

Date of Approval: November 23, 2005

FREEDOM OF INFORMATION SUMMARY

Supplemental NADA 141-216

QUEST Plus Gel

moxidectin/praziquantel

**Additional indications for the treatment and control
of *Cylicocyclus radiatus* and *Petrovinema poculatus***

Sponsored by:
Fort Dodge Animal Health
Division of Wyeth
800 Fifth St. NW.
Fort Dodge, IA 50501

1. General Information:

- a. File Number: NADA 141-216
- b. Sponsor: Fort Dodge Animal Health
Division of Wyeth
800 Fifth St. NW.
Fort Dodge, IA 50501
- Drug Labeler Code: 000856
- c. Established Name: Moxidectin and praziquantel
- d. Proprietary Names: QUEST Plus Gel
- e. Dosage Form: Oral Gel
- f. How Supplied: Packaged in ready-to-use SURE-DIAL syringes. Each syringe contains adequate QUEST Plus Gel to treat one horse with a body weight of up to 1250 lbs, or multiple horses and ponies with combined body weights of 1250 lbs.
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: 20 mg moxidectin/mL (2.0% w/v) and 125 mg praziquantel/mL (12.5% w/v).
- i. Route of Administration: Oral
- j. Species/Class: Equine
- k. Recommended Dosage: The recommended dose level is 0.4 mg moxidectin and 2.5 mg praziquantel/kg (2.2 lb) body weight.
- l. Pharmacological Category: Anthelmintic
- m. Indications: For the treatment and control of the following stages of gastrointestinal parasites of horses and ponies:

Large strongyles:

Strongylus vulgaris – (adult and L₄/L₅ arterial stages)

Strongylus edentatus – (adult and tissue stages)

Triodontophorus brevicauda – (adults)

Triodontophorus serratus – (adults)

Small Strongyles (adults):

Cyathostomum spp., including
Cyathostomum catinatum
Cyathostomum pateratum

Cylicostephanus spp., including
Cylicostephanus calicatus
Cylicostephanus goldi
Cylicostephanus longibursatus
Cylicostephanus minutus

Cylicocyclus spp., including
Cylicocyclus insigne
Cylicocyclus leptostomum
Cylicocyclus nassatus
Cylicocyclus radiatus

Coronocyclus spp., including
Coronocyclus coronatus
Coronocyclus labiatus
Coronocyclus labratus

Gyalocephalus capitatus

Petrovinema poculatus

Small Strongyles:

Undifferentiated luminal larvae

Encysted cyathostomes:

Late L₃ and L₄ mucosal cyathostome larvae

Ascarids:

Parascaris equorum – (adults and L₄ larval stages)

Pinworms:

Oxyuris equi - (adults and L₄ larval stages)

Hairworms:

Trichostrongylus axei - (adults)

Large-mouth stomach worms:

Habronema muscae - (adults)

Horse stomach bots:

Gasterophilus intestinalis - (2nd and 3rd instars)

Gasterophilus nasalis - (3rd instars)

Tapeworms:

Anoplocephala perfoliata - (adults)

One administration suppresses strongyle egg production for 84 days.

- n. Effect of Supplement: The supplement provides for the use of QUEST Plus gel for the treatment and control of adult *Cylicocyclus radiatus* and *Petrovinema poculatus* based on results from additional dose confirmation studies.

2. Effectiveness:

Approval of this supplemental NADA was based on three dose confirmation studies performed utilizing QUEST Gel (moxidectin). These studies support approval of QUEST Plus Gel, as QUEST Plus Gel contains the same amount of active ingredient (moxidectin 20 mg/mL) as QUEST Gel and is used at the same dose rate (0.4 mg moxidectin/kg (2.2 lb) body weight). Please refer to the supplemental NADA 141-087 Freedom of Information (FOI) Summary (2005), for a description of the three dose confirmation studies supporting this supplemental approval. Please also refer to the original NADA 141-216 FOI Summary dated May 14, 2003.

3. Target Animal Safety:

This supplemental NADA does not require re-evaluation of target animal safety data. Please refer to the original NADA 141-216 Freedom of Information (FOI) summary dated May 14, 2003.

4. Human Safety:

This drug is intended for use in horses and ponies, 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. Do not ingest. If swallowed, induce vomiting. Wash hands and contaminated skin with soap and water. If accidental contact with eyes occurs, flush repeatedly with water. If irritation or any other symptom attributable to exposure to this product persists, consult your physician."

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 QUEST Plus Gel, when used under labeled conditions of use, is safe and effective for the treatment of the gastrointestinal parasites specified on the product label in horses and ponies six months of age and older.

QUEST Plus Gel 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the indications for adult *Cylicocyclus radiatus* and *Petrovinema poculatus*, which are approved in this supplement. This exclusivity is based on the new studies conducted for substantial evidence of effectiveness.

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.

QUEST Plus is under the following U.S. patent:

<u>U.S. Patent Number</u>	<u>Date of Expiration</u>
4,916,154	April 10, 2007
6,893,652	July 24, 2022

6. Attachments:

Facsimile Labeling is attached as indicated below:

Package insert

Syringe label

Printed outer carton