Approval Date: October 24, 2006

# FREEDOM OF INFORMATION SUMMARY

# SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

## ANADA 200-320

## EQUELL
## (ivermectin)

**The effect of the supplement is to incorporate CVM requested changes to the label's "WARNING" and "INDICATIONS" sections and to add expired three-year exclusivity claims**

**Sponsored by:**

**Virbac Animal Health, Inc.**

**FREEDOM OF INFORMATION SUMMARY**

***1. GENERAL INFORMATION:***

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| a. File Number | ANADA 200-320 |
| b. Sponsor: | Virbac AH, Inc.<br>3200 Meacham Blvd.<br>Ft. Worth, TX 76137<br><br>Drug Labeler Code: 051311 |
| c. Established Name: | Ivermectin |
| d. Proprietary Name: | EQUELL |
| e. Dosage Form: | Paste |
| f. How Supplied: | Syringe containing 6.42 g (0.225 oz) |
| g. How Dispensed: | OTC |
| h. Amount of Active Ingredients: | Each milligram of the paste contains 0.0187 milligram (1.87 %) ivermectin. |
| i. Route of Administration: | Oral |
| j. Species/Class: | Equine |
| k. Recommended Dosage: | 91 mcg ivermectin per pound (200 mcg/kg) of body weight |
| l. Pharmacological Category: | Anthelmintic and boticide |
| m. Indications: | EQUELL (ivermectin) Paste provides effective 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*;<br><br>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. Pioneer Product: EQVALAN; ivermectin; NADA 134-314; Merial Ltd.

o. Effect of Supplement: The effect of the supplement is to incorporate CVM requested changes to the label's "WARNING" and "INDICATIONS" sections and to add expired three-year exclusivity claims

## *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 May 29, 1984, for more details. 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: "**Not for use in humans. Keep this and all drugs out of reach of children.**"

## *4. AGENCY CONCLUSIONS:*

This supplemental 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 EQUELL, when used under its proposed conditions of use, is safe and effective for its labeled indications.

## *5. ATTACHMENTS:*

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

<u>Generic Labeling for ANADA 200-320:</u>
Product label, Package insert, Carton

<u>Pioneer Labeling for NADA 134-314:</u>
Product label, Package insert, Carton