Approval Date: September 12, 1991

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 133-953

B. Sponsor

Mobay Corporation
Animal Health Division
P. O. Box 390
Shawnee, KS 66201

C. Proprietary Name

Vercom Paste Anthelmintic

D. Established Name

febantel and praziquantel

E. Dosage Form

Paste

F. Dispensing Status

Rx

G. Dosage Regimen

Dogs and Cats:

1 g/7.5 lb body weight (BW) given to mature dogs and cats (10 mg febantel and 1.0 mg praziquantel/kg BW) given daily for 3 consecutive days.

Puppies and Kittens younger than 6 mo. of age:

1 g/5 lb BW (15 mg febantel and 1.5 mg praziquantel/kg BW) given on a full stomach daily for 3 consecutive days.

H. Route of Administration

Oral; directly into the mouth or, for mature animals, mixed with food and fed to the animal.

I. Indication

Vercom Paste Anthelmintic is indicated for the removal of the following nematode parasites (these are unchanged by this supplement):

In Dogs and Puppies:

- Hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*)
- Ascarids (*Toxocara canis*, *Toxocara leonina*)
- Whipworms (*Trichuris vulpis*)
- Tapeworms (Dipylidium caninum and *Taenia pisiformis*)

In Cats and Kittens:

- Hookworms (*Ancylostoma tubaeforme*)
- Ascarids (*Toxocara cati*)

Tapeworms (*Dipylidium caninum* and *Taenia taeniaeformis*)

J. Effect of Supplement

This supplement provides for the addition of the following warning statement to the label: "Warning: Consider alternative therapy or use with caution in animals with pre-existing liver or kidney dysfunction."

II. EFFECTIVENESS

Well-controlled critical anthelmintic studies (which involved the sacrificing of animals and examination to determine the number of parasites in the intestinal tract) were conducted to establish and confirm the minimum effective dose of Vercom paste. These studies are included in the original FOI Summary for Vercom Paste, NADA 133-953 (50 FR 19167). Additional data were collected and a supplement was approved extending the parasite spectrum for which the drug is approved, and this FOI summary is also available (53 FR 48533).

III. TARGET ANIMAL SAFETY

This supplement provides for the addition of the following warning statement to the label, "Warning: Consider alternative therapy or use with caution in animals with pre-existing liver or kidney dysfunction."

The addition of this warning is based on data gathered during the safety evaluation of febantel alone for Rintal Tabs, NADA 140-912. A summary of this data can be found in the F.O.I. for that product under the heading, General Safety Evaluation (General Safety Evaluation for the Use of Febantel Tablets in Cats). It was shown in this study, that, at elevated doses, toxicity may be increased in the animal already compromised by hepatic or renal disease.

IV. HUMAN FOOD SAFETY

A. Human Food Safety

Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of NADA. The drug (febantel and praziquantel) is labeled for use in dogs and cats only.

B. Safety Relative to Possession, Handling and Administration

Laboratory animal toxicity studies verify the lack of potential hazards to human handling of the formulation. The label states: Keep out of reach of children.

V. AGENCY CONCLUSIONS

Under the Center's supplemental approval policy (55 FR 46045), published November 1, 1990, this is a Category II change because it provides solely for the addition of a user warning statement. The approval of this supplemental application has no adverse effect on the safety and effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety and effectiveness data in the parent application. Safety is enhanced by the addition of the following labeling statement:

"Warning: Consider alternative therapy or use with caution in animals with pre-existing liver or kidney dysfunction."

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F), this approval does not qualify for any term of marketing exclusivity because no new clinical or field investigations conducted by the sponsor were essential to the approval of this supplemental NADA.

The expertise of a trained professional is required for a definitive diagnosis, to monitor the results of treatment, and determine the occurrence of adverse effects; therefore, the drug is a prescription product.

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.