Approval Date: March 30, 1991

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 131-675

B. Sponsor

Hoechst-Roussel Agri-Vet Company
Route 202-206
P.O. Box 2500
Somerville, NJ 08876-1258

C. Proprietary Name

SAFE-GUARD® Type "A" Medicated Article (Premix)

D. Established Name

fenbendazole

E. Dosage Form

This supplement provides for a Type A medicated article; containing 8% fenbendazole for use in Type C medicated swine feed.

F. Dosage Regimen

No change in the currently approved dosage of nine (9) mg fenbendazole/kg body weight (4.08 mg fenbendazole per pound) to be fed as the sole ration over a period of 3 to 12 days.

G. Indication

3-12 DAY TREATMENT REGIMEN (TOTAL DOSAGE 9 MG/KG BODY WEIGHT) FOR REMOVAL OF:

Lungworms: *Metastrongylus apri*, *Metastrongylus pudendotectus*

Gastrointestinal worms: Adult and larvae (L3, L4 stages, liver, lung, intestinal forms) large roundworm (*Ascaris suum*); nodular worms (*Oesophagostomum dentatum*,*O. quadrispinulatum*); small stomach worm (*Hyostrongylus rubidus*); Adult and larvae (L2, 3, 4 stages -intestinal mucosal forms) whipworm (*Trichuris suis*)

Kidneyworm: Adult and larvae *Stephanurus dentatus*

H. Effect of Supplement

This supplement provides for an additional Type A medicated article (premix) containing 8% fenbendazole for the same indications for use in Type C medicated

swine feed as the currently approved Type A medicated articles containing 4% and 20% fenbendazole. See 21 CFR 558.258.

II. EFFECTIVENESS

No additional effectiveness studies were needed for this supplemental NADA, because effectiveness was shown in approved NADA 131-675. See 49 F.R., p. 3846, 1/31/84; 53 F.R., p. 48533, 12/1/88; and 55 F.R., p. 48230/1, 11/20/90.

III. TARGET ANIMAL SAFETY

No additional target animal safety studies were needed for this supplemental NADA, because TAS was shown in the approved NADA 131-675 (49 F.R., p. 3846, 1/31/84).

IV. HUMAN FOOD SAFETY

No additional human safety studies were needed for this supplemental NADA, because human food safety was shown in NADA 131-675 (49 F.R., p. 3846, 1/31/84).

V. AGENCY CONCLUSIONS

This supplemental NADA provides for the addition of a Type A medicated article containing 8% fenbendazole. The formulation is not different from the 4% and 20% articles already approved except for the concentration of fenbendazole (8%).

Under the Center's supplemental approval policy (55 F.R., p. 46045; 11/1/90) this is a Category II change which provides for a Type A medicated article concentration for the manufacture of Type C medicated swine feed. This change is not expected to have an adverse affect on the safety and effectiveness of this new animal drug. This action did not require a reevaluation of the underlying safety and effectiveness data in the parent application.

Under the Generic Animal Drug and Patent Term Restoration Act of 1988, this approval does not qualify for an exclusivity period under Section 512(c)(2)(f)(iii) because the active ingredient in this product has been approved under Section 512(b) of the FD&C Act for the same indications at the same dose as approved NADA 131-675 (49 F.R., p. 3856, 1/31/84).

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.