Approval Date: December 31, 1996

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 141-035

B. Sponsor

Ciba Animal Health, Ciba-Geigy Corporation
P.O. Box 18300
Greensboro, NC 27419-8300

C. Proprietary Name

Program® Tablets

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	No. Tablet(s) Per Month	mg Lufenuron Per Tablet	Color
Up to 10 lbs.	1	45 mg	Brown
11-20 lbs.	1	90 mg	Red
21-45 lbs.	1	204.9 mg	Yellow
45-90 lbs.	1	409.8 mg	White

Dogs over 90 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.

H. Effect of Supplement

This supplemental provides for changing from Rx to OTC and addition of an Adverse Reactions section to the product labeling.

II. EFFECTIVENESS

The effectiveness of the product is not affected by this supplement. Refer to the FOI Summary for the original approval dated November 23, 1994.

III. TARGET ANIMAL SAFETY

The following statement has been added to the labeling, based on adverse drug experience reports.

ADVERSE REACTIONS: The following adverse reactions have been reported in dogs after giving Program tablets: vomiting, depression/lethargy, pruritus (itchy, scratchy skin), urticaria (wheals, hives), diarrhea, anorexia (loss of appetite) and skin congestion (red skin).

For additional safety information, refer to the FOI Summary for the original approval dated November 23, 1994.

IV. AGENCY CONCLUSIONS

The product is being changed from Rx to OTC for the following reasons: 1) the condition to be treated (fleas) can be adequately diagnosed and the course of the disease (infestation) can be followed by the layperson such that an assessment can be made of the success or lack of success of the product; 2) experience with the product and other products with similar mechanisms of action demonstrates that the public is now familiar with the use of flea products which act at the level of flea egg without having an effect on the adult flea; and 3) adequate instructions for the safe and effective lay use have been written (attached).

According to the Center's supplemental approval policy (21 CFR 514.106), this is a Category II change. This supplement provides for a change in the prescription or over-the-counter status of a drug product (change from Rx to OTC) and a change in statements regarding side effects (addition of an Adverse Reactions section to the label). The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug. Accordingly, this approval did not require a reevaluation of the safety or effectiveness data in the parent application.

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.