Approval Date: November 9, 2006

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-407

Lincomycin-Spectinomycin Water Soluble Powder
lincomycin hydrochloride/spectinomycin dihydrochloride pentahydrate

Indications for use: For use in chickens up to 7 days of age as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

Sponsored by:

Agri Laboratories, Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-407
b. Sponsor:	Agri Laboratories, Ltd. P.O. Box 3103 St. Joseph, MO 64503 Drug Labeler Code: 057561
c. Established Name:	Lincomycin hydrochloride/spectinomycin dihydrochloride pentahydrate
d. Proprietary Name:	Lincomycin-Spectinomycin Water Soluble Powder
e. Dosage Form:	Soluble powder
f. How Supplied:	2.65 oz (75 grams) pouch
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	Lincomycin 16.7 grams Spectinomycin 33.3 grams
i. Route of Administration:	Oral
j. Species/Class:	Chickens
k. Recommended Dosage:	2 grams antibiotic activity per gallon of drinking water (1 packet per 25 gallons of drinking water). Administer as the sole source of water for the first 5-7 days of life.
l. Pharmacological Category:	Antimicrobial
m. Indications:	For use in chickens up to 7 days of age as an aid in the control of airsacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-

	spectinomycin and complicated chronic respiratory disease (air sac infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.
n. Pioneer Product:	L-S 50 Water Soluble Powder; lincomycin hydrochloride/spectinomycin sulfate tetrahydrate; NADA 046-109; Pharmacia & Upjohn Co., a Division of Pfizer, Inc.

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 is required to show that the generic product is bioequivalent to the pioneer, which has been 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 the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Agri Laboratories, Ltd**.** was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Lincomycin-Spectinomycin (lincomycin hydrochloride/spectinomycin dihydrochloride pentahydrate) Water Soluble Powder. The generic product is administered as a water soluble powder, contains similar active 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, L-S 50 Water Soluble Powder, (lincomycin hydrochloride/ spectinomycin sulfate tetrahydrate**)**, the subject of Pharmacia & Upjohn Co., a Division of Pfizer, Inc, NADA 046-109, was approved on June 27, 1973.

3. HUMAN SAFETY:

- **Tolerances for Residues:**
  The tolerances established for the pioneer product apply to the generic product.

A tolerance of 0.1 part per million for negligible residues of spectinomycin in uncooked edible tissues is established for chickens under 21 CFR 556.600. A tolerance of lincomycin in chickens is not required under 21 CFR 556.360.

- **Withdrawal Times:**
  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 0 hours has been established for lincomycin hydrochloride/spectinomycin dihydrochloride pentahydrate (21 CFR 520.1265).

- **Regulatory Method for Residues:**
  The procedure for the determination lincomycin hydrochloride in tissues is a microbiological test using *Sarcina lutea* (ATCC 9341). The analytical method for the determination of parent spectinomycin residues in tissues utilizes an HPLC ion exchange separation with post-column derivatization and fluorescence detection. The validated methods are 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 the oral product Lincomycin-Spectinomycin Water Soluble Powder, 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:

<u>Generic Labeling for ANADA 200-407:</u>
Lincomycin-Spectinomycin Water Soluble Powder – Container Label - 2.65 oz. (75 grams) packet
Lincomycin-Spectinomycin Water Soluble Powder – Shipping Label - 12 x 2.65 oz. (75g) packets, 144 x 2.65 oz. (75g) packets

<u>Pioneer Labeling for NADA 046-109:</u>
L-S 50 Water Soluble Powder (lincomycin hydrochloride/spectinomycin sulfate tetrahydrate) – Container Label – 2.65 oz. (75.0 grams)