Date of Approval: July 13, 2004

FREEDOM OF INFORMATION SUMMARY

NADA 141-214

ZIMECTRIN Gold Paste

ivermectin/praziquantel

This supplement amends the ZIMECTRIN Gold (ivermectin/praziquantel) Paste labeling to reflect a change in the indications section. Specifically, under the sub-heading Small Strongyles, the labeling has been revised to separate the listing of adult species from the fourth-stage larvae. The label language has also been revised for treatment frequency; removing the eight week intertreatment interval because treatment frequency should be based on a parasite control program designed specifically for each horse. A new precaution statement has also been added.

Sponsored by:

Merial Ltd.

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1. GENERAL INFORMATION:

a.	File Number:	NADA 141-214
b.	Sponsor:	Merial Ltd. 3239 Satellite Blvd. Building 500 Duluth, GA 30096-4640 Drug Labeler Code: 050604
c.	Established Name:	Ivermectin/praziquantel
d.	Proprietary Name:	ZIMECTRIN Gold Paste
e.	Dosage Form:	Paste containing 1.55 % ivermectin and 7.75% praziquantel
f.	How Supplied:	Individual dose syringe contains sufficient paste to treat one 1250 lb horse orally. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb of body weight
g.	How Dispensed:	OTC
h.	Amount of Active Ingredients:	Each syringe contains 113.8 mg of ivermectin and 567.5 mg praziquantel
i.	Route of Administration:	Oral
j.	Species/Class:	Equine
k.	Recommended Dosage:	91 mcg ivermectin per lb (200 mcg/kg) and 454 mcg praziquantel per lb (1.0 mg/kg) body weight
l.	Pharmacological Category:	Anthelmintic
m.	Indications:	For treatment and control of the following parasites in horses: **Tapeworms** - *Anoplocephala perfoliata,* **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 of *Onchocerca* sp.

n. Effect of Supplement: This supplement amends the ZIMECTRIN Gold (ivermectin/praziquantel) Paste labeling to reflect a change in the indications section. Specifically, under the sub-heading Small Strongyles, the labeling has been revised to separate the listing of adult species from the fourth-stage larvae. The label language has also been revised for treatment frequency; removing the eight week intertreatment interval because treatment frequency should be based on a parasite control program designed specifically for each horse. A new precaution statement has also been added.

2. EFFECTIVENESS:

This supplement revises the indications to better reflect the original effectiveness data. Specifically, the new language separates out the unspeciated fourth-stage larvae from the speciated adult small strongyles. The new language reads as follows: "**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"

No new data was required for this supplement to NADA 141-214 (original approval April 17, 2003) and this supplement did not require review of the original effectiveness data for this product.

3. TARGET ANIMAL SAFETY:

No new data was required for this supplement to NADA 141-214 (original approval April 17, 2003) and this supplement did not require review of the original target animal safety data for this product.

However, post-marketing adverse events reported to the CVM Adverse Drug Event (ADE) database have included reports of swelling and irritation of the mouth, lips, and tongue following administration of ZIMECTERIN Gold Paste. These reactions have been transitory in nature.

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 ZIMECTRIN Gold Paste is safe and effective for the labeled claim.

The drug is available over-the-counter for lay use. Routine deworming of horses is a widely accepted and recommended practice performed by the layperson. A diagnosis of parasite infection prior to deworming is not necessary. The syringe carton and package outsert contain detailed directions for use.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category I change. Therefore, this action did not require a reevaluation of the safety and effectiveness data in the parent application.

6. ATTACHMENTS:

Facsimile labeling is attached as indicated below:

Carton

Package Outsert

Syringe Label