FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 140-819

Strongid® 48
(pyrantel tartrate)

Sponsored by:

Pfizer, Inc.

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FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

NADA Number: 140-819

Sponsor: Pfizer, Inc.
235 East 42nd Street
New York, NY 10017-5755

Established Name: pyrantel tartrate

Tradename: Strongid® 48

Marketing Status: OTC

Supplement Effect: This supplement provides for revised feeding instructions. It also provides for movement of the parasite *Triodontophorus* spp. from the Large Strongyles to the Small Strongyles in the indications section.

II. INDICATIONS FOR USE

Strongid® 48 is recommended for the prevention of Strongylus vulgaris larval infestation in horses. For control of the following parasites in horses: Large Strongyles (adults): *S. vulgaris*, *S. edentatus*; Small Strongyles (adults and fourth-stage larvae): *Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., Cylicodontophorus spp., Poteriostomum spp., *Triodontophorus* spp.; Pinworms (adults and fourth-stage larvae): *Oxyuris equi*; Ascarids (adults and fourth-stage larvae): *Parascaris equorum*.

III. DOSAGE FORM, ROUTE OF ADMINISTRATION, AND RECOMMENDED DOSAGE

A. *Dosage Form*: Type A Medicated Article and Type C Medicated Feeds

B. *Route of Administration*: Oral

C. *Approved Dose*: Feed continuously at the rate of 1.2 milligrams per pound (2.64 milligrams per kilogram) of body weight daily.

IV. EFFECTIVENESS

Additional effectiveness studies were not necessary for the proposed label changes.

V. ANIMAL SAFETY

Additional safety studies were not necessary for the proposed label changes.

VI. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA comply with the requirements of section 512 of the Act and demonstrate that pyrantel tartrate, when used under the proposed conditions of use, is safe and effective for the listed indications.

In accordance with 21 CFR 514.106(b)(1)(vii), this is a category I change. The approval of this change did not require a reevaluation of the safety and effectiveness data in the parent application.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for non food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, or any studies of animal safety required for the approval and conducted or sponsored by the applicant.

VII. APPROVED PRODUCT LABELING

Facsimile labeling is attached:

Type A Medicated Article
Type C Blue Bird Labeling
- 4.8 g/lb
- 9.6 g/lb