Date of Approval: February 1, 2002

FREEDOM OF INFORMATION SUMMARY

ANADA 200-274

Indication for use: For treatment of infectious arthritis and mycoplasma pneumonia in swine

Sponsored by:
Alpharma, Inc.
Fort Lee, NJ 07024

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number	200-274
Sponsor:	Alpharma, Inc. One Executive Drive Fort Lee, NJ 07024 21 CFR 510.600: Labeler Code 046573
Established Name:	Lincomycin HCL
Trade/Proprietary Name:	Lincomycin Injectable 30 %
Dosage Form:	Injectable
How Supplied:	100 mL multidose vials
How Dispensed:	OTC
Amount of Active Ingredients:	Each mL contains 300 mg of lincomycin HCL
Route of Administration:	Intramuscular
Species:	Swine
Labeled Dosage	5 milligrams per pound of body weight per day for 3 to 7 days
Indications for Use:	Infectious arthritis and mycoplasma pneumonia
Pharmacological Category:	Antibacterial
Pioneer Product:	Lincomix® 300 Injection manufactured by Pharmacia & Upjohn Co. (NADA 034-025)

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, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. 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, Alpharma, Inc. was granted a waiver on May 27, 1993, from conducting an *in vivo* bioequivalence study for Lincomycin Injectable 30 %. The generic and pioneer products contain the same active and inactive ingredients and are injectable 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 522.1260- 48 hours in swine.

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. 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 Injectable 30 % is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments:

Pioneer Labeling:

Package Insert

100 mL vial

Generic Labeling:

Package Insert

100 mL vials

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.