Sept. 22, 1999

FREEDOM OF INFORMATION SUMMARY

I. IDENTIFICATION.

ANADA Number: **200-233**

Sponsor:

Alpharma Animal Health Division
Highway 71 North
P.O. Box 309
Lowell, Arkansas 72745

Trade Name: LINCO SOLUBLE

Generic Name: Lincomycin Hydrochloride Soluble Powder 40 %

Marketing Status: OTC

Pioneer Product: Lincomycin Hydrochloride Soluble Powder (Lincomix Soluble Powder) NADA 111-636.

II. INDICATIONS FOR USE

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

III. DOSAGE FORM, ROUTE OF ADMINISTRATION AND RECOMMENDED DOSAGE:

Dosage Form: Soluble Powder

Route of Administration: Lincomycin Hydrochloride Soluble powder is administered orally in the drinking water.

Recommended Dosage:

Swine:

For treatment, the drug is administered to swine at 3.8 mg lincomycin per pound of body weight per day for a maximum of 10 days.

Broiler Chickens:

The drug is administered to broiler chickens at a dose rate of 64 mg of lincomycin per gallon of drinking water for a maximum of 7 days.

IV. TARGET ANIMAL SAFETY AND 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, and the ANADA relies on the target animal safety, effectiveness, and human food safety data in the new animal drug application (NADA) for the pioneer. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the agency will grant a waiver from the requirement of an in vivo bioequivalence study ((Fifth GADPTRA Policy Letter, 55 FR 24645, June 18, 1990; Bioequivalence Guidance, 1996, 61 FR 26182, May 24, 1996).

Based on the formulation characteristics of the generic product, Alpharma Animal Health Division was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product LINCO SOLUBLE (lincomycin hydrochloride soluble powder). The generic product is administered as an oral solution, 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 as finally administered. The pioneer product is Lincomix Soluble Powder (lincomycin hydrochloride soluble powder) the subject of Pharmacia & Upjohn Company's (formerly The Upjohn Company) NADA 111-636, approved on January 2, 1983.

V. HUMAN FOOD SAFETY

Tolerance:

The tolerances established for the pioneer product apply to the generic product. Tolerances for lincomycin of 0.6 ppm in liver and 0.1 ppm in muscle are established for swine. A tolerance for tissue residues in chickens is not required (21 CFR 556.360).

Withdrawal Times:

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 times for lincomycin hydrochloride soluble powder are established under 21 CFR 520.1263c: six days for swine and zero days for broiler chickens. Lincomycin soluble powder is not for use in layer and breeder 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 display in FDA's Freedom of Information Public Room, 5600 Fishers Lane, Rockville, MD 20857. The method is also on file at the Center for Veterinary Medicine, HFV-199, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855.

VI. AGENCY CONCLUSIONS

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

Attachments:

generic product labeling
pioneer product labeling