 milligrams per kilogram (mg/kg) body weight as a drench, **Cattle -** Give 2 mL (milliliter) per 100 lb body weight. **Sheep-** Give 2 mL (milliliter) per 50 lb body weight
l. Pharmacological Category:	Anthelmintic

m. Indications:	Levamisole hydrochloride is a broad spectrum anthelmintic and is effective against the following adult nematode infections in cattle and sheep: **SHEEP:** **Stomach Worms**: *Haemonchus contortus, Trichostrongylus axei, Teladorsagia circumcincta.* **Intestinal Worms:** *Trichostrongylus colubriformis, Cooperia curticei, Nematodirus spathiger, Bunostomum trigonocephalum, Oesophagostomum columbianum, Chabertia ovina* **Lungworms:** *Dictyocaulus filaria* **CATTLE:** **Stomach Worms:** *Haemonchus placei, Ostertagia ostertagi, Trichostrongylus axei* **Intestinal Worms:** *Trichostrongylus longispicularis, Cooperia oncophora, Cooperia punctata, Nematodirus spathiger, Bunostomum phlebotomum, Oesophagostomum radiatum* **Lungworms:** *Dictyocaulus viviparus*
n. Pioneer Product:	LEVASOLE Soluble Drench Powder; Levamisole hydrochloride; NADA 112-051; Schering-Plough Animal Health Corp.

2. 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 (GADPTRA) of 1988, 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 and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA Sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2002).

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Levamisole Hydrochloride Soluble Drench Powder. The generic product is administered orally in drinking water, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product LEVASOLE (Levamisole hydrochloride) Soluble Drench Powder, the subject of Schering-Plough Animal Health Corp., NADA 112-051, was approved on December 23, 2003.

3. HUMAN SAFETY:

- **Tolerance**
  The tolerance established for the pioneer product applies to the generic product. A tolerance of 0.1 part per million is established for negligible residues of Levamisole hydrochloride in the edible tissues of cattle, sheep, and swine (21 CFR 556.350).

- **Withdrawal Times**
  When a waiver from the requirement of an *in* vivo bioequivalence study is granted, April 9, 2001, the withdrawal times are those previously assigned to the pioneer product. The withdrawal times for Levamisole Hydrochloride Soluble Drench Powder is established for cattle, 48 hours prior to slaughter (21 CFR 520.1242a(e)(1)(iii)). In sheep the withdrawal time established is 72 hours prior to slaughter (21 CFR 520.1242a(e)(2)(iii)).

- **Regulatory Method for Residues**
  A regulatory method is not required because one was not required for the pioneer products.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Levamisole Hydrochloride Soluble Drench Powder, when used under its 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 follows:

Generic Labeling for ANADA 200-386:
Levamisole Hydrochloride Drench Powder;
1.8 oz (52 g) preprinted pouch
14.21 oz (403 g) bottle, water fill line indicated on label
21.34 oz (605 g) bottle, water fill line indicated on label

Pioneer Labeling for NADA 112-051:
LEVASOLE Soluble Drench Powder;
21.34 oz (605 g) preprinted pouch
1.8 oz (52 g) preprinted pouch