Date of Approval: October 1, 2002

FREEDOM OF INFORMATION SUMMARY

ANADA 200-303

Indications for use: Treatment of swine dysentery (bloody scours) and control of necrotic enteritis in broiler chickens

Sponsored by:
Phoenix Scientific, Inc.
St. Joseph, Missouri 64503

1. GENERAL INFORMATION:

a. ANADA Number	200-303
b. Sponsor:	Phoenix Scientific, Inc. 3915 S. 48th St. Terrace St. Joseph, Missouri 64503 21 CFR 510.600: Labeler Code: 059130
c. Established Name:	Lincomycin HCL Soluble Powder
d. Trade/Proprietary Name:	Lincomycin Hydrochloride Soluble Powder
e. Dosage Form:	Soluble Powder
f. How Supplied:	40 g foil packets
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Each 40 g packet contains 16 grams of lincomycin HCL
i. Route of Administration:	Oral
j. Species:	Swine and Broiler chickens
k. Labeled Dosage and Administration:	**Swine:**
Dosage:	Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water. In clinical studies, this dose rate provided an average of 3.8 mg of lincomycin per pound of body weight per day.
Treatment period:	The drug should be administered for a minimum of 5 consecutive days beyond the disappearance of symptoms (bloody stools) up to a maximum of 10 consecutive days.

Administration:	One packet (40 g) will medicate 64 gallons of drinking water providing 250 mg/gallon.
Indications for Use:	Lincomycin Soluble Powder is indicated in swine for the treatment of dysentery (bloody scours).
l. Labeled Dosage and Administration:	**Broiler chickens:**
Dosage:	Administer at a dose rate of 64 mg of lincomycin per gallon of drinking water.
Treatment Period:	The drug should be administered for 7 consecutive days.
Administration:	One packet (40g) will medicate 250 gallons of drinking water providing 64 mg/gallon.
Indications for Use:	Lincomycin Soluble Powder is indicated in broiler chickens for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.
m. Pharmacological Category:	Antibacterial
o. Pioneer Product:	Lincomix® Soluble Powder manufactured by Pharmacia & Upjohn Co. (NADA 111-636)

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 drug 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 is shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint 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 conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October, 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on May 24, 1999, from conducting an *in vivo* bioequivalence study for Lincomycin Hydrochloride Soluble Powder. The generic and pioneer products contain the same active and inactive ingredients in nearly the same concentration as the pioneer and are oral solutions.

3. HUMAN FOOD SAFETY:

WITHDRAWAL TIME

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for Lincomycin is established under 21 CFR 520.1263c. There is a zero-day withdrawal period for swine or chickens.

TOLERANCE

Under section §556.360, **Lincomycin,** the tolerances for lincomycin of 0.6 part per million in liver and 0.1 part per million in muscle are established for swine. A tolerance for residues of lincomycin in chickens is not required. The ADI for total residues of lincomycin is 25 micrograms per kilogram of body weight per day.

HUMAN SAFETY RELATIVE TO POSSESSION, HANDLING, AND ADMINISTRATION:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed 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 Hydrochloride Soluble Powder is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments:

Pioneer Labeling:
40 gram packet

Generic Labeling:
50 packet carton/box label
40 gram packet

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) 827-6567.