FREEDOM OF INFORMATION SUMMARY

Supplement to NADA 141-087

QUEST™ (moxidectin) 2% Equine Oral Gel

Additional indication for the treatment and control of *Gasterophilus nasalis* (3rd instars)

Sponsor: Fort Dodge Animal Health
Supplemental Freedom of Information (FOI) Summary
QUEST™ (moxidectin) 2% Equine Oral Gel

1. General Information

NADA Number: 141-087

Sponsor: Fort Dodge Animal Health
Division of American Home Products Corp.
800 Fifth Street, NW.
Fort Dodge, IA 50501

Generic Name: moxidectin

Tradename: QUEST™ (moxidectin) 2% Equine Oral Gel

Marketing Status: Over-The-Counter (OTC)

Effects of Supplement:

a. New indication: For the treatment and control of *Gasterophilus nasalis* (3^{rd} instars)

b. Labeling Change: The precautions section is revised to read "This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result." The photograph on the carton was changed to remove the picture of a young foal.

2. Indications For Use

QUEST (moxidectin) 2% Equine Oral Gel, when administered at the recommended dose level of 0.4 mg moxidectin/kg (2.2 lb.) body weight, has been demonstrated to be effective in 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 administration of the recommended dose rate of QUEST 2% Equine Oral Gel also suppresses strongyle egg production for 84 days.

3. Dosage Form, Route of Administration and Recommended Dosage

Dosage Form:

QUEST (moxidectin) 2% Equine Oral Gel is a ready-to-use formulation containing 20 mg moxidectin/mL (2.0% on a weight/volume basis). It is packaged in disposable syringes calibrated with specific settings which enable accurate administration of the gel based on the body weight of the treated animal.

Route of Administration:

The product is formulated as a palatable gel which is administered to horses and ponies by inserting the syringe applicator into the animal's mouth through the interdental space and depositing the gel in the back of the mouth near the base of the tongue.

Recommended Dose Rate:

The recommended dose level is 0.4 mg moxidectin/kg (2.2 lb.) body weight.

4. Effectiveness

An original new animal drug application for QUEST (moxidectin) 2% Equine Oral Gel (NADA 141-087) was approved on July 11, 1997 (62 FR 42902, August 11, 1997) and is codified in 21 CFR 520.1452. This supplemental NADA 141-087 approval involves the addition of a new indication for the treatment and control of *Gasterophilus nasalis* (3rd instars) with a single administration of QUEST Gel at the currently approved 0.4 mg/kg body weight dose rate. The approval of the new indication is based on two clinical studies.

Experiments 0863-E-UK-10-95 and 0876-E-US-14-98 were conducted to confirm the effectiveness of a single oral administration of QUEST (moxidectin) 2% Equine Oral Gel against the larval stages of *Gasterophilus nasalis*. In these studies, ponies and horses with naturally-acquired *G. nasalis* infections were treated with 0.4 mg/kg body weight QUEST Gel. The animals were euthanized at 35 and 14 days (respectively) post treatment for parasite recovery and identification. The number of parasites recovered from the treated animals were compared with the number of parasites found in the untreated control animals. Percent effectiveness was determined by comparison of the arithmetic means of the treated and control animal parasite counts. 100% effectiveness against *G. nasalis* (3rd instars) was documented in each study.

a. Study Number: 0863-E-UK-10-95

Clinical Investigator: G. C. Coles, Ph.D.
University of Bristol
Bristol BS18 7DU United Kingdom

Test Animals/Source of Infection: Naturally-infected, wild Dartmoor ponies

Treatment Design:

Treatment Groups	Number Treated
Untreated Control	8
Moxidectin Equine Gel, 0.4 mg/kg body weight	8

Test Duration: 35 days

Observations: No adverse reactions to treatment were reported.

Results of Treatment: At the time of necropsy, seven control ponies (7/8) were infected with *Gasterophilus nasalis* (3rd instars). Treatment was 100% effective against *G. nasalis* in this experiment.

Table 1. Effectiveness of moxidectin oral gel against *Gasterophilus nasalis* 3rd instars in Study 0863-E-UK-10-95

Test Parameter	Control	Treated	% Effectiveness
Number of horses infected at necropsy/ Number in treatment group	7/8	0/8	N/A
Arithmetic mean	25.6	0	100
Geometric mean	13.5	0	100
Range	1-68	0	N/A

b. Study Number: 0876-E-US-14-98

Clinical Investigator: Craig R. Reinemeyer, DVM, Ph.D.
East Tennessee Clinical Research, Inc.
Knoxville, Tennessee 37922

Test Animals/Source of Infection: Naturally-infected, mixed-breed horses

Treatment Design:

Treatment Groups	Number Treated
Untreated Control	7
Moxidectin Equine Gel, 0.4 mg/kg body weight	7

Test Duration: 14 days

Observations: *Gasterophilus* spp. infections were determined by endoscopic exam prior to initiation of this experiment. No adverse reactions to treatment were reported.

Results of Treatment: All control ponies (7/7) were infected with *Gasterophilus nasalis* (3^{rd} instars). Treatment was 100% effective against *G. nasalis* (3^{rd} instars) in this experiment.

Table 2. Effectiveness of moxidectin oral gel against *Gasterophilus nasalis* 3rd instars in Study 0876-E-US-14-98

Test Parameter	Control	Treated	% Effectiveness
Number of horses infected at necropsy/ Number in treatment group	7/7	0/7	N/A
Arithmetic mean	27.4	0	100
Geometric mean	18.1	0	100
Range	5-77	0	N/A

5. Animal Safety

The approval of this supplemental NADA 141-087 is for a new indication. It does not change the dose level, frequency or route of administration of QUEST (moxidectin) 2% Equine Oral Gel or the class or species of treated animals. Consequently, no additional animal safety data were required for approval of this new indication. Information regarding the safety of QUEST Gel to treat horses and ponies is located in Section 5 (pages 19-27) of the original NADA 141-087 Freedom of Information Summary (July 11, 1997).

The precautions section of the labeling was modified in response to reports of misuse of the product in dogs.

6. Human Safety

Human Food Safety

QUEST (moxidectin) 2% Equine Oral Gel is specifically labeled: "Do not use in horses or ponies intended for food." Because the drug is not intended for use in food-producing animals, human food safety data were not required for the original or supplemental NADA 141-087 approval.

User Safety

The addition of the new indication approved in this NADA 141-087 supplement in no way affects the physical characteristics of QUEST (moxidectin) 2% Equine Oral Gel or the way it is administered. Consequently, no user safety data were required for the supplemental approval.

7. Agency Conclusions

The data in support of this supplemental NADA comply with the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and Section 514.8 of the implementing regulations. The data demonstrate that QUEST™ moxidectin 2% Equine Oral Gel, when used under labeled conditions, is safe and effective for the treatment and control of *Gasterophilus nasalis* (3^{rd} instars).

Under section 512(c)(2)(F)(iii) of the FFDCA, this supplemental approval for non food producing animals qualifies for three years of marketing exclusivity beginning on the date of the supplemental approval because the application contains substantial evidence of the effectiveness of the drug involved, or studies of animal safety required for the approval of the application and conducted or sponsored by the applicant. The three years of marketing exclusivity applies only to the treatment and control of *Gasterophilus nasalis* (3rd instars) for which the supplemental application was approved.

8. Labeling (attached)

Package Insert
Syringe Label
Printed Outer Carton