Date of Approval: April 2, 2003

FREEDOM OF INFORMATION SUMMARY

ANADA 200-315

Lincomycin Injection
(Lincomycin Hydrochloride)
25mg/mL, 100 mg/mL, 300 mg/mL

Swine Antibiotic

Indications for use: 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.

Sponsored by:

Veterinary Laboratories, Inc.
12340 Santa Fe Trail Drive
Lenexa, KS 66215

FREEDOM OF INFORMATION SUMMARY

1. General Information:

a. *File Number:*	ANADA 200-315
b. *Sponsor:*	Veterinary Laboratories, Inc. 12340 Santa Fe Trail Dr. Lenexa, KS 66215 21 CFR 510.600: Drug Labeler Code: 000857
c. *Established Name:*	Lincomycin Hydrochloride Monohydrate
d. *Proprietary Name:*	Lincomycin Injection 25; Lincomycin Injection 100; Lincomycin Injection 300
e. *Dosage Form:*	Liquid (solution)
f. *How Supplied:*	100 mL vials containing 25, 100, and 300 mg lincomycin hydrochloride per mL.
g. *How Dispensed:*	OTC
h. A*mount of Active Ingredients:*	25, 100, 300 mg lincomycin hydrochloride per mL of sterile finished product
i. *Route of Administration:*	Sterile Intramuscular Injection
j. *Species/Class:*	Swine
k. *Recommended Dosage:*	The usual daily dosage for arthritis or mycoplasma pneumonia is 5.0 mg/lb. BW intramuscularly once daily for 3-7 days as needed. When using Lincomycin Injection containing 25 mg/mL, 1 mL/5 lb. BW will provide 5 mg/lb. When using Lincomycin Injection containing 100 mg/mL, 1 mL/20 lb. BW will provide 5 mg/lb. When using Lincomycin Injection containing 300 mg/mL, 1 mL/60 lb. BW will provide 5 mg/lb.
l. *Pharmacological Category:*	Antimicrobial
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® Injectable manufactured by Pharmacia & Upjohn Co., NADA 034-025, 25 mg/mL, 100 mg/mL, and 300 mg/mL.

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 data and drug 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 2000).

Safety and effectiveness for this generic animal drug, Lincomycin Injection, were established by demonstration of chemical equivalence to the pioneer product, Lincomix® Injectable (NADA 034-025). Based on this demonstrated equivalency, a waiver of the *in vivo* bioequivalence studies was granted on September 16, 1999. The generic and pioneer products contain the same active ingredients and are parenteral solutions intended for use in swine by the intramuscular route of administration.

3. HUMAN SAFETY

• Tolerance

The tolerances (21 CFR 556.360) established for the pioneer product apply to the generic product. Tolerances (21 CFR 556.360) for lincomycin in swine of 0.6 part per million in liver and 0.1 part per million in muscle are established. The acceptable daily intake (ADE) for total residues of lincomycin is 25 micrograms per kilogram of body weight per day.

• Withdrawal Time

When a waiver of the *in vivo* bioequivalence study is granted, then the withdrawal period established for the pioneer product will be assigned to the generic product. A 2-day (48 hr)

withdrawal period is required for swine treated intramuscularly with lincomycin at 5 mg/lb BW.

• Human Safety Relative to Possession, Handling and Administration

Labeling contains adequate caution/warning statements. Human Warnings are provided on the product label as follows: "Not for human use." "Keep out of reach of children." "Swine intended for human consumption should not be slaughtered within 48 hours of latest treatment."

• Regulatory Method for Residues

The analytical method for detection of lincomycin residues in tissues is the test using *Sarcina lutea* (ATCC 9341). This method is on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed 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 Lincomycin Injection, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Labeling:

Pioneer Labeling for NADA 034-025:
Lincomix® Injectable – 25 mg/mL, 100 mg/mL, 300 mg/mL

Generic Labeling for ANADA 200-315:
Lincomycin Injection™ – 25 mg/mL, 100 mg/mL, 300 mg/mL

Veterinary Laboratories, Inc. is the manufacturer and Sparhawk Laboratories, Inc. is the distributor of this generic product.

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.