Approval Date: August 2, 2006

# FREEDOM OF INFORMATION SUMMARY

# ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

## ANADA 200-368

## LINCOMED 100 and LINCOMED 300
## lincomycin hydrochloride

**Indications for use: For the treatment of arthritis caused by susceptible organisms and for mycoplasma pneumonia.**

**Sponsored by:**

**Cross Vetpharm Group Ltd.**

**FREEDOM OF INFORMATION SUMMARY**

***1. GENERAL INFORMATION:***

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|---|---|
| a. File Number: | ANADA 200-368 |
| b. Sponsor: | Cross Vetpharm Group Ltd.<br>Broomhill Rd.<br>Tallaght, Dublin 24<br>Ireland<br>Drug Labeler Code: 061623 |
| US Agent: | Bimeda, Inc.<br>Linda M. Duple<br>Directory, North American Regulatory Affairs<br>2836 Dolliver Park Ave<br>Lehigh, IA 50557 |
| c. Established Name: | Lincomycin hydrochloride |
| d. Proprietary Name: | LINCOMED 100 and LINCOMED 300 |
| e. Dosage Form: | Sterile solution |
| f. How Supplied: | 100 mL vial |
| g. How Dispensed: | Rx |
| h. Amount of Active Ingredients: | 100 mg/mL and 300 mg/mL |
| i. Route of Administration: | Intramuscular |
| j. Species/Class: | Swine |
| k. Recommended Dosage: | 5 mg/lb body weight (1 mL per 20 lbs of body weight) |
| l. Pharmacological Category: | Antimicrobial |

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|---|---|
| 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 100 Injectable and LINCOMIX 300 Injectable; lincomycin hydrochloride; NADA 034-025; Pharmacia & Upjohn, 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, Cross Vetpharm Group Ltd. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product LINCOMED 100 and LINCOMED 300 (lincomycin hydrochloride). The generic product is administered as a sterile solution, contains the same 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, LINCOMIX 100 Injectable and LINCOMIX 300 Injectable (lincomycin hydrochloride), the subject of Pharmacia & Upjohn Co., a Division of Pfizer, Inc, NADA 034-025, was approved on June 6, 1967.

## *3. HUMAN SAFETY:*

- **Tolerances for Residues:**

  The tolerance established for the pioneer product applies to the generic product. A tolerance of 0.6 parts per million in the liver and 0.1 parts per million in muscle is established for lincomycin residues of swine 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 48 hours has been established for lincomycin in swine (21 CFR 522.1260).

- **Regulatory Method for Residues:**

  The procedure for the determination lincomycin hydrochloride in tissues is a microbiological test using *Sarcina lutea* (ATCC 9341). 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 injectable products LINCOMED 100 and LINCOMED 300, when used under their proposed conditions of use, are safe and effective for their labeled indications.

## *5. ATTACHMENTS:*

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

<u>Generic Labeling for ANADA 200-368:</u>
LINCOMED 100 (lincomycin hydrochloride) – Container and outsert label – 100 mL
LINCOMED 300 (lincomycin hydrochloride) – Container and outsert label – 100 mL

Pioneer Labeling for NADA 034-025:
LINCOMIX 100 Injectable (lincomycin hydrochloride) – Container Label – 100 mL
LINCOMIX 300 Injectable (lincomycin hydrochloride) – Container Label – 100 mL
Package insert
LINCOMIX 100 Injectable (lincomycin hydrochloride) – Carton Label
LINCOMIX 300 Injectable (lincomycin hydrochloride) – Carton Label