

Approval Date: March 17, 2004

FREEDOM OF INFORMATION SUMMARY

Supplement to NADA 141-087

QUEST Gel

moxidectin

Allows for the addition of new small strongyle species to the indications

Sponsored by:

Fort Dodge Animal Health

FREEDOM OF INFORMATION SUMMARY

1. General Information:

- a. File Number: NADA 141-087
- b. Sponsor: Fort Dodge Animal Health
Division of Wyeth
800 Fifth Street NW
Fort Dodge, Iowa 50501
- Drug labeler code: 000856
- c. Established Name: moxidectin
- d. Proprietary Name: 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 - (adults 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

Coronocyclus spp., including

Coronocyclus coronatus

Coronocyclus labiatus

Coronocyclus labratus

Gyalocephalus capitatus

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)

One dose 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 *Coronocyclus labratus*. Also, the label descriptions of the currently-approved small strongyle genera are being revised to add included species for which data already exists in the NADA file and to reflect changes in scientific nomenclature.

2. Effectiveness:

The use of moxidectin gel for the treatment and control of *Coronocyclus labratus* was established in two dose confirmation studies. The first study is study #EQ-92-2 and is described in the original Freedom of Information (FOI) summary for QUEST (moxidectin) Gel dated July 11, 1997. The second study, which is new to this NADA file, is study #0696-E-US-06-00 and is described in the original FOI summary for QUEST PLUS (moxidectin / praziquantel) Gel (NADA 141-216) dated May 14, 2003. In this second study, the effect of the test substance on *Coronocyclus labratus* was attributed to the moxidectin component.

3. Target Animal Safety:

This approval does not affect this section of the summary. Please refer to the original NADA 141-087 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 other 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

the 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 labeled for OTC use. Routine deworming of horses is a widely accepted and recommended practice performed by the lay person. 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 addition of *Coronocyclus labratus* to the indications for which this supplement is approved. This decision is based on the fact that new data was required for this approval.

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.

Moxidectin is under the following U.S. patent number:

U.S. Patent Number
4,916,154

Date of Expiration
April 10, 2007

6. Attachments:

Facsimile Labeling is attached as indicated below:

Package insert

Syringe label

Printed outer carton