Date of Approval: September 16, 2005

FREEDOM OF INFORMATION SUMMARY

NADA 141-215

EQUIMAX Paste

ivermectin 1.87%/praziquantel 14.03%

This supplement provides for a revised Indications section with respect to small strongyles for EQUIMAX Paste.

Sponsored by:

Virbac AH, Inc.
3200 Meacham Blvd.
Fort Worth, TX 76137

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1. GENERAL INFORMATION:

a. File Number:	NADA 141-215
b. Sponsor:	Virbac AH, Inc. 3200 Meacham Blvd. Ft. Worth, TX 76137 Drug Labeler Code: 051311
c. Established Name:	ivermectin/praziquantel
d. Proprietary Name:	EQUIMAX
e. Dosage Form:	A paste containing ivermectin 1.87% and praziquantel 14.03%
f. How Supplied:	Individual dose syringe contains sufficient paste to treat one 1320 lb horse orally. Each weight marking on the syringe plunger delivers enough paste to treat 220 lb bodyweight
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each milligram of EQUIMAX Paste contains 0.0187 milligram (1.87%) ivermectin and 0.1403 milligram (14.03%) praziquantel. Each syringe contains 120.1 mg of ivermectin and 897.6 mg praziquantel
i. Route of Administration:	Oral
j. Species/Class:	Equine
k. Recommended Dosage:	91 mcg ivermectin per lb (200 mcg/kg) bodyweight and 0.68 mg praziquantel per lb (1.5 mg/kg) bodyweight
l. Pharmacological Category:	Anthelmintic and Boticide
m. Indications:	Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. EQUIMAX (ivermectin/praziquantel) Paste is indicated for the treatment and control of the following parasites: Tapeworms

Anoplocephala perfoliata

Large Strongyles (adults)
Strongylus vulgaris (also early forms in blood vessels)
Strongylus edentatus (also tissue stages)
Strongylus equinus
Triodontophorus spp.
Small Strongyles (adults, including those resistant to some benzimidazole class compounds)
Cyathostomum spp.
Cylicocyclus spp.
Cylicostephanus spp.
Cylicodontophorus spp.
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.
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 is a regulatory supplement requested by the Division of Surveillance to bring product labeling into compliance with the pioneer product. Therefore, this supplement provides for separation of small strongyle fourth-stage larvae from the small strongyle adults, which are speciated in the indication section of the product labeling. In addition, it revises the Warning statement to read “Do not use in horses intended for human consumption.”

2. EFFECTIVENESS:

The clinical effectiveness of the recommended dosage of 91 mcg ivermectin per pound (200 mcg/kg) of body weight and 0.68 mg praziquantel per pound (1.5 mg/kg) of body weight is contained in the original Freedom of Information Summary for NADA 141-215 dated July 11, 2003. No additional clinical effectiveness data were required for this supplement.

3. TARGET ANIMAL SAFETY:

The safety of the recommended dosage of 91 mcg ivermectin per pound (200 mcg/kg) of body weight and 0.68 mg praziquantel per pound (1.5 mg/kg) of body weight is contained in the original Freedom of Information Summary for NADA 141-215 dated July 11, 2003. The supplemental approval dated July 30, 2004 provided for the safe use of EQUIMAX Paste in breeding, pregnant or lactating mares.

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 supplement.

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 eating and smoking when handling. Wash hands after use. Avoid contact with eyes. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse reactions in users, to obtain more information, or to obtain a MSDS, contact Pfizer at 1-800-366-5288." The Virbac product is distributed by Pfizer Inc.

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 demonstrate that EQUIMAX Paste when used under the labeled conditions of use is safe and effective for the treatment and control of roundworms (ascarids, strongyles and lungworms), tapeworms and bots in horses.

The drug is available over-the-counter for lay use because adequate directions for use are provided and oral antiparasitic treatments in horses are routinely performed by the layperson.

This approval for 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 II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application.

EQUIMAX Paste is under the following U.S. patent number:

U.S. Patent Number	Date of Expiration
5,824,653	11/27/2015

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

Package Insert
Syringe Label
Carton Label