February 4, 1999

FREEDOM OF INFORMATION SUMMARY

ORIGINAL NEW ANIMAL DRUG APPLICATION

ANADA 200-241

Lincomycin Hydrochloride Soluble Powder

SWINE: Lincosol Soluble Powder is indicated for the treatment of swine dysentery (bloody scours)

BROILER CHICKENS: Lincosol Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin

Sponsored by:

Med-Pharmex, Inc.
2727 Thompson Creek Rd
Pomona, CA 91767-1861

FREEDOM OF INFORMATION SUMMARY:

I. General Information:

ANADA Number: **200-241**

Sponsor Name and Address:
Med-Pharmex, Inc.
2727 Thompson Creek Rd
Pomona, CA 91767-1861

Established Name:
Lincomycin Hydrochloride soluble powder

Trade Name:
Lincosol Soluble Powder

Marketing Status: OTC

Dosage Form:
The product is available in the form of a soluble powder for oral administration

Pioneer Product:
Pharmacia & Upjohn's Lincomix® Soluble Powder, NADA 111-636

II. Indications for Use:

SWINE: Lincosol Soluble Powder is indicated for the treatment of swine dysentery (bloody scours)

BROILER CHICKENS: Lincosol Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

III. Route of Administration and Recommended Dosages:

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) or one scoop (40 g) will medicate 64 gallons of drinking water providing 250 mg/gallon. One 80-g packet or two scoops will medicate 128 gallons of drinking water providing 250 mg/gallon.
Indications for Use:	Lincomycin Soluble is indicated in swine for the treatment of dysentery (bloody scours).
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 (40 g) or one scoop (40 g) will medicate 250 gallons of drinking water providing 64 mg/gallon. One 80-g packet or two scoops will medicate 500 gallons of drinking water providing 64 mg/gallon.
Indications for Use:	Lincosol Soluble Powder is indicated in broiler chickens for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.

IV. TARGET ANIMAL SAFETY AND 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, and the ANADA relies on the target animal safety, effectiveness, and human food safety data in the new animal drug application (NADA) for the pioneer. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product is also required. 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; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, 1996).

Based on the formulation characteristics of the generic product, Med-Pharmex, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product LINCOSOL SOLUBLE POWDER (lincomycin hydrochloride soluble powder). The generic product is administered as an oral solution, contains the same active ingredient 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 is Lincomix® Soluble Powder (lincomycin hydrochloride soluble powder), the subject of the Upjohn Company's (now Pharmacia & Upjohn Company) NADA 111-636, approved on January 2, 1983.

V. HUMAN FOOD SAFETY

Tolerances

The tolerances established for the pioneer product apply to the generic product. A tolerance of 0.1 part per million is already established for negligible residues in the edible tissues of swine under 21 CFR 556.360(a). A tolerance for tissue residues in chickens is not required (21 CFR 556.360(b)).

Withdrawal Times

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 times for lincomycin HCl soluble powder are established under 21 CFR 520.1263c: Six days for swine and zero days for broiler chickens. Lincomycin HCl is not approved for use in layer and breeder chickens.

Regulatory Method for Residues

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Sarcina lutea* (ATCC 9341). The method is on display in FDA's Freedom of Information Public Room, 5600 Fishers Lane, Rockville, MD 20857.

VI. 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 Hydrochloride Soluble Powder when used under the proposed conditions of use, is safe and effective for its labeled indications.

Attachments:

generic product labeling