Date of Approval: Aug. 9, 2004

FREEDOM OF INFORMATION SUMMARY

NADA 140-439

EQVALAN Liquid For Horses

(ivermectin)

This supplement amends the EQVALAN (ivermectin) Liquid For Horses labeling to add four species of internal parasites and to reflect a change in the Indications section which separates the listing of adult small strongyle species from their related fourth-stage larvae.

Sponsored by:

Merial Ltd.

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1. GENERAL INFORMATION:

a.	File Number:	NADA 140-439
b.	Sponsor:	Merial Ltd. 3239 Satellite Blvd. Building 500 Duluth, GA 30096-4640 Drug Labeler Code: 050604
c.	Established Name:	Ivermectin
d.	Proprietary Name:	EQVALAN Liquid For Horses
e.	Dosage Form:	Liquid containing 1% ivermectin for administration by stomach tube or oral drench
f.	How Supplied:	100 mL plastic bottle. Each bottle contains sufficient ivermectin to treat ten 1100 lb (500 kg) horses.
g.	How Dispensed:	Rx
h.	Amount of Active Ingredients:	Each mL contains 10 mg of ivermectin
i.	Route of Administration:	Oral
j.	Species/Class:	Equine
k.	Recommended Dosage:	91 mcg ivermectin per lb (200 mcg/kg)
l.	Pharmacological Category:	Anthelmintic
m.	Indications:	For treatment and control of the following parasites in horses: **Large strongyles** (adults)-*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus* and *Craterostomum acuticaudatum*; **Small Strongyles** (adults, including those resistant to some benzimidazole class compounds)-*Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*,

Cylicodontophorus spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; **Small Strongyles**-fourth stage larvae; **Pinworms** (adults and fourth stage larvae)-*Oxyuris equi*; **Ascarids** (adults and third and fourth stage larvae)-*Parascaris equorum*; **Hairworms** (adults)-*Trichostrongylus axei*; **Large-mouth Stomach Worms** (adults)-*Habronema muscae*; **Bots** (oral and gastric stages)-*Gasterophilus spp*. including *G. intestinalis* and *G. nasalis*; **Lungworms** (adults and fourth stage larvae)-*Dictyocaulus arnfieldi*; **Intestinal Threadworms** (adults)-*Strongyloides westeri*; **Summer Sores** caused by *Habronema* and *Draschia* spp. cutaneous third stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

n. Effect of Supplement: This supplement amends the EQVALAN (ivermectin) Oral Liquid For Horses labeling to add four species of internal parasites and to reflect a change in the Indications section which separates the listing of adult small strongyle species from their related fourth-stage larvae. Specifically, the supplement provides for the use of ivermectin oral liquid for the treatment and control of *Craterostomum acuticaudatum*, *Petrovinema poculatum*, and *Coronocyclus* spp. including *Coronocyclus coronatus* and *Coronocyclus labratus*. In addition, under the sub-heading Small Strongyles, the labeling has been revised to separate the listing of adult species from their related fourth-stage larvae.

2. EFFECTIVENESS:

This supplement revises the label Indications to add four species of internal parasites. Substantial evidence of effectiveness is based on an effectiveness study using ivermectin as a different approved dosage form, an oral paste, and on a demonstration of bioequivalence between the paste and the oral solution.

The bioequivalence of EQVALAN Liquid For Horses (NADA 140-439 original approval July 1, 1987) with EQVALAN Paste For Horses (NADA 134-314 original approval May 29, 1984) is contained in a Freedom of Information Summary for NADA 140-439. EQVALAN Liquid For Horses is expected to be effective for all of the parasites for which EQVALAN Paste For Horses is approved.

Based on the current data for EQVALAN Paste for Horses (supplemental approval to NADA 134-314 dated April 2, 2003), the following parasite species have been added to the label for EQVALAN Liquid For Horses: *Triodontophorus brevicauda* and *Triodontophorus serratus*, *Craterostomum acuticaudatum*, *Gasterophilus intestinalis* and *Gasterophilus nasalis*, *Coronocyclus coronatus*, *Coronocyclus labiatus*, and *Coronocyclus labratus, Cyathostomum catinatum* and *Cyathostomum pateratum*, *Cylicocyclus insigne*, *Cylicocyclus leptostomum*, *Cylicocyclus nassatus*, and *Cylicocyclus brevicapsulatus, Cylicostephanus calicatus*, *Cylicostephanus goldi*, *Cylicostephanus longibursatus*, and *Cylicostephanus minutus*, and *Petrovinema poculatum*.

3. TARGET ANIMAL SAFETY:

No new data was required for this supplement to NADA 140-439 (original approval July 1, 1987) and this supplement did not require review of the original target animal safety data for this product.

4. HUMAN SAFETY:

This drug is intended for use in horses, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: "Not for use in humans. Keep this and all drugs out of the reach of children." "Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes." "Do not use in horses intended for human consumption."

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrates that EQVALAN Liquid For Horses is safe and effective for the labeled claim.

This drug is a prescription product. Administration of this product by stomach tube or oral drench requires the knowledge and experience of a veterinarian.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, parts of this supplemental approval for non-food producing animals qualify for three years of marketing exclusivity beginning August 9, 2004. The three years of marketing exclusivity applies only to the treatment and control of the following parasites: *Craterostomum acuticaudatum*, *Petrovinema poculatum*, and *Coronocyclus* spp. including *Coronocyclus coronatus* and *Coronocyclus labratus*.

In accordance with 21 CFR 514.106(b) (2), this is a Category II change which did not require reevaluation of other underlying safety or effectiveness data.

6. ATTACHMENTS:

Facsimile labeling is attached as indicated below:

Carton

Package Insert

Bottle Label