

Date of Approval: JUN 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)

SpecLinx-50TM

(Brand of Lincomycin-Spectinomycin soluble powder)

Water Soluble Powder

For use in Chickens Only

Antibacterial and
Antimycoplasmal

This packet contains:

Lincomycin hydrochloride Equivalent to lincomycin	16.7 grams
Spectinomycin dihydrochloride pentahydrate Equivalent to spectinomycin	33.3 grams
Total Antibiotic Activity	50.0 grams

▶ **WARNING: NOT FOR HUMAN USE** ◀
▶ **KEEP OUT OF REACH OF CHILDREN** ◀

Restricted Drug - Use Only as Directed (California)

Net Wt: 75 g (2.65 oz)

ANADA 200-380, Approved by FDA

Manufactured by:
Bimeda, Inc.
Le Sueur, MN 56053

Bimeda, Inc is a division of
Cross Vetpharm Group, Ltd.



Bimeda

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Bimeda



DIRECTIONS FOR USE

INDICATIONS: For use in chickens up to 7 days of age as an aid in the control of: Aisaccutitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin.

Complicated Chronic Respiratory Disease (Air Sac Infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.

DOSAGE: Provide 2 grams (g) antibiotic activity per gallon of drinking water. Administer as the sole source of water for the first 5 to 7 days of life.

ADMINISTRATION:

Amount of SpecLinx-50™	Amount of Drinking Water
1 packet	25 gallons

For proportioners delivering 1 ounce of solution per gallon of drinking water, dissolve contents of 5 packets in each gallon of proportioner solution.

IMPORTANT: Chickens should consume water at the following approximate rate to insure intake of the required dose of lincomycin-spectinomycin indicated:

Broilers and Layer Replacements (Light and Heavy)

Age (Weeks)	Daily Water Intake Gallons/1000	Dosage Mg Antibiotic/Lb
1	5	50-65

CAUTION: Discard medicated drinking water daily and replace with fresh medicated drinking water.

Store at controlled room temperature 20° to 25°C (68° to 77°F).

Product No. 1LIN009
8LIN010-503

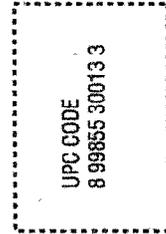
SpecLinx-50 is a Trademark of Bimeda, Inc.



TAKE TIME



OBSERVE LABEL
DIRECTIONS



60009

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August 11, 2004

SpecLinx-50TM

(Brand of Lincomycin-Spectinomycin soluble powder)

Water Soluble Powder

For use in Chickens Only

*Antibacterial and
Antimycoplasmal*

This packet contains:

Lincomycin hydrochloride	
Equivalent to lincomycin	83.5 grams
Spectinomycin dihydrochloride pentahydrate	
Equivalent to spectinomycin	166.5 grams
Total Antibiotic Activity	250.0 grams

▶ **WARNING: NOT FOR HUMAN USE** ◀
KEEP OUT OF REACH OF CHILDREN

Restricted Drug - Use Only as Directed (California)

Net Wt: 375 g (13.2 oz)

ANADA 200-380, Approved by FDA

Manufactured by:
Bimeda, Inc.
Le Sueur, MN 56058

Bimeda, Inc is a division of
Cross Vetpharm Group, Ltd.



Bimeda

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DIRECTIONS FOR USE

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

Complicated Chronic Respiratory Disease (Air Sac Infection) caused by *Escherichia coli* and *M. gallisepticum*
susceptible to lincomycin-spectinomycin

DOSAGE: Provide 2 grams (g) antibiotic activity per gallon of drinking water. Administer as the sole source of water
for the first 5 to 7 days of life

ADMINISTRATION:

Amount of SpecLinx-50™	Amount of Drinking Water
1 packet	125 gallons

For proportioners delivering 1 ounce of solution per gallon of drinking water, dissolve contents of 1 packet in
each gallon of proportioner solution

IMPORTANT: Chickens should consume water at the following approximate rate to insure intake of the required dose of
lincomycin-spectinomycin indicated

Broilers and Layer Replacements (Light and Heavy)

Age (Weeks)	Daily Water Intake Gallons/1000	Dosage Mg Antibiotic/Lb
1	5	50-65

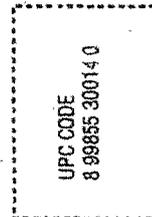
CAUTION: Discard medicated drinking water daily and replace with fresh medicated drinking water

Store at controlled room temperature 20° to 25°C (68° to 77°F)

TAKE TIME  OBTAIN LABEL DIRECTIONS

Product No. 1LIN010
8LIN012-503

SpecLinx-50 is a Trademark of Bimeda, Inc.



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AUG 23 2004

August 11, 2004

SpecLinx-50TM

(Brand of Lincomycin-Spectinomycin soluble powder)
Water Soluble Powder

For use in Chickens Only *Antibacterial and Antimycoplasmal*

Each packet contains:

Lincomycin hydrochloride	16.7 grams
Equivalent to lincomycin	16.7 grams
Spectinomycin d hydrochloride pentahydrate	33.3 grams
Equivalent to spectinomycin	33.3 grams
Total Antibiotic Activity	50.0 grams

Product No. 1L1009 8LIN011-503

WARNING: NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN

Restricted Drug - Use Only as Directed (California)
Store at controlled room temperature 20° to 25° C (68° to 77° F)

Net Wt: 12 X 75g (2.65 Oz)

ANADA 200-380, Approved by FDA

TAKE TIME  OBSERVE LABEL DIRECTIONS

Manufactured by: Bimeda, Inc.
Le Sueur, MN 56058
Bimeda, Inc is a division of
Cross Vetpharm Group, Ltd.

 **Bimeda**

SpecLinx-50 is a Trademark of Bimeda, Inc.

UPC CODE
8 99855 39013 4

LOT:
EXP:

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AUG 23 2004

NDC 0009-0108-09



lincomycin-spectinomycin
Antibacterial and Antimycoplasmal



FOR USE IN CHICKENS ONLY

This bottle contains:
Lincomycin hydrochloride, equivalent to lincomycin 16.7 grams
Spectinomycin sulfate tetrahydrate, equivalent to spectinomycin 33.3 grams
Pharmacia Total Antibiotic Activity 50.0 grams
& Upjohn NADA #46-109, Approved by FDA

NET WT. 2.65 OZ
(75.0 grams)

PEEL HERE FOR
SPANISH LANGUAGE

DIRECTIONS FOR USE

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. Complicated Chronic Respiratory Disease (Air Sac Infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.
DOSAGE: Provide 2 grams (g) antibiotic activity per gallon of drinking water. Administer as the sole source of water for the first 5 to 7 days of life.
ADMINISTRATION:

Amount of L-S 50	Amount of Drinking Water
1 bottle	25 gallons
For proportioners delivering 1 ounce of solution per gallon of drinking water, dissolve contents of 5 bottles in each gallon of proportioner solution.	

IMPORTANT: Chickens should consume water at the following approximate rate to insure intake of the required dose of lincomycin-spectinomycin indicated:

Broilers and Layer Replacements (Light and Heavy)

Age (Weeks)	Daily Water Intake Gallons/1000	Dosage mg Antibiotic/lb
1	5	50-65

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LOT
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Pharmacia & Upjohn Company
Kalamazoo, MI
49001, USA

CAUTION: Discard medicated drinking water daily and replace with fresh medicated drinking water

Warning: Not for human use.

Store at Controlled Room Temperature 20° to 25° C (68° to 77° F) [see USP].

Restricted Drug—Use Only as Directed (California)

