SPARHAWK
LABORATORIES, INC.

0466 6 JUN 21 A9:19

June 19, 2006

Dockets Management Branch, HFA-305
Room 1-23
Food and Drug Administration
12420 Parklawn Drive
Rockville, MD 20857

SUITABILITY PETITION

The undersign submits this petition as set forth in 21 CFR 10.30 to change the dosage form of NADA 11-315 from Neomycin Soluble Powder to Liquid as an amendment. Data and information to support this request has been submitted to CVM as Neomycin Liquid (ANADA 200-379).

Documentation including previous communication with Center for Veterinary Medicine, Pharmacia and Upjohn's Biosol Label, active and inactive ingredient list and our proposed label is included with this petition.

Sparhawk Laboratories, Inc. also request categorical exclusion from the need to prepare an environmental assessment for this application based on the April 1, 2001 revision of 21 CFR 25.33a (1).

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes information known to the petitioner which is unfavorable to the petition.

Respectfully submitted,

Bert Hughes
President / CEO

EBH/wkp

2006P-0263 CP1

12340 Santa Fe Trail Drive • Lenexa, Kansas 66215-3591 • Phone (913) 888-7500 • Fax (913) 888-6741
Toll Free (800) 255-6368 • sli@sparhawklabs.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JINAD 10-670

December 6, 1999

Bert Hughes
President/C.E.O.
Veterinary Laboratories, Inc.
12340 Santa Fe Trail Drive
Lenexa, KS 66215-0000

Dear Mr. Hughes:

We acknowledge receipt of your submission dated November 24, 1999, for the establishment of a JINAD for the investigational use of neomycin sulfate liquid in cattle, swine, sheep and goats pursuant to the Federal Food, Drug, and Cosmetic Act, [section 512(j)] and 21 CFR part 511.

Your submission has been assigned **JINAD number 10-670** and has been forwarded to the proper reviewer for consideration. Please refer to this number when submitting any future correspondence pertaining to the use of the aforementioned drug.

This letter does not authorize the use of edible products derived from treated food producing animals. If the intended use is in food producing animals, edible products of investigational animals may be used for food only with prior authorization granted by the U.S. Food and Drug Administration.

Sincerely,

Carol Goolsby
Technical Information Specialist
Center for Veterinary Medicine
HFV-199

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JINAD 10670 R0000

FEB 14 2000

Bert Hughes
President/CEO
Veterinary Laboratories, Inc.
12340 Santa Fe Trail Drive
Lenexa, KS 66215

Dear Mr. Hughes:

We refer to your submission dated November 24, 1999, which requested a waiver from *in vivo* bioequivalence requirements for a generic copy of Pharmacia & Upjohn's Biosol® (neomycin sulfate) Liquid, ANADA 200-113.

We have reviewed your submission and have the following comments:

Your generic product is an oral solution that contains the same active ingredient and similar inactive ingredients in the same concentrations as the pioneer.

Your request for a waiver of *in vivo* bioequivalence testing is granted on the condition that the information in your ANADA continues to show that your proposed generic product is equivalent to the pioneer, Biosol® Liquid.

In any future written correspondence regarding this submission, please refer to our submission code JINAD 10670 R0000.

Sincerely yours,

Lonnie W. Luther, Ph.D., P.A.S.
Chief, Generic Animal Drug and
Quality Control Staff
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

November 24, 1999

Food and Drug Administration
Center for Veterinary Medicine
Document control Unit HFV – 199
7500 Standish Place
Rockville, MD 20855

Veterinary Laboratories, Inc. intends to submit an Abbreviated New Animal Drug Application (ANADA) under the provisions of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) for:

Product: Biosol Liquid.
ANADA Product: Pharmacia & Upjohn
Biosol Liquid
ANADA 200-113

Veterinary Laboratories, Inc. hereby respectfully request a waiver of in vivo bioequivalence studies as outlined in the FDA's policy letter Number 5, dated April 12, 1990.

Enclosed are:

1. Copies of the label for Pharmacia & Upjohn Biosol Liquid. (Attactment A)

2. An itemized list of the active and inactive ingredients and their concentrations in the proposed generic product. (Attachment B)

3. A list of the pH and specific gravity of the Pharmacia & Upjohn Bisol Liquid and the pH and specific gravity of the proposed generic product. (Attachment C)

We hope this information will be sufficient to allow for approval of our request for waiver of the requirement for in vivo bioequivalence studies.

Sincerely,

Bert Hughes
President/C.E.O.

Enclosed

EBH/wkp

(Attachment A)

Restricted Drug—Use Only As Directed (California)
For Oral Use in Animals Only

Dosage and Administration: Administer to cattle, swine, sheep and goats at a dose of 10 mg neomycin sulfate per pound of body weight in divided doses for a maximum of 14 days.

Dosage Schedule for treatment of colibacillosis:

Pounds of Body Weight	Amount of BIOSOL Liquid Per Day in Divided Doses
25 lbs	1/4 teaspoonful
50 lbs	1/2 teaspoonful
100 lbs	1 teaspoonful
300 lbs	1 tablespoonful
600 lbs	1 fluid ounce

Teaspoon = U.S. Standard Measure

BIOSOL Liquid may be given undiluted or diluted with water.
Herd Treatment: Each bottle will treat 9,600 pounds body weight. Therefore, estimate the total number of pounds body weight of the animals to be treated and administer one (1) fluid ounce for each 600 pounds. The product should be added to the amount of drinking water to be consumed in 12-24 hours. Provide medicated water as the sole source of water each day until consumed, followed by non-medicated water as required. Fresh medicated water should be prepared each day.
Individual Animal Treatment: To provide 10 mg neomycin sulfate per pound of body weight, mix one (1) teaspoon in water or milk for each 100 pounds body weight. Administer daily either as a drench in divided doses or in the drinking water to be consumed in 12-24 hours.

