Approval Date: May 29, 2003

FREEDOM OF INFORMATION SUMMARY

Supplement to NADA 141-087

Quest® (moxidectin) Gel

Fort Dodge Animal Health

Raises the minimum age limit for use of this product from 4 months up to 6 months of age.

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 (moxidectin) Gel
e. Dosage Form:	Oral
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 L_4/L_5 arterial stages) *Strongylus edentatus* - (adult and tissue stages) *Triodontophorus brevicauda* - (adults) *Triodontophorus serratus* - (adults)

Small strongyles

Cyathostomum spp. (adults)
Cylicocyclus spp. (adults)
Cylicostephanus spp. (adults)
Gyalocephalus capitatus - (adults)
Undifferentiated lumenal larvae

Encysted cyathostomes

Late L_3 and L_4 mucosal cyathostome larvae

Ascarids

Parascaris equorum - (adults and L_4 larval stages)

Pin worms

Oxyuris equi - (adults and L_4 larval stages)

Hair worms

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 dose suppresses strongyle egg production for 84 days.

n. Effect of Supplement: Raise the minimum age limit for use of this product from 4 months up to 6 months of age.

2. Effectiveness:

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 October 4, 1999.

3. Target Animal Safety:

The original new animal drug application for QUEST (moxidectin) Gel (NADA 141-087) was approved on July 11, 1997 (62 FR 42902, August 11, 1997) and is codified in 21 CFR 520.1452. The terms of this approval specify that the drug can be administered to horses and ponies four months of age and older. An analysis of the post-marketing adverse drug event (ADE) database for QUEST Gel by the CVM Division of Surveillance indicates that there is a higher incidence of adverse reactions in horses less than 6 months of age, horses weighing less than 250 pounds, and older horses that are thin and debilitated. The most common signs in these groups are ataxia, depression/lethargy, and/or recumbency. The occurrence of these signs, especially in young animals and small breed ponies is correlated to reports of overdosing. The following ADE data were reported over a five-year period from 1997 through 2002:

	Number of reports of this sign in horses less than six month of age*	Total number of reports of this sign in horses of all ages*
Ataxia	111	196
Depression/Lethargy	71	168
Recumbency	90	150

*In some instances affected horses are reported under more than one of these signs.

To preclude the potential for the occurrence of these signs of overdosing in young horses, the terms of the NADA 141-087 approval are being amended to specify QUEST Gel should only be administered to horses and ponies six months of age and older. As indicated in the QUEST Gel labeling, the body weight of all treated horses should be carefully estimated to preclude overdosing and use of the product in thin and debilitated horses should be avoided.

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 administered as a single oral dose containing 0.4 mg moxidectin/kg body weight 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.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

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 numbers:

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