



288 County Road 28
Le Sueur, MN 56058
TEL: (507) 665-3316
FAX: (507) 665-6062

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January 22, 2001

Dockets Management Branch
HFA-305, Room 4-62
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Lincomycin-Spectinomycin Water
Soluble Powder

Subject: Suitability Petition

Enclosed are four copies of a Suitability Petition submitted by Bimeda, Inc. for Lincomycin-Spectinomycin Water Soluble Powder. Bimeda, Inc. requests the Commissioner to permit the filing of an Abbreviated New Animal Drug Application (ANADA) for a proposed product that differs from the approved pioneer product LS50 Water Soluble, sponsored by The Upjohn Company, under NADA 046-109.

Permission is hereby requested to substitute the spectinomycin sulfate tetrahydrate as found in the pioneer combination drug product with spectinomycin dihydrochloride pentahydrate in the proposed ANADA. We have included in this Suitability Petition information required as defined in the June 7, 1989, second policy letter on the implementation of the Generic Animal Drug and Patent Term Restoration Act.

Should you have any questions regarding this Suitability Petition, I can be reached at (515) 359-2248.

Sincerely,

Linda M. Duple
Regulatory Affairs Coordinator

Enclosures

OIP-0045

A Division of Cross Vetpharm Group Limited

CP1

SUITABILITY PETITION

Submitted by

Bimeda, Inc.

288 County Road 28

Le Sueur, MN 56058

For

Combination Water Soluble Animal Drug Product

JAN 22 2001

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PETITION

1. **Identification**

Bimeda, Inc.
288 County Road 28
Le Sueur, MN 56058

2. **Appropriate Citation**

Bimeda, Inc. submits this petition under Section 512(n)(3) of the Federal Food, Drug and Cosmetic Act.

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ACTION REQUESTED

Bimeda, Inc. requests the Commissioner to permit the filing of an Abbreviated New Animal Drug Application (ANADA) for a proposed product that differs from the approved pioneer product.

Pioneer Product

Brand Name: LS 50 Water Soluble
Company: The Upjohn Company
NADA: 046-109
Active Ingredients: A. Lincomycin hydrochloride monohydrate
B. Spectinomycin sulfate tetrahydrate
Species: Chickens

Permission is hereby requested to substitute the spectinomycin sulfate tetrahydrate as found in the pioneer combination drug product with spectinomycin dihydrochloride pentahydrate in the proposed ANADA. The presence of lincomycin hydrochloride monohydrate in the proposed formulation will remain unchanged and all other claims, species, labeling and conditions of use will remain unchanged from the pioneer with the exception of permitted changes.

Proposed Product

Brand Name: To be determined (water soluble powder)
Company: Bimeda, Inc.
NADA: To be assigned
Active Ingredients: A. Lincomycin hydrochloride monohydrate
B. Spectinomycin dihydrochloride pentahydrate
Species: Chickens

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STATEMENT OF GROUNDS

In accordance with the sixth policy statement dated October 17, 1990, issued by the Center for Veterinary medicine, "Eligibility of a New Salt or Ester of a Pioneer Animal Drug for an ANADA", the Agency will consider an ANADA for a difference salt or ester if "...the petition seeks a change in one active ingredient in a combination product...and the different salt or ester is previously approved..."

This request meets both of the stated criteria in that the only change is replacement of the spectinomycin sulfate tetrahydrate with spectinomycin dihydrochloride pentahydrate and spectinomycin dihydrochloride pentahydrate was previously approved by the Center for Veterinary Medicine under NADA 38-661, Spectam Water Soluble Concentrate on June 1, 1969, for use in chickens.

As will be determined upon review of NADA 38-661 the sponsor of that NADA and the petitioner are the same entity. One of the major reasons for this request is to allow this petitioner to utilize a drug substance of which they have thorough knowledge. In addition, the manufacturer will be able to maintain inventory of one drug rather than two to produce either of their products. Maintaining inventories of both salts would be burdensome and unnecessary in this instance.

Pioneer label claim --

"Spectinomycin sulfate tetrahydrate, equivalent to spectinomycin.....33.3 grams"

Proposed generic label claim --

"Spectinomycin dihydrochloride pentahydrate, equivalent to spectinomycin.....33.3 grams"

Both spectinomycin sulfate tetrahydrate and spectinomycin dihydrochloride pentahydrate produce a true solution in water and when dissolved in water dissociate completely from their respective salts to the components in solution listed below:

Spectinomycin Salt Form

Resulting Aqueous Solution Components

Spectinomycin dihydrochloride 5 H₂O

Spectinomycin + 2 HCl + H₂O

Spectinomycin sulfate 4 H₂O

Spectinomycin + H₂SO₄ + 4 H₂O

- The spectinomycin in solution is identical whether supplied by the dihydrochloride or the sulfate salt.
- Both salts are strong acids that would tend to decrease the pH of the solution.
- The water contributions of the dissociated salts are insignificant in an aqueous solution.

Conclusion:

In solution, the Label Claim of "Spectinomycin ... 33.3 grams" is met equally well by using either Spectinomycin dihydrochloride 5 H₂O or Spectinomycin sulfate 4 H₂O.

This type of action has previously been requested and approved on February 7, 1991, for Sanofi Animal Health under Number: 90P-0434/CP and on March 9, 2000, for Phoenix Scientific under Number: 00P-0117/CP1.

