Approval Date: March 17, 1994

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 092-444

B. Sponsor

Pfizer, Inc.
1107 S State Route 291
Lee's Summit, Missouri 64081-2998

C. Proprietary Name

Rumatel® 88

D. Established Name

morantel tartrate

E. Dosage Form

Type A medicated article to be mixed with feed to produce Type C medicated feed.

F. Dispensing Status

OTC

G. Dosage Regimen

Medicated feed is to be fed at the rate of 0.44 grams morantel tartrate per 100 lb of body weight.

H. Route of Administration

These drugs are administered orally by adding the Type A medicated article to feed to make a complete feed (Type C medicated feed)

I. Indication

Cattle: For the removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp. *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).

Goats: For the removal and control of mature gastrointestinal nematode infections of goats including *Haemonchus contortus*, *Ostertagia* (*Teladorsagia*) *circumcincta*, and *Trichostrongylus axei*.

J. Effect of Supplement

This supplement provides for an additional claim for use of this Type A medicated article to produce Type C medicated feed for Goats.

II. EFFECTIVENESS

Efficacy data from the FOI summary for PMF 5366, 57 FR 49486, November 2, 1992, demonstrated that morantel tartrate at 10 mg/kg body weight, as a single treatment, is efficacious in removing 99.3, 97.7, and 91.4%, respectively, of adult *Haemonchus contortus*, *Ostertagia* (*Teladorsagia*) *circumcincta*, and *Trichostrongylus axei* from the abomasum of goats.

III. TARGET ANIMAL SAFETY

Target animal safety data from the FOI summary for PMF 5366, 57 FR 49486, November 2, 1992, demonstrated that administration of morantel tartrate in feed at 10 times the recommended dose for 3 consecutive days is safe and nontoxic to goats.

IV. HUMAN FOOD SAFETY

Toxicity Testing: These have been adequately addressed in the FOI summary for PMF 5366.

Target tissues, marker residues, and tolerances: Because this is a minor species application, the target tissues, marker residues and tolerances for morantel tartrate residues in cattle were applied to goat. The target tissue is liver, and, because the drug is approved for use in lactating animals, milk is also considered a target tissue. The marker residue for both liver and milk is N-methyl-l,3-propanediamine (MAPA). The tolerance for MAPA in liver is 0.7 ppm (21 CFR 556.425). Although an official tolerance for MAPA in milk was not established in 21 CFR 556.425, a research (unofficial) tolerance of 91 ppb of MAPA was established based on data submitted to support the dairy cattle approval. Therefore, a tolerance of 91 ppb of MAPA was used to evaluate residues of morantel tartrate in goat milk.

Withdrawal Time: Residue depletion data submitted under PMF 5366, 57 FR 49486, November 2, 1992, support a 30 day withdrawal period for a single 10 mg morantel tartrate/kg body weight dose to goats and a zero milk discard period for a single 10 mg morantel tartrate/kg body weight dose to goats.

V. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA comply with the requirements of section 512 of the Act and demonstrate that morantel tartrate, when used under the proposed conditions of use, is safe and effective for the removal and control of gastrointestinal nematodes in goats.

Based on tissue and milk residue studies, a 30 day slaughter period and a 0-day milk discard period are assigned for goats treated with morantel tartrate at the recommended dosage.

The original approval of morantel tartrate was as an over-the-counter drug. Accurate diagnosis of parasitism in goats, which is the new species to be added to the label, can be made with reasonable degree of certainty by the layman. Adequate directions for use

have been written for the layman, and the conditions for use prescribed on the labeling are likely to be followed in practice. Therefore, the Center for Veterinary Medicine (CVM) has concluded that this product shall have over-the-counter marketing status.

The agency has carefully considered the potential environmental 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 Dr., Rockville, Maryland 20857.

Under the Center's supplemental approval policy 21 CFR 514.106(b)(2), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug.

Under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for food producing animals does not qualify for marketing exclusivity because the supplemental application does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

VI. ATTACHMENTS

Copies of applicable labels may be obtained by writing to the:
Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

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.