

I. GENERAL INFORMATION

A. File Number

NADA 139-191

B. Sponsor

Purina Mills, Inc.
835 South Eighth Street
St. Louis, Missouri 63201

C. Proprietary Name

Dog Wormer Chewable Tablets

D. Established Name

pyrantel pamoate

E. Dosage Form

Purina Dog Wormer Chewable Tablets are formulated in two sizes of chewable oral tablets at concentrations of 22.7 mg and 113.5 mg pyrantel base as pyrantel pamoate per tablet.

F. Recommended Dosages

22.7 mg pyrantel base as pyrantel pamoate chewable tablet - 1 tablet per each 10 lbs. of dog body weight for dogs weighing over 5 lbs. and 1 tablet for dogs weighing less than 5 lbs.

113.5 mg pyrantel base as pyrantel pamoate chewable tablet - 1 tablet per 50 lbs. of dog body weight. Tablet may be broken in half to provide 1/2 tablet for 25 lbs. of body weight.

Label directions are designed to provide a minimum of 2.27 mg pyrantel base per pound body weight for dogs weighing more than 5 pounds body weight, and 4.54 mg pyrantel base per pound body weight for dogs weighing 5 lbs. or less. Tablets are scored to facilitate breaking of tablet for more accurate dosage. Since anthelmintics cannot be relied upon to prevent reinfection or to remove larvae not present in the intestinal tract at the time of initial treatment, for maximum control, it is recommended that puppies be treated at 2, 3, 4, 6, 8 and 10 weeks of age. Lactating bitches should be treated 2-3 weeks after whelping. Adult dogs should be routinely treated at monthly intervals to protect against *T. canis* reinfection. Retreatment of adult dogs may be necessary at monthly intervals as determined by laboratory fecal examinations or in animals kept in known contaminated quarters.

G. Route of Administration

Pyrantel pamoate chewable tablets are administered orally by offering by hand or in the dogs food container with or without food.

H. Indication

For removal of ascarids (*Toxocara canis*; *Toxascaris leonina*) and hookworms (*Ancylostoma caninum*; *Uncinaria stenocephala*) in dogs and puppies.
To prevent reinfection of *Toxocara canis* in puppies and adult dogs and in lactating bitches after whelping.

II. EFFECTIVENESS

The effectiveness of Purina Dog Wormer Tablets has been established by data contained in approved NADA 101-331 (see attached Freedom of Information Summaries for Pyrantel Pamoate Tablets for Dogs). This original application demonstrated that Purina Dog Wormer continues to be effective when administered as a chewable tablet.

A. Bioequivalence

Physical and chemical data demonstrated bioavailability and therapeutic equivalency of the approved regular tablet (NADA 101-331) and the chewable tablet (NADA 139-191). The dose and amount of active ingredient (Pyrantel Pamoate) in the regular tablet and in the chewable tablet are identical. Pyrantel Pamoate administered orally is not readily absorbed into the systemic circulation. The primary site of action as an anthelmintic is in the gastrointestinal tract. The disintegration time for both the regular tablet and the chewable tablet is less than 10 minutes. The chewable tablets contain no excipients that would significantly alter or interfere with the therapeutic activity of pyrantel pamoate in the intestinal tract. Therefore, therapeutic equivalence of the two tablets has been demonstrated; the efficacy of the chewable tablets has been established.

B. Palatability

1. Home Environmental Test

a. Name and address of investigator who did the study.

Mrs. GERALYN BUSENSKI
Checkerboard Kitchens
Ralston Purina Company
St. Louis, Missouri 63164

b. Purpose of Study

To demonstrate that Purina Dog Wormer Chewable Tablets are palatable when hand offered to dogs in non-competitive home environments.

c. Test Animals

Forty dogs of all sizes, both sexes and many breeds were hand offered the chewable tablet and allowed a maximum of 15 minutes to fully consume the tablet. Dogs are owned and housed in the homes of non-biased participants who regularly test dog food and treat products in their homes. All dogs are from a single animal environment to exclude competition.

d. Test Product

Owners determined weight of their dog and received a "coded" pouch containing the premeasured dosage of Dog Wormer Chewable Tablets. Dosage made up of small and/or large tablets, whole and/or broken depending upon dog size.

e. Results

Ninety-four percent (94%) consumed the tablet within the 15 minutes provided. One dog refused to eat the tablet and one ate only when it was added to its food.

C. Acceptance Test

1. Name and address of investigator who did the study:

Mr. C. W. Dickerson
Health Industries Research
Pet Nutrition Department
Purina Research Farm
Gray Summit, MO.

2. Purpose of Study

To demonstrate acceptability of Purina Dog Wormer Chewable Tablets containing pyrantel pamoate to various breeds, sizes and sexes of dogs.

3. Test Animals

Dogs were penned individually or with its litter. Dogs were offered both large and/or small tablets in order to obtain more exact dosage and to determine palatability of both sizes by hand and allowed 15 minutes to consume.

4. Results

Eighty-six out of 89 dogs (97%) fully consumed the allotted dosage within the 15 minute time period.

III. TARGET ANIMAL SAFETY

The animal safety of pyrantel pamoate oral dosage forms has been adequately demonstrated per Pfizer's approved NADA 100-237. Pfizer, Inc. provided authorization to Purina Mills, Inc. on 5/20/75 to refer to safety data contained in Pfizer, Inc. NADA's 91-739, 100-237 and 16-803 in support of NADA 101-331 on page 00035. Pfizer letters dated July 7, 1987 and July 21, 1987 reaffirm authorization for Purina Mills Inc. to reference the above stated NADA's.

IV. HUMAN FOOD SAFETY

A. Human Food Safety:

As labeled, the drug poses no hazard to human safety pertaining to drug residues, because it is labeled for use in dogs only.

B. Human Safety Relative to Possession, Handling and Administration:

The labeling contains an adequate caution statement.

V. AGENCY CONCLUSIONS

Data submitted satisfy the requirements of section 512 of the Act and demonstrate that Purina Wormer Chewable Tablets (Pyrantel Pamoate) when used under its proposed conditions of use are safe and effective for labeled indications. The product is for oral administration to dogs with adequate directions for use which the layman can reasonably be expected to follow in practice. The agency therefore concluded that Purina Dog Wormer Chewable Tablets (Pyrantel Pamoate), may be provided to the public on an over-the-counter basis.

VI. ATTACHMENTS

- 1) 4-tablet package, front and back panels, for puppies and small dogs
- 1) 80-tablet package, front and back panels, for puppies and small dogs
- 2) 2-tablet package, front and back panels, for large dogs
- 3) 40-tablet package, front and back panels, for large dogs

Copies of these labels may be obtained by writing to the:
Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.