

April 07, 2004

12 7 11 113-7 1111

Dockets Management Branch  
HFA-305  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Gentamicin Sulfate Oral Liquid

**CITIZEN PETITION  
(ANADA SUITABILITY PETITION)**

First Priority, Inc. hereby submits this petition under Section 512(n)(3) of the Federal Food, Drug and Cosmetic Act to seek permission from the Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine, to file an Approved Abbreviated New Animal Drug Application (ANADA) which differs in the concentration of the active ingredient from the innovator product.

*A. Action requested*

First Priority, Inc. seeks permission to file an ANADA for a generic equivalent of the innovator product, Garacin® (gentamicin sulfate) Pig Pump Oral Solution, NADA 130-464, Schering-Plough Animal Health, which differs from the innovator product in the concentration of gentamicin sulfate.

The change in concentration is necessitated because the delivery pump for the innovator product is 1.15 mL/dose while First Priority, Inc.'s delivery pump delivers 1.05 mL/dose. The First Priority, Inc. formulation and a comparison of the First Priority, Inc. product's physical properties to the innovator's are listed below.

**FIRST PRIORITY GENTAMICIN SULFATE ORAL LIQUID**

Component	mg/mL	mg/dose	g/Liter
Gentamicin, USP*	4.86 mg	5.10 mg	4.86 g
Sodium meta-bisulfite, NF	2.00 mg	2.10 mg	2.1 g
Disodium Edetate, USP	0.100 mg	0.105 mg	0.100 g
Sodium Acetate, USP	7.46 mg	7.83 mg	7.46 g
Acetic Acid, Glacial, USP	3.00 mg	3.15 mg	3.00 g
Methyl Paraben, NF	1.30 mg	1.365 mg	1.30 g
Propyl Paraben, NF	0.20 mg	0.21 mg	0.20 g
Purified Water, USP	q.s. to 1 mL	q.s. to 1.05 mL	q.s. to 1 L
<b>TOTAL</b>	<b>1 mL</b>	<b>1.05 mL</b>	<b>1 Liter</b>

\*as Gentamicin Sulfate. Activity corrected for gentamicin on as is basis. Specification of raw material is NLT 590 mcg/mg on dried basis.

\*\*One application of the pump delivers 1.05 ml. See attached validation for volume delivered.

2004P-0167

CPI

## PHYSICAL PROPERTIES

Garacin® Schering-Plough Animal Health	Gentamicin Sulfate Oral Liquid First Priority, Inc.
1.15 mL/dose	1.05 mL/dose
4.35 mg/mL (5.0 mg/dose)	4.86 mg/mL (5.1 mg/dose)
pH 4.30	pH 4.20
Specific Gravity 1.009	Specific Gravity 1.007

Three copies of all proposed labeling for the requested change in concentration of the active ingredient, gentamicin sulfate