Date of Approval: December 6, 2004

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-377

LINCOMED Soluble Powder
(Lincomycin hydrochloride)

For use in swine and broiler chickens

LINCOMED is indicated for control of necrotic enteritis caused by *Clostridium* perfringens susceptible to lincomycin in broiler chickens and the treatment of swine dysentery (bloody scours).

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-377
b. Sponsor:	Cross Vetpharm Group Ltd. Broomhill Rd, Tallaght Dublin 24, Ireland Drug Labeler Code: 061623
c. Established Name:	Lincomycin hydrochloride
d. Proprietary Name:	LINCOMED Soluble Powder
e. Dosage Form:	Soluble powder
f. How Supplied:	1.41 oz (40 gm) packet 25 x 40 gm packaging 2.82 oz (80 gm) packet 25 x 80 gm packaging 2 lb. (907.2 gm) pail 6 x 2 lb (907.2 gm) packaging
g. How Dispensed:	OTC
h. Amount of Active Ingredients:	1.41 oz (40 gm) packet contains as active ingredient Lincomycin hydrochloride equivalent to lincomycin 16.0 g. 2.82 oz (80 gm) packet contains as active ingredient Lincomycin hydrochloride equivalent to lincomycin 32.0 g. 2 lb. (907.2 gm) pail contains as active ingredient Lincomycin hydrochloride equivalent to lincomycin 400 mg.
i. Route of Administration:	Oral
j. Species/Class:	Swine and broiler chickens
k. Recommended Dosage:	Administer at a dose rate of 250 mg of lincomycin per gallon of drinking water.
l. Pharmacological Category:	Antibacterial

m. Indications:	SWINE: LINCOMED Soluble Powder is indicated for the treatment of swine dysentery (bloody scours). BROILER CHICKENS: LINCOMED Soluble Powder is indicated for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin.
n. Pioneer Product:	LINCOMIX Soluble Powder; Lincomycin hydrochloride; NADA 111-636; Pharmacia & Upjohn Co.

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 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, Cross Vetpharm Group, Ltd. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product LINCOMED Soluble Powder. The generic product is administered orally in drinking water, 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 (lincomycin hydrochloride) Soluble Powder, the subject of Pharmacia & Upjohn Co., NADA 111-636 approved on January 28, 1983.

3. HUMAN SAFETY:

- **Tolerance**
  The tolerance established for the pioneer product applies to the generic product. A tolerance for residues of lincomycin in chickens is not required. Tolerances for lincomycin of 0.6 part per million in liver and 0.1 part per million in muscle are established (21 CFR 556.360).

- **Withdrawal Times**
  When a waiver from the requirement of an *in vivo* bioequivalence study is granted, August 11, 2002, the withdrawal times are those previously assigned to the pioneer product.

  For this reason, no withdrawal period is required before slaughter of swine or broiler 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 file at the Center for Veterinary Medicine, FDA, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that LINCOMED (lincomycin hydrochloride) Soluble Powder, when used under its proposed conditions for use, is safe and effective for its labeled indications.

5. ATTACHEMENTS:

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

Generic Labeling for ANADA 200-377:
LINCOMED Soluble Powder;
- 1.41 oz (40 gm) packet (front panel)
- 1.41 oz (40 gm) packet (back panel)
- 25 x 40 gm packaging
- 2.82 oz (80 gm) packet (front panel)
- 2.82 oz (80 gm) packet (back panel)
- 25 x 80 gm packaging
- 2 lb. (907.2 gm) pail
- 6 x 2 lb (907.2 gm) packaging

Pioneer Labeling for NADA 111-636:
LINCOMIX Soluble Powder;
- 1.41 oz (40 gm) packet
- 48 x 40 gm packaging
- 2.82 oz (80 gm) packet
- 24 x 80 gm packaging
- 5.64 oz (160 gm) label
- 16.92 oz (480 gm) label