Approval Date: August 1, 1998

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 141-035

B. Sponsor

Novartis Animal Health US, Inc.
Post Office Box 26402
Greensboro, NC 2740

C. Proprietary Name

Program® Flavor Tabs™

D. Established Name

Lufenuron Tablets

E. Dosage Form, Route of Administration and Recommended Dosage

For Use in Dogs: PROGRAM Flavor Tabs are given orally, once a month, at the recommended minimum dosage of 4.5 mg/lb (10 mg/kg).

Recommended Dosage Schedule for Dogs

Body Weight	Lufenuron Per Tablet
Up to 10 lbs.	45 mg
11-20 lbs.	90 mg
21-45 lbs.	204.9 mg
45-90 lbs.	409.8 mg

Dogs over 90 lbs. are provided the appropriate combination of tablets.

For Use in Cats: PROGRAM Flavor Tabs are given orally, once a month, at the recommended minimum dosage of 13.6 mg/lb (30 mg/kg).

Recommended Dosage Schedule for Cats

Body Weight	Lufenuron Per Tablet
Up to 6 lbs.	90 mg
7-15 lbs.	204.9 mg

Cats over 15 lbs. are provided the appropriate combination of tablets

F. Dispensing Status

OTC

G. Indication

PROGRAM Flavor Tabs are indicated for use in dogs and puppies six weeks of age and older for the prevention and control of flea populations and in cats and kittens, six weeks of age and older for the control of flea populations. Lufenuron controls flea populations by preventing the development of flea eggs and does not kill adult fleas. Concurrent use of insecticides may be necessary for adequate control of adult fleas.

H. Effect of Supplement

This supplemental provides for adding a flavored tablet formulation with the same indications as the non-flavored tablets.

II. EFFECTIVENESS

The effectiveness of PROGRAM Flavor Tabs is based upon existing Novartis product approvals for lufenuron (PROGRAM Tablets, NADA 141-035, PROGRAM Suspension, NADA 141-026). The flavoring agent used in this formulation has been adequately tested for palatability in existing Novartis product approvals (PROGRAM Cat Flavor Tablets, NADA 141-062, SENTINEL Flavor Tablets, NADA 141-084).

III. TARGET ANIMAL SAFETY

The safety of PROGRAM Flavor Tabs is based upon existing Novartis product approvals for lufenuron (PROGRAM Tablets, NADA 141-035, PROGRAM Suspension, NADA 141-026).

IV. AGENCY CONCLUSIONS

The data in support of this NADA comply with the requirements of Section 512 of the Act and Part 514 of the implementing regulations. The data demonstrate that PROGRAM Flavor Tabs (lufenuron), when used under labeled conditions of use, are safe and effective.

Because adequate directions for the safe and effective lay use of PROGRAM Flavor Tabs could be written, the product has been labeled for over-the-counter distribution.

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.

Patent # 5,416,102 expires May 2012; Patent # 5,420,163 expires May 2012; Patent # 4,798,837 expires January 2006.

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.