Approval Date: February 13, 2004

FREEDOM OF INFORMATION SUMMARY

Original Abbreviated New Animal Drug Application

ANADA 200-351

Lincomycin Injectable
25mg/mL, 100 mg/mL, 300 mg/mL
(lincomycin hydrochloride monohydrate)

Swine Antimicrobial

For the treatment of infectious forms of arthritis caused by organisms sensitive to its activity and for mycoplasma pneumonia

Sponsored by:

Phoenix Scientific, Inc.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-351
b. Sponsor:	Phoenix Scientific, Inc. 3915 South 48th Street Terrace St. Joseph, MO 64503 Drug Labeler Code: 059130
c. Established Name:	Lincomycin hydrochloride monohydrate
d. Trade/Propriety Name:	Lincomycin Injectable, USP
e. Dosage Form:	Sterile solution
f. How Supplied:	100 mL bottles
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	25, 100, and 300 mg lincomycin hydrochloride per mL of sterile finished product
i. Route of Administration:	Intramuscular
j. Species/Class:	Swine; 300 mg/mL concentration is for use in swine weighing 300 lb or more.
k. Recommended Dosage:	The usual daily dosage for arthritis or mycoplasma pneumonia is 5.0 mg/lb of body weight (bwt) intramuscularly once daily for 3-7 days as needed. When using Lincomycin Injectable containing 25 mg/mL, 1 mL/5 lb bwt will provide 5 mg/lb. When using Lincomycin Injectable containing 100 mg/mL, 1 mL/20 lb bwt will provide 5 mg/lb/ When using Lincomycin Injectable containing 300 mg/mL, 1 mL/60 lb bwt will provide 5 mg/lb. Do not treat within 48 hours of slaughter.
l. Pharmacological Category:	Antimicrobial

m. Indications:	For the treatment of infectious forms of arthritis caused by organisms sensitive to its activity. This includes most of the organisms responsible for the various infectious arthritides in swine, such as staphylococci, streptococci, *Erysipelothrix* and *Mycoplasma spp.* It is also indicated for the treatment of mycoplasma pneumonia.
n. Pioneer Product:	LINCOMIX 25, 100, and 300 Injectable; lincomycin hydrochloride monohydrate; NADA 034-025; Pharmacia & Upjohn Company

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Bioequivalence Guidance October, 2000).

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Lincomycin Injectable, USP. The generic product is administered as an intramuscular injection, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, LINCOMIX Injectable (lincomycin hydrochloride monohydrate), the subject of Pharmacia & Upjohn Company NADA 034-025, was approved on June 6, 1967.

3. HUMAN FOOD SAFETY:

- **Tolerances**

  The tolerances established for the pioneer product apply to the generic product. Tolerances of 0.6 part per million in liver and 0.1 part per million in muscle are established for lincomycin residues in swine under 21 CFR 556.360. An acceptable daily intake (ADI) for total residues of lincomycin is 25 micrograms per kilogram of body weight per day.

- **Withdrawal Time:**
  Because a waiver of the in vivo bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

  The withdrawal time of 2 days has been established for Lincomycin Injectable, USP in swine treated intramuscularly at a dose of 5 mg/lb bwt (21 CFR 522.1260).

- **Regulatory Method for Residues:**

  The analytical method for determination of Lincomycin Injectable, USP in tissues is the test using *Sarcina lutea* (ATCC 9341). This method is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that Lincomycin Injectable, USP, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-351:
Lincomycin Injectable, USP – 25 mg/mL, 100 mg/mL, and 300 mg/mL; vial labels and package insert

Pioneer Labeling for NADA 034-025:
LINCOMIX Injectable - 25 mg/mL, 100 mg/mL, and 300 mg/mL; vial labels and package insert