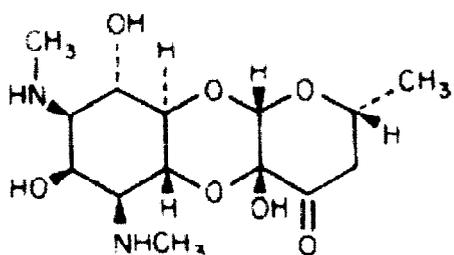
Included in this section is a Chemical Structure Comparison of the Spectinomycin salts.

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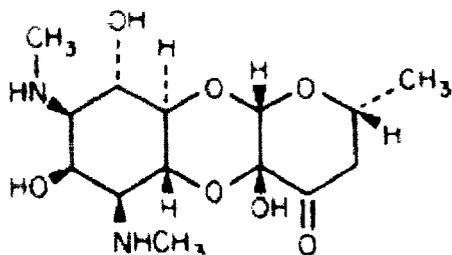
Chemical Structure Comparison:

Spectinomycin Dihydrochloride Pentahydrate



Reference: Remington's Pharmaceutical Sciences
19th Edition

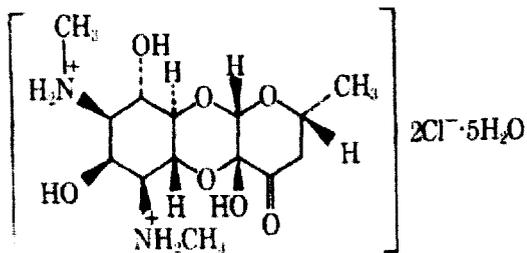
Spectinomycin Sulfate Tetrahydrate



Reference: Adapted from the Structure above.

Spectinomycin Dihydrochloride Pentahydrate

(Showing the two Hydrogen ions, each associated with an amine group in the parent molecule)



Reference: Remington's Pharmaceutical Sciences
16th Edition

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ENVIRONMENTAL IMPACT

The submission and review of a suitability petition is a routine administrative and management activity and will not normally be expected to have an environmental impact. We, therefore, hereby request a waiver from the requirements of submitting an environmental impact statement under 21 CFR 25.24 (a)(8) Categorical Exclusions.

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ECONOMIC IMPACT

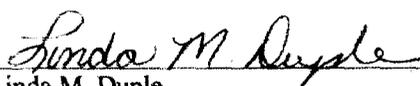
We hereby request a waiver form the requirements of this section for this petition.

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CERTIFICATION

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views upon which the petition relies, and that it contains representative data and information known to the petitioner which are unfavorable to this petition.

 1/22/01
Linda M. Duple

Regulatory Affairs Coordinator
Bimeda, Inc.
288 County Road 28
Le Sueur, MN 56058

(515) 359-2248

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LABELING

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PROPOSED LABELING

1. Identification of a *trade name* has not yet been determined.
2. Replaced Spectinomycin sulfate tetrahydrate with Spectinomycin dihydrochloride pentahydrate.
3. Pharmacia & Upjohn company name and logo replaced with Bimeda, Inc.
4. All references on pioneer labeling reflecting LS50 will be replaced with either Lincomycin-Spectinomycin or *trade name*.
5. Added "For Animal Use Only" and "Keep Out of Reach of Children" to the main panel.
6. NDC will not be printed on proposed labeling.

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**Lincomycin-Spectinomycin
Water Soluble Powder**

Antibacterial and Antimycoplasmal

For Use in Chickens Only

FOR DIRECTIONS – SEE REVERSE SIDE

This packet contains:

Lincomycin hydrochloride, equivalent to lincomycin.....15.7 grams
Spectinomycin dihydrochloride pentahydrate,
equivalent to spectinomycin.....33.3 grams
Total Antibiotic Activity 50.0 grams

FOR ANIMAL USE ONLY
NOT FOR HUMAN USE
KEEP OUT OF REACH OF CHILDREN

ANADA XXX-XXX, Approved by FDA

NET CONTENTS:
75.0 g (2.65 OZ)

Manufactured by:
Bimeda, Inc.
LeSueur, MN 56058

Bimeda

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 Lincomycin-Spectinomycin 1 packet	Amount of Drinking Water 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 room temperature
Restricted Drug –
Use only as Directed (California)

Take time observe label directions

Lot No.
Exp. Date

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PIONEER LABELING

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NDC 0009-0108-06



lincomycin-spectinomycin
Antibacterial and Antimycoplasmal

LOT 250CM
EXP 05/2004

FOR USE IN CHICKENS ONLY



FOR DIRECTIONS-SEE REVERSE SIDE

This packet contains:

Lincomycin hydrochloride, equivalent to lincomycin	16.7 grams
Spectinomycin sulfate tetrahydrate, equivalent to spectinomycin	33.3 grams
Total Antibiotic Activity	50.0 grams

NET WT. 2.65 OZ (75.0 grams)



Pharmacia & Upjohn

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V-27-284

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 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.

Warning: Not for human use

Store at room temperature

813 526 003 **Restricted Drug—Use Only as Directed (California)**

Pharmacia & Upjohn Company • Kalamazoo, MI 49001, USA

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Dur, MN 56058



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Rockville, MD 20857