Date of Approval: February 13, 2003

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 128-620

Panacur®/Safe-Guard® (fenbendazole) Suspension 10%

"To change the marketing status for use in goats from Prescription (Rx) to Over-The-Counter (OTC) and revise the Indication Section for goats to update the labeling."

SPONSORED BY:

INTERVET, INC.

I. GENERAL INFORMATION

NADA Number: 128-620

Sponsor: Intervet, Inc.
405 State Street
Millsboro, Delaware 19966-0318

Drug Labeler Code: 057926

Established Name: fenbendazole

Proprietary Names: Panacur®/Safe-Guard®

Marketing Status: Currently, Safe-Guard® is OTC for beef and dairy cattle; Panacur® is Rx for beef and dairy cattle, horses, and goats.

Effects of Supplement: 1) The marketing status of fenbendazole suspension for use in goats is changed from prescription (Rx) to over-the-counter (OTC) by removing goats from the Panacur® Suspension 10% label and by adding goats to the Safe-Guard® Suspension 10% label. The formulation of the two products is identical.

2) The indications for use in goats are revised from "…for the removal and control of stomach and intestinal worms *Haemonchus contortus* and *Ostertagia circumcincta*" to "…for the removal and control of stomach worms (adults) *Haemonchus contortus* and *Teladorsagia circumcincta*."

II. INDICATIONS FOR USE

SAFE-GUARD® (fenbendazole) suspension 10%
Beef and dairy cattle: for the removal and control of:

Lungworm: (*Dictyocaulus viviparus)*

Stomach worm (adults): *Ostertagia ostertagi* (brown stomach worm).

Stomach worm (adults & 4th stage larvae): *Haemonchus contortus/placei* (barberpole worm), *Trichostrongylus axei* (small stomach worm)

Intestinal worm (adult and 4th stage larvae): *Bunostomum phlebotomum* (hookworm), *Nematodirus helvetianus* (thread-necked intestinal worm), *Cooperia oncophora* and *C. punctata* (small intestinal worm), *Trichostrongylus colubriformis* (bankrupt worm), *Oesophagostomum radiatum* (nodular worm).

Goats: for the removal and control of stomach worms (adults) *Haemonchus contortus* and *Teladorsagia circumcincta*.

III. DOSAGE

A. Dosage Form: Suspension

B. Route of Administration: Oral, as a drench

C. Recommended Dosage: Beef and Dairy Cattle: 5.0 mg/kg (2.3 mg/lb)
Beef Cattle only (Panacur label): 10 mg/kg (4.6 mg/lb)
Goats: 5.0 mg/kg (2.3 mg/lb)

IV. EFFECTIVENESS

No further effectiveness data were required from the original approval for goats under PMF 5118 dated March 28, 1991, and NADA 128-620 dated April 25, 1994. This was a minor species approval. Adequate directions for use have been written for the layperson and the conditions of use prescribed on the label are likely to be followed in practice. The indication revision has been made for the following reasons. The scientific community has changed the genus name for *Ostertagia* to *Teladorsagia* for the goat parasite. The terminology "and intestinal" has been removed from the indication as both *Haemonchus contortus* and *Teladorsagia circumcincta* are stomach worms. The term adult has been added since the studies conducted for the indication were only in the adult parasite.

V. ANIMAL SAFETY

No further target animal safety data were required from the original approval for goats under PMF 5118 dated March 28, 1991, and NADA 128-620 dated April 25, 1994.

VI. HUMAN SAFETY

No further human food safety data were required from the original approval for goats under PMF 5118 dated March 28, 1991, and NADA 128-620 dated April 25, 1994. There is a 6-day withdrawal period for slaughter, a withdrawal period for milk has not been established, and fenbendazole suspension is not for use in lactating goats.

VII. AGENCY CONCLUSIONS

The information submitted in support of this supplemental NADA satisfies the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and of the implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) for Panacur®/Safe-Guard® (fenbendazole) Suspension 10%, to allow for a

change in the marketing status for use in goats from Rx to OTC and to revise the goat indication section.

The Agency has concluded that this product shall have over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions of use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2)(viii), this is a Category II change which did not require a reevaluation of the safety or effectiveness data in the parent application.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualify for marketing exclusivity beginning on the date of approval because the supplemental application does not contain substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for the approval of the application and conducted or sponsored by the applicant.

VIII. APPROVED PRODUCT LABELING (attached)

A. Safe-Guard® (fenbendazole) Suspension 10% - 1000 mL (33.8 oz) plastic container
B. Safe-Guard® (fenbendazole) Suspension 10% - 3785 mL (1 gallon) plastic container

Copies of applicable labeling may be obtained by writing to:

Freedom of Information Staff (HFI-35)
Food and Drug Administration, Room 12A16
5600 Fishers Lane
Rockville, MD 20857