Approval Date: December 31, 1996

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 141-026

B. Sponsor

Ciba Animal Health
Ciba-Geigy Corporation
Post Office Box 18300
Greensboro, NC 27419-8300

C. Proprietary Name

PROGRAM® Suspension

D. Established Name

Lufenuron Suspension

E. Dosage Form

Oral Suspension

F. Dispensing Status

OTC

G. Dosage Regimen

The ingredients of PROGRAM Suspension are formulated into an oral suspension, packaged in two sizes of unit dose packs, for administration as appropriate for the weight of the cat (see below) at monthly dosing intervals. Each PROGRAM Suspension unit dose pack provides the minimum recommended dose of 30 mg lufenuron per kilogram of body weight.

Cat Weight	Unit Dose Packs per Month	Lufenuron Per Unit Pack Dose	Unit Dose Pack Color
Up to 10 lbs.	1 small	135 mg	Orange
11 to 20 lbs.	1 large	270 mg	Green

Cats over 20 lbs. are provided the appropriate combination of packs.

H. Route of Administration

PROGRAM Suspension should be mixed with food and offered to the cat. The cat should be observed to ensure that the entire dose is consumed. Give in conjunction with a full meal. In multi-cat households, cats should be separated during treatment to achieve adequate dosing in each cat.

I. Indication

PROGRAM Suspension is indicated for use in cats and kittens, six weeks of age and older, for the control of flea populations.

J. Effect of Supplement

Change from Rx to OTC and addition of an Adverse Reactions section to the product label.

II. EFFECTIVENESS

The effectiveness of the product is not affected by this supplement. Refer to the FOI Summary for the original approval dated March 28, 1995.

III. 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 cats after giving Program suspension: vomiting, depression/lethargy, anorexia (loss of appetite), diarrhea, dyspnea (labored breathing), pruritus (itchy, scratchy skin), and skin disorder.

For additional safety information, refer to the FOI Summary for the original approval dated March 28, 1995.

IV. HUMAN SAFETY

Data on human safety, pertaining to consumption of drug residues in food, were not required for approval of this supplement. This drug is labeled for use in cats which are non-food animals.

V. 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.