

Date of Approval Letter: October 25, 2002

FREEDOM OF INFORMATION SUMMARY

ANADA 200-313

Levamisole Hydrochloride Soluble Pig Wormer

Indication for use: A broad spectrum anthelmintic
Effective against nematode infections in swine.

Sponsored by:

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1 GENERAL INFORMATION

ANADA 200-313

ANADA/GENERIC SPONSOR:

Phoenix Scientific, Inc.
3915 South 48th Street Terrace
St. Joseph, MO 64503

- a. **Established Name:** Levamisole Hydrochloride
- b. **Trade Name/Proprietary Name:** Levamisole Hydrochloride Soluble Pig Wormer
- c. **Dosage Form:** Soluble Powder
- d. **How Supplied:** Levamisole Hydrochloride Soluble Pig Wormer (18.15 grams of levamisole hydrochloride activity) is supplied with 20.17 g levamisole hydrochloride (0.712 oz) in a 500 mL graduated HDPE bottle.
- e. **How Dispensed:** OTC
- f. **Amount of Active Ingredients:** Each bottle contains the equivalent of 18.15 grams of levamisole hydrochloride activity
- g. **Species:** Swine
- h. **Labeled Dosage and Indications:** (Refer to attached labeling for additional details on mixing instructions)

SWINE- INDICATIONS

A broad-spectrum anthelmintic effective against the following nematode infections: Large roundworms (*ascaris suum*), nodular worms (*Oesophagostomum spp.*), intestinal thread worms (*Strongyloides ransomi*) and lungworms (*Metastrongylus spp.*)

Do not administer within 72 hours of slaughter for food.

DOSAGE

Dissolve contents of bottle in 500 mL, add 10 mL this solution per gallon of drinking water.

- i. Pioneer Product “Listed” Product: Tramisol® Soluble Pig Wormer (levamisole hydrochloride).
NADA # 112-049

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, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer’s new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. A tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter, Bioequivalence Guideline, October 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study on Levamisole Hydrochloride Soluble Pig Wormer by a letter dated May 19, 1999. The generic and pioneer products are water-soluble powders with the same active ingredients and no differences in the inactive ingredients which would affect absorption of the active ingredients.

3 HUMAN FOOD SAFETY:

Tolerance

The tolerances established for the pioneer product apply to the generic product. Tolerances are established for residues of levamisole hydrochloride in uncooked edible tissues of swine at 0.1 part per million (negligible residues).

[21 CFR 556.350]

Withdrawal Time:

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for Levamisole Hydrochloride Soluble Pig Wormer is established under:

21 CFR 520.1242a (3) (iii) Swine – 72 hours before slaughter

Regulatory Method for Residues:

No new method required for this approval

Human Safety Relative to Possession, Handling and Administration:

Labeling Contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This ANADA submitted under 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that Levamisole Hydrochloride Soluble Pig Wormer, when used under its proposed conditions of use, is safe and effective for the labeled indications.

Attachments: The following **generic** labeling and currently approved **pioneer** labeling are attached.

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| Generic Labeling | 1. Facsimile package labeling for generic product, as AM Tech®. Levamisole Hydrochloride Pig Wormer. |
| Pioneer Labeling | 2 Pioneer package labeling for Tramisol® Soluble Pig Wormer |