F R E E D O M O F I N F O R M A T I O N

S U M M A R Y

Levamisole Phosphate Injectable Solution

ANADA 200-271

Agri Laboratories, Ltd.

P.O. Box 3103

St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION

ANADA Number: 200-271

Sponsor: Agri Laboratories, Ltd.
P. O. Box 3103
St. Joseph, MO 64503-0103

Generic Name: Levamisole Phosphate Injectable Solution, 13.65%

Trade Name: N/A

Marketing Status: OTC

Pioneer Product: Levasole Injectable Solution
NADA 126-742, Schering Plough, Inc.

2. INDICATIONS FOR USE

Levamisole Phosphate is a sterile solution recommended for the treatment of cattle infected with the following parasites. Each mL of solution contains levamisole phosphate equivalent to 136.5 mg of levamisole hydrochloride.

STOMACH WORMS: *(Haemonchus,Ostertagia, Trichostrongylus)*

INTESTINAL WORMS: *(Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum, Chabertia)*

LUNGWORMS: *(Dictyocaulus)*

3. DOSE INFORMATION

A. DOSAGE FORM: Injection

B. ROUTE OF ADMINISTATION:

Levamisole Phosphate Injectable Solution, 13.65% is for subcutaneous injection in cattle.

C. ESTABLISHED DOSAGE:

Inject subcutaneously in the mid-neck region at the rate of 2 mL per 100 lb body weight. It is recommended that no more than 10 mL be injected at one site.

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

The maturation of some helminth species may be arrested at a pre-adult stage when adult worm populations are heavy.

Cattle that are severely parasitized or maintained under conditions of constant helminth exposure may require retreatment within two to four weeks after the first treatment.

NOTE: Careful weight estimates are essential for proper performance of this product.

4. 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. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will be required to include bioequivalence and residue studies. A tissue residue study will generally be required to accompany a clinical end-point, pharmacologic end-point, and blood level bioequivalence studies that can not quantify the the concentration of the drug in the blood throughtout the established withdrawl peroid. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalency study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalency Guideline, April 1990).

Based upon the formulation characteristics of the generic product, AgriLabs, Ltd. was granted a waiver from conducting an *in vivo* bioequivalency study for Levamisole Phosphate Injectable Solution, 13.65%. The generic product is administered as a subcutaneous injection.

It contains the same active ingredient and drug concentration as the pioneer product. It is the same dosage form as the pioneer and contains no inactive ingredients that may significantly affect absorption of the active ingredient.

In lieu of *in vivo* bioequivalency testing, chemical equivalence of the generic product to the pioneer product was demonstrated. Testing was conducted by CIA Labs of St. Joseph, Missouri. Product identity and potency testing was conducted using a validated

High Pressure Liquid Chromatography (HPLC) method. The results of the testing procedures adequately demonstrate chemical equivalence to the pioneer product.

5. HUMAN FOOD SAFETY:

Tolerance

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.1 ppm is established for Levamisole residues in the uncooked edible tissues of cattle under 21 CFR 556.350.

Withdrawal Time

Under the CVM Bioequivalence Guidelines, when a generic product is granted a waiver of in vivo bioequivalence testing, the withdrawal period established for the pioneer product is also assigned to the generic product.

For Levamisole Phosphate Injectable Solution, 13.65%, a withdrawal period of 7 days has been established for cattle (21 CFR 522.1244).

Regulatory Method for Residues

The analytical method for the determination of Levamisole in the tissues uses a chemical procedure.

6. 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 levamisole phosphate injectable solution when used under the proposed conditions of use, is safe and effective for its labeled indications.

Attachments: Labeling

Generic Labeling

Pioneer Labeling