Approval Date: January 11, 1993

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 111-798

B. Sponsor

Miles Inc.
Agriculture Division
P.O. Box 390
Shawnee Mission, Kansas 66201

C. Proprietary Name

Droncit® Feline Cestocide Tablets

D. Established Name

praziquantel

E. Dosage Form

Tablet

F. Dosage Regimen

The 11.5 mg tablet is administered orally to cats 4 pounds and under.

G. Route of Administration

Oral

H. Indication

The indications for use remains the same as currently approved. Droncit Feline Cestocide Tablets are indicated for the removal of the following feline cestodes: *Dipylidium caninum* and *Taenia taeniaeformis*.

I. Effect of Supplement

This supplement amends the NADA to provide for a 11.5 mg spherical tablet, which is half the concentration of the previously approved 23 mg tablet, for cats.

II. SAFETY AND EFFECTIVENESS

The approval of the 11.5 mg tablet did not require safety and effectiveness data. The approval was based on an environmental assessment, labeling, and manufacturing information on containers/closures, dissolution, and stability of the 11.5 mg tablets.

III. 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 this supplement. The drug is used in cats, which are non-food animals.

B. Human Safety Relative to Possession, Handling and Administration

The labeling contains adequate directions for use and thus poses no human safety hazard.

IV. AGENCY CONCLUSIONS

Under the Center's supplemental approval policy (55 FR 46045: codified at 21 CFR 514.106), published November 1, 1990, this is a Category II change because it provides for a new tablet size. The approval of this supplemental new animal drug application is supported by adequate safety and effectiveness data for this new animal drug. Accordingly, this approval did not require a re- evaluation of the safety and effectiveness data in the parent application. 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.

V. ATTACHMENTS

1. Unit label- 6 (11.5 mg) tablets
2. Leaflet- package insert
3. Printed Bag
4. Multi-carton
5. Shipper stencil

Copies of applicable 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.