Date of Approval: December 31, 2001

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 111-636

LINCOMIX® Soluble Powder
(lincomycin hydrochloride)

"For Revision of the Approved LINCOMIX Soluble Powder Insert Labeling Replacing a Caution for Use Only in Swine Weighing Less than 250 Pounds with a Caution Indicating Safety Has Not Been Demonstrated for Pregnant Swine or Swine Intended for Breeding."

SPONSORED BY:

PHARMACIA & UPJOHN

I. GENERAL INFORMATION

NADA Number: 111-636

Sponsor: Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, Michigan 49001

Established Name: Lincomycin Hydrochloride

Proprietary Name: LINCOMIX® Soluble Powder

Marketing Status: OTC

Effect of Supplement: Provides for revision of the approved LINCOMIX Soluble Powder Insert Labeling replacing a caution for use only in swine weighing less than 250 pounds with a caution indicating safety has not been demonstrated for pregnant swine or swine intended for breeding.

II. INDICATIONS FOR USE

Swine: For the treatment of swine dysentery (bloody scours).
Broiler chickens: For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

III. DOSAGE

A. Dosage Form

Soluble powder

B. Route of Administration

Oral

C. Recommended Dosage

Swine: 250 mg of lincomycin per gallon of drinking water
Broiler chickens: 64 mg of lincomycin per gallon of drinking water

IV. EFFECTIVENESS

No further effectiveness data were required.

V. ANIMAL SAFETY

The 250-pound weight restriction has been removed due to swine feeding practices today resulting in heavier weights being reached in pigs before slaughter. The statement "The safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding." has been added to the label to caution against use in these animals.

VI. HUMAN SAFETY

No further human food safety data were required.

VII. AGENCY CONCLUSIONS

The information submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and implementing regulations at Part 514 of Title 21, Code of Federal Regulations (21 CFR 514) for LINCOMIX® Soluble Powder for Swine, allows for the removal of the 250 lb weight restriction.

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

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

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Under section 512(c)(2)(F)(iii) of the FFDCA, this approval for food-producing animals does not qualifies for marketing exclusivity beginning on the date of approval because the supplemental application contains 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

LINCOMIX® Soluble Powder facsimile label.

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, Maryland 20857