Date of Approval: December 23, 2003

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 112-051

LEVASOLE Soluble Drench Powder
(levamisole hydrochloride)

"To combine NADA 112-050 for sheep with NADA 112-051 for cattle under NADA 112-051 and to revise the indications to specify genus species of parasites."

SPONSORED BY:

SCHERING-PLOUGH ANIMAL HEALTH

1. GENERAL INFORMATION

a. File Number: 112-051

b. Sponsor: Schering-Plough Animal Health Corp.
1095 Morris Ave.
Union, NJ 07083

Drug Labeler Code: 000061

c. Established Name: Levamisole hydrochloride

d. Proprietary Name: LEVASOLE Soluble Drench Powder

e. Dosage Form: Soluble powder

f. How Supplied: 0.46 oz (13 g) packet labeled for sheep only; 1.8 oz (52 g) packet and 21.34 oz (605 g) bottle labeled for cattle and sheep

g. How Dispensed: OTC

h. Amount of Active Ingredients: 11.7 grams in the 0.46 oz packet, 46.8 grams in the 1.8 oz packet, and 544.5 grams in the 21.34 oz bottle

i. Route of Administration: Oral

j. Species/Class: Cattle and sheep

k. Recommended Dosage: Administer as a single dose drench at 8 mg/kg BW.

l. Pharmacological Category: Anthelmintic

m. Indications: LEVASOLE (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. Effect of Supplement: Provides for combining NADAs 112-050 and 112-051 for sheep and cattle, respectively, with labeling for the 1.8 oz and 21.34 oz containers bearing the indications for both these species and the 0.46 oz container bearing the indications for sheep; only to be marketed under NADA 112-051. The drug formulation of both NADAs is identical and the indications will be the same with the exception that the parasites will be listed according to genus species and that it is effective against only adult nematodes. Additionally, the dose of 8 mg/kg will be inserted into the dosage and administration section.

2. EFFECTIVENESS

Effectiveness data were generated in NADAs 42-740 (approved December 4, 1970) and 39-357 (approved October 29, 1969) for sheep and cattle, respectively. NADAs 112-050 (approved October 16, 1979) and 112-051 (October 16, 1979) for sheep and cattle, respectively, referenced the effectiveness data in NADAs 42-740 and 39-357 for their approval. Since the original approvals, the agency has requested that the indications in the labeling for anthelmintic drugs identify the parasites for which the drug is effective to genus species. The labeling of the original approvals identified the parasites to genus only. The original effectiveness studies were reexamined and the appropriate genus species were determined. They have been incorporated into the labeling. No further effectiveness data were required.

3. TARGET ANIMAL SAFETY

Target animal safety data were generated in NADAs 42-740 (approved December 4, 1970) and 39-357 (approved October 29, 1969) for sheep and cattle, respectively. NADAs 112-050 (approved October 16, 1979) and 112-051 (October 16, 1979) for sheep and cattle, respectively, referenced the target animal safety data in NADAs 42-740 and 39-357 for their approval. No further target animal safety data were required.

4. HUMAN SAFETY

Human safety data were generated in NADAs 42-740 (approved December 4, 1970) and 39-357 (approved October 29, 1969) for sheep and cattle, respectively. NADAs 112-050 (approved October 16, 1979) and 112-051 (October 16, 1979) for sheep and cattle, respectively, referenced human safety data in NADAs 42-740 and 39-357 for their approval. No further human food safety data were required. 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.

5. AGENCY CONCLUSIONS

The information submitted in support of this supplemental NADA satisfies the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that LEVASOLE Soluble Drench Powder for Sheep and Cattle is safe and effective against certain adult nematode infections, and allow for the combination of NADAs 112-050 and 112-051 so that the product can be marketed with labeling that contains both sheep and cattle indications.

The Agency has concluded that this product shall retain over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions for use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2), this is a Category II change which did not require a reevaluation of the effectiveness and safety data in the parent applications.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualify for marketing exclusivity.

No patent information was submitted with the application.

6. ATTACHMENTS:

LEVASOLE Soluble Drench Powder facsimile display carton for the 0.46 oz packets

LEVASOLE Soluble Drench Powder facsimile label for the 0.46 oz and 1.8 oz packets and the 21.34 oz bottle.