Approval Date: April 25, 1994

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 128-620

B. Sponsor

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

C. Proprietary Name

PANACUR®

D. Established Name

fenbendazole

E. Dosage Form

Fenbendazole 10% suspension will be marketed as an oral anthelmintic in 1000 mL multidose glass bottle.

F. How Supplied

Size and Description of container

G. Dispensing Status

OTC

H. Dosage Regimen

A single dosage of 5 mg fenbendazole per kg of body weight.

I. Route of Administration

Oral

J. Indication

For the removal and control of stomach and intestinal worms, *Haemonchus contortus* and *Ostertagia circumcincta*, in goats.

K. Effect of Supplement

This supplement provides for an expanded use of fenbendazole in a new species (goats).

II. EFFECTIVENESS

This has been addressed in PMF 5118, 56 FR 13650, April 3, 1991.

III. TARGET ANIMAL SAFETY

This has been addressed in PMF 5118, 56 FR 13650, April 3, 1991.

IV. HUMAN FOOD SAFETY

a. *Toxicity Studies* - These have been adequately addressed in the original approval.

b. *Tolerance for Residues* - A tolerance of 0.8 ppm is established for parent fenbendazole in liver of goats.

c. *Metabolism and Total Residue Depletion Studies* - Adequate data on metabolism have been submitted for cattle under approved NADA 128-620 and no unique metabolites of toxicological concern are anticipated to result from the recommended use of fenbendazole in goats.

d. *Withdrawal Time* - Residue depletion data submitted under PMF 5118, 56 FR 13650, April 3, 1991, support a 6-day preslaughter withdrawal time for goats treated with the recommended dose of fenbendazole 10% suspension.

V. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of Section 512 of the Food, Drug, and Cosmetic Act and 21 CFR 514.106 of the implementing regulations. The data demonstrate that fenbendazole 10% suspension Panacur ® is safe and effective, when used in accordance with labeling directions, for the removal and control of stomach and intestinal worms, Haemonchus contortus and Ostertagia circumcincta, in goats.

The human food safety data submitted under PMF 5118, 56 FR 13650, April 3, 1991, indicate that the goats treated with fenbendazole at the recommended dosage will require 6 days for the depletion of fenbendazole residue from the edible tissues.

The agency concludes that appropriate directions for use have been written for prescription use of this oral suspension drug in goats. The currently approved fenbendazole suspension is codified in Section 21 CFR 520.905a for use in cattle.

The agency has carefully considered the potential environment effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact (FONSI) and the evidence supporting that finding are contained in an environmental assessment which may be seen in the Dockets Management Branch (HFA 305), Park Building (Room 1-23), 12420 Parklawn Drive, Rockville, MD 20855.

Under the agency's supplemental approval policy, 21 CFR 514.106(b)(2)(vii), this is a Category II change that did not require a reevaluation of the safety and effectiveness data contained in the Public Master File (PMF) 5118.

Under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval does not qualify for marketing exclusivity because no new clinical or field investigations (other than bioequivalence or residue studies) and no new human food safety studies (other than bioequivalence or residue studies) essential to the approval of the supplement were conducted or sponsored by the applicant.

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.