Approval Date: December 11, 1985

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 138-941

B. Sponsor

The Upjohn Company
Agricultural Division
Kalamazoo, MI 49001

C. Proprietary Name

Lincomix®/Banminth®

D. Established Name

lincomycin hydrochloride/pyrantel tartrate

E. Dispensing Status

OTC

F. Indication

For reduction in the severity of swine mycoplasmal pneumonia caused by *Mycoplasma hyopneumoniae*; aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophaqostomum spp*) infections of swine when fed in accordance with directions for use.

II. EFFECTIVENESS

The efficacy of pyrantel tartrate at 96 and 200 grams per ton against large roundworms and nodular worms was established in NADA 43-290, 38 FR 3402, 2/6/73.

The efficacy of lincomycin at 200 grams per ton against myco-plasmal pneumonia in swine was established in NADA 97-505, 47 FR 52145, ll/l9/82.

The drugs act independently of each other. Lincomycin has no indication for anthelmintic activity and pyrantel tartrate no indication for mycoplasmal pneumonia.

The requirement to conduct studies to demonstrate the independent claims of these drugs when used in combination has been satisfied in NADA 116-044 (47 FR 30244, 7/14/82} which provides for the use of 96 grams of pyrantel tartrate with 40 and 100 grams of lincomycin. Although NADA 116-040 is for the use of 96 grams of pyrantel tartrate with 40-100 grams of lincomycin, this NADA contains studies to demonstrate the individual claims of these drugs when fed in combination at 96 grams of pyrantel tartrate and 200 grams of lincomycin. In addition, analytical tests demonstrate that the two drugs do not chemically interfere with each other.

III. TARGET ANIMAL SAFETY

Please refer to the Animal Safety-sections of the FOI Summary data submitted for NADA 116-044.

IV. HUMAN FOOD SAFETY

Please refer to the Human Safety sections of the FOI Summary data submitted for NADA 116-044, 47 FR 30244, 7/14/82.

V. AGENCY CONCLUSIONS

Approval of this original NADA is based on safety and effectiveness data in Pfizer's approved NADAs 43-290 and 116-044. Use of the data in these NADAs to support this application has been authorized by Pfizer.

Pyrantel tartrate and lincomycin have been approved individually and the residues have been shown to be below the regulated tolerance at 6 days of withdrawal. Since the drugs are currently marketed for the claim, this approval poses no significant increase in the frequency of human exposure to residues of the drugs. Accordingly, this original NADA has been treated as a category II supplement which did not require a reevaluation of the human safety supporting the parent applications.

VI. ATTACHMENTS

1. Banminth® (pyrantel tartrate) product label
2. Banminth® (pyrantel tartrate) mixing and use directions

Copies of these labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20855

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.