Date of Approval: May 23, 2008

FREEDOM OF INFORMATION SUMMARY

Supplemental Abbreviated New Animal Drug Application

ANADA 200-326

BIMECTIN Paste 1.87%
(ivermectin)

Oral Paste for use in Horses

This supplement provides for the addition of claims no longer protected by marketing exclusivity; the addition of a parasite species not covered by exclusivity; revised packaging; and minor label revisions.

Sponsor:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-326
b. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Rd. Tallaght, Dublin 24 Ireland Drug Labeler Code: 061623 U.S. Agent: Linda M. Duple Bimeda, Inc. 2836 Dolliver Park Avenue Lehigh, IA 50557
c. Established Name:	Ivermectin
d. Proprietary Name:	BIMECTIN Paste 1.87%
e. Dosage Form:	Paste
f. How Supplied:	Individual syringe containing 6.08 g paste
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	1.87% ivermectin
i. Route of Administration:	Oral
j. Species/Class:	Horses, not intended for human consumption
k. Recommended Dosage:	Each syringe contains sufficient paste to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight.
l. Pharmacological Category:	Anthelmintic and boticide
m. Indications:	Consult your veterinarian for assistance in the diagnosis, treatment and control of parasitism. BIMECTIN (ivermectin) Paste provides effective 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 Stronglyes** – Fourth-stage larvae; **Pinworms** (adults and fourth-stage larvae) – *Oxyuris equi*; **Ascarids** (adults, third-stage 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-stages 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. Pioneer Product: EQVALAN Paste 1.87%; ivermectin; NADA 134-314; Merial, Ltd.

o. Effect of Supplement: This supplement provides for new indications for use claims no longer protected by a three-year exclusivity period that expired on April 2, 2006: **Large Strongyles** – *Craterostomum acuticaudatum*; **Small Strongyles** – *Petrovinema poculatum* and *Coronocyclus* spp. including *C. coronatus*, and *C. labratus*.

The generic labeling includes an additional indication for use claim for a parasite species not protected by exclusivity, *C. labiatus*.

This supplement also provides for revised packaging and minor label revisions.

2. 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 (GADPTRA) of 1988, 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 and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an in vivo bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

The sponsor demonstrated *in vivo* bioequivalence via a blood-level bioequivalence study of the generic and pioneer ivermectin pastes in horses. Refer to the original Freedom of Information (FOI) Summary dated January 19, 2005, for more detail. The pioneer product, EQVALAN the subject of Merial Ltd., NADA 134-314, was approved on May 29, 1984.

3. 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 ANADA.

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

4. 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 BIMECTIN Paste 1.87% for use in horses, when used under the proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and current approved pioneer labeling are attached as indicated below:

Generic Labeling: BIMECTIN Paste 1.87%, ANADA 200-326

Syringe label; clear plastic sleeve packaging for the syringe; individual carton packaging for the syringe; display carton for syringe packaged in plastic sleeve; and display carton for syringe packaged in individual carton

Pioneer Labeling: EQVALAN Paste 1.87%, NADA 134-314

Syringe label; carton label; package outsert