CAUTION: To administer the stated dosage, the concentration of neomycin required in medicated water must be adjusted to compensate for variation in age and weight of animal, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects water consumption.

If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression, or going off feed develop, oral neomycin is not indicated as the sole treatment since systemic levels of neomycin are not obtained due to low absorption from the gastrointestinal tract.

Important: Treatment should continue 24 to 48 hours beyond remission of disease symptoms, but not to exceed a total of 14 consecutive days. Animals not drinking or eating should be treated individually by drench.

WARNING: Not for human use. Keep out of reach of children. Discontinue treatment prior to slaughter by at least the number of days listed below for appropriate species:

Cattle	1 day
Sheep	2 days
Swine and goats	3 days

A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

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

813 834 108

Pharmacia & Upjohn Company
Kalamazoo, MI 49001, USA

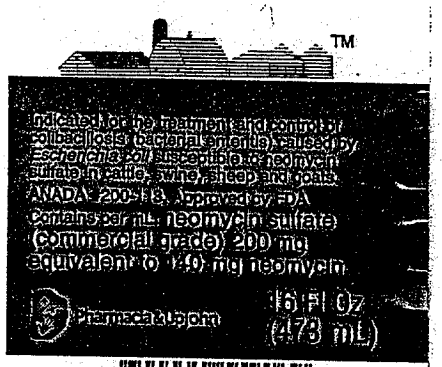
NDC 0009-0559-06

BIOSOL®

Liquid

Neomycin Sulfate
(commercial grade)

Antibacterial



LOT 99CRR
EXP 11/2002

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NEOMYCIN LIQUID

mg/mL

Active Ingredient	Concentration per mL
Neomycin (As Neomycin Sulfate)	140mg/mL

Inactive Ingredient	Concentration per mL
Potassium Sorbate	1.5 mg/mL
Sodium Metabisulfite	1.0 mg/mL
Sodium Citrate – $2H_2O$	5.0 mg/mL
Methyl Paraben	1.8 mg/mL
Propyl Paraben	0.2 mg/mL
Water for Injection	qs to 1 mL

Restricted Drug-Use Only As Directed (California)
For Oral Use in Animals only

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Dosage Schedule for treatment of colibacillosis:

Pounds of Body Weight	Amount of Neomycin Solution Per Day in Divided Doses
25 lbs	1/4 teaspoonful
50 lbs	1/2 teaspoonful
100 lbs	1 teaspoonful
300 lbs	1 tablespoonful
600 lbs	1 fluid ounce

Teaspoon = U.S. Standard Measure
Neomycin Solution may be given undiluted or diluted with water.
Herd Treatment: Each bottle will treat 9,600 pounds body weight. Therefore, estimate the total number of pounds body weight of the animals to be treated and administer one (1) fluid ounce for each 600 pounds. The product should be added to the amount of drinking water to be consumed in 12-24 hours. Provide medicated water as the sole source of water each day until consumed, followed by non-medicated water as required. Fresh medicated water should be prepared each day.
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N-1050-05 Iss. 6-03

NEOMYCIN
SOLUTION

Neomycin Sulfate (commercial grade)
Antibacterial
FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN

Indicated for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin sulfate in cattle, swine, sheep and goats.

Contains per mL: neomycin sulfate (commercial grade) 200 mg equivalent to 140 mg neomycin

NET CONTENTS: 16 Fl (478mL)

SPARHAWK LABORATORIES, INC.

If symptoms persist after using this preparation for 2 or 3 days, consult a veterinarian. If symptoms such as fever, depression, or going off feed develop, oral neomycin is not indicated as the sole treatment since systemic levels of neomycin are not obtained due to low absorption from the gastrointestinal tract.

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

ANADA# XXX-XXX Approved by F.D.A.

TAKE TIME OBSERVE LABEL DIRECTIONS

Manufactured by Veterinary Laboratories
Distributed by Sparhawk Laboratories

Lot No. Exp. Date

Enlarged 130%

CUSTOMER PROOF • pdf format • CHECK CAREFULLY!

Tabco, Inc. • (913) 287-3333 • fax (913) 287-3338 • 1323 S. 59th street • Kansas City, KS 66106 • www.tabcoinc.com

Customer: Sparhawk **P.O. #:** Rachel **CYREL #:** 32279(jb)

Salesperson: Joe Bidnick • jbidnick@tabcoinc.com **Customer Service:** Kathy Roper • kroper@tabcoinc.com

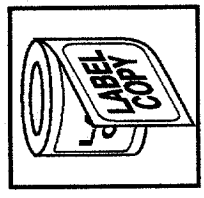
Date 3/11/03 6/25/03 7/2/03 **Unwind #:** 4

desc.: Neomycin 16oz **size:** 3 " x 6 "

varnish: ☐ Yes ☐ No **colors:** 202 877 Black

☐ pattern

☒ flood



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Approved by: _____ ☐ OK as shown ☐ OK w / corrections ☐ make corrections and resubmit **Date:** _____