Date of Approval: November 23, 2005

FREEDOM OF INFORMATION SUMMARY

Supplement NADA 141-087

QUEST Gel

moxidectin

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 141-087
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
d. Proprietary Names:	QUEST Gel
e. Dosage Form:	Oral Gel
f. How Supplied:	Packaged in ready-to-use SURE-DIAL syringes. Each syringe contains adequate QUEST Gel to treat one horse with a body weight of up to 1150 lbs, or multiple horses and ponies with combined body weights of 1150 lbs.
g. How Dispensed:	OTC
h. Amount of Active Ingredient:	20 mg moxidectin/mL (2.0% w/v)
i. Route of Administration:	Oral
j. Species/Class:	Equine
k. Recommended Dosage:	The recommended dose level is 0.4 mg moxidectin/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 L_4/L_5 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 lumenal larvae

Encysted cyathostomes:
Late L_3 and L_4 mucosal cyathostome larvae

Ascarids:
Parascaris equorum – (adults and L_4 larval stages)

Pinworms:
Oxyuris equi - (adults and L_4 larval stages)

Hairworms:
Trichostrongylus axei - (adults)

Large-mouth stomach worms:
Habronema muscae - (adults)

Horse stomach bots:
Gasterophilus intestinalis - (2^{nd} and 3^{rd} instars)
Gasterophilus nasalis - (3^{rd} instars)

One administration suppresses strongyle egg production for 84 days.

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

2. Effectiveness:

Three dose confirmation studies were conducted using a common protocol to confirm the effectiveness of QUEST Gel administered at the recommended use level of 0.4 mg moxidectin per kg body weight (2.2 lb) against endoparasites of horses. Endoparasites found at necropsy were identified to species and developmental stage.

Dose Confirmation Study 0876-E-US-20-03

Investigator: Craig R. Reinemeyer, DVM, Ph.D.

Study Location: East Tennessee Clinical Research, Rockwood, Tennessee

Animals: 24 horses (12 females, 12 males) aged 1 to 2 years with natural parasite infections

Treatment Groups: Blocks were formed based on baseline strongyle fecal egg counts. Horses within blocks were randomly assigned to either an unmedicated control treatment or a single dose of QUEST Gel at the labeled dose rate of 0.4 mg moxidectin per kg (2.2 lb) body weight.

Route of Administration: Oral

Duration of Study: Animals were necropsied by block on Days 12, 13 or 14.

Measurements: Stomach contents and washings, small intestine contents and washings, and cecum, ventral colon and dorsal colon attached parasites and contents were examined for parasites.

Observations: No adverse reactions were noted in the 12 treated animals.

Dose Confirmation Study 0876-E-US-21-03

Investigator: Jenifer Edmonds, DVM, Ph.D.

Study Location: Johnson Research, Parma, Idaho

Animals: 24 horses and ponies (9 females, 6 geldings, 9 males) aged 1 to 12 years with natural parasite infections

Treatment Groups: Blocks were formed based on baseline strongyle fecal egg counts. Horses within blocks were randomly assigned to either an unmedicated control treatment or a single dose of QUEST Gel at the labeled dose rate of 0.4 mg moxidectin per kg (2.2 lb) body weight.

Route of Administration: Oral

Duration of Study: Animals were necropsied by block on Days 13 or 14.

Measurements: Stomach contents and washings, small intestine contents and washings, and cecum, ventral colon and dorsal colon attached parasites and contents were examined for parasites.

Observations: No adverse reactions were noted in the 12 treated animals.

Dose Confirmation Study 0876-E-US-22-03

Investigator: Allan J. Paul, DVM, M.S.

Study Location: University of Illinois, Urbana, Illinois

Animals: 24 horses and ponies (9 females, 12 geldings, 3 males) aged 1 to 4 years with natural parasite infections

Treatment Groups: Blocks were formed based on baseline strongyle fecal egg counts. Horses within blocks were randomly assigned to either an unmedicated control treatment or a single dose of QUEST Gel at the labeled dose rate of 0.4 mg moxidectin per kg (2.2 lb) body weight.

Route of Administration: Oral

Duration of Study: Animals were necropsied by block on Days 12 or 13.

Measurements: Stomach contents and washings, small intestine contents and washings, and cecum, ventral colon and dorsal colon attached parasites and contents were examined for parasites.

Observations: No adverse reactions were noted in the 12 treated animals.

Statistical Methods

Data from the 72-horse data set (36 QUEST-treated and 36 untreated controls) were subjected to appropriate statistical analyses for each parasite species in which an adequate number of untreated control animals were infected. Counts were transformed by the $Y = \log_{10}(\text{count} + 1)$ transformation prior to performing analyses. Effectiveness was calculated as:

$$\% \text{ Efficacy} = \left(\frac{\text{Mean Count Control Group} - \text{Mean Count QUEST Group}}{\text{Mean Count Control Group}} \right) * 100$$

QUEST Gel was considered effective if each of three conditions were met:

1) Efficacy was $\geq$ 90% based on geometric means,
2) At least 6 adequately infected control horses were infected with the same specific genus/species/stage of parasite, and
3) The geometric mean parasite count in horses treated with QUEST Gel was significantly less than the geometric mean parasite count in untreated animals at $p < 0.05$.

Results of the three dose confirmation studies (0876-E-US-20-03, 0876-E-US-21-03 and 0876-E-US-22-03):

The cumulative data from the three dose confirmation studies demonstrate that QUEST Gel, when used at the labeled dose, is effective in the treatment and control of *Cylicocyclus radiatus* adults and *Petrovinema poculatus* adults.

3. Target Animal Safety:

This supplemental NADA does not require re-evaluation of target animal safety data. Please refer to the original NADA 141-087 Freedom of Information (FOI) summary dated July 11, 1997, and the supplemental NADA 141-087 FOI summary dated May 29, 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 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 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 Gel is under the following U.S. patent:

U.S. Patent Number	Date of Expiration
4,916,154	April 10, 2007

6. Attachments:

Facsimile Labeling is attached as indicated below:

Package insert

Syringe label

Printed outer carton