

Date of Approval: June 7, 2005

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-380

SPECLINX-50

(lincomycin hydrochloride monohydrate and spectinomycin dihydrochloride pentahydrate)

Water Soluble Powder

Chickens

For use as an aid in the control of Airsacculitis and complicated Chronic Respiratory Disease (Air Sac Infection) in chickens up to 7 days of age.

Sponsored by:

Cross Vetpharm Group Ltd.

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

- a. File Number: ANADA 200-380
- b. Sponsor: Cross Vetpharm Group Ltd.
Broomhill Road, Tallaght
Dublin 24, Ireland
- Drug Labeler Code: 061623
- US Agent: Linda M. Duple
Director, North American Regulatory Affairs
Bimeda, Inc.
A Division of Cross Vetpharm Group Ltd.
2836 Dolliver Park Ave.
Lehigh, IA 50557
- c. Established Names: Lincomycin hydrochloride monohydrate and spectinomycin dihydrochloride pentahydrate
- d. Proprietary Name: SPECLINX-50
- e. Dosage Form: Soluble powder
- f. How Supplied: 75 g (2.65 oz) pouch
375 g (13.2 oz) pouch
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each 75 g packet contains 16.7 g of lincomycin as lincomycin hydrochloride monohydrate and 33.3 g of spectinomycin as spectinomycin dihydrochloride pentahydrate.
- Each 375 g packet contains 83.5 g of lincomycin as lincomycin hydrochloride monohydrate and 166.5 g of spectinomycin as spectinomycin dihydrochloride pentahydrate.
- i. Route of Administration: Oral
- j. Species/Class: Chicken/up to 7 days of age
- k. Recommended Dosage: Provide 2 g antibiotic activity per gallon of drinking water. Administer as the sole source of water for the first 5 to 7 days of life.

- l. Pharmacological Category: Antimicrobial
- m. Indications: For use in chickens up to 7 days of age as an aid in the control of: Airsacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin and complicated Chronic Respiratory Disease (Air Sac Infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.
- n. Pioneer Product: L-S 50 WATER SOLUBLE Powder; lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate; NADA 046-109; Pharmacia and Upjohn Co., 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 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 Guidance, revised 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 SPECLINX-50 (lincomycin hydrochloride monohydrate and spectinomycin dihydrochloride pentahydrate) Water Soluble Powder. The generic product is administered as an oral solution, contains similar 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. Suitability Petition Number SP 01P0045/CP1 was approved on April 20, 2001, allowing Cross Vetpharm Group Ltd. to substitute spectinomycin sulfate tetrahydrate found in the pioneer product with spectinomycin dihydrochloride pentahydrate in the proposed generic product. The suitability petition further stipulated that the presence of lincomycin hydrochloride monohydrate in the proposed generic formulation will remain unchanged from that of the pioneer product. The pioneer product L-S 50 WATER SOLUBLE Powder (lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate), the subject of Pharmacia and Upjohn Co., A Division of Pfizer, Inc., NADA 046-109, was approved on June 27, 1973.

3. **HUMAN SAFETY:**

- **Tolerance for Residues:**

The tolerances established for the pioneer product apply to the generic product. A tolerance for residues of lincomycin in chickens is not required (21 CFR 556.360). A tolerance of 0.1 ppm is established for negligible residues of spectinomycin in the uncooked edible tissues of chicken under 21 CFR 556.600. The acceptable daily intake for total residues of spectinomycin is 25 micrograms per kilogram of body weight per day (21 CFR 556.600).

- **Withdrawal Times:**

Because a waiver of the *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product. There are no withdrawal times for this product in the 21 CFR.

- **Regulatory Method for Residues:**

The analytical method for detection of residues of the lincomycin in tissues is the microbiological test using *Sarcina lutea* (ATCC 9341). The analytical method for detection of parent spectinomycin residues in tissues utilizes an HPLC ion exchange separation with post-column derivatization and fluorescence detection.

Both methods are found 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 SPECLINX-50, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. **ATTACHMENTS:**

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

Generic Labeling for ANADA 200-380:

SPECLINX-50 (lincomycin hydrochloride monohydrate and spectinomycin dihydrochloride pentahydrate) Water Soluble Powder

Packet Label – (Front and Back), 75.0 grams (2.65 oz) and 375 g (13.2 oz) sizes

Box Label – 12 X 75g (2.65 oz) and 6 X 375 g (13.2 oz)

Pioneer Labeling for NADA 046-109:

L-S 50 WATER SOLUBLE Powder (lincomycin hydrochloride monohydrate and spectinomycin sulfate tetrahydrate)

Bottle Label – (Front and Back side-by-side), 2.65 oz (75.0 grams)