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 (Oesophagostomum 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 mycoplasmal pneumonia in
swine was established in NADA 97-505, 47 FR 52145, 11/19/82.

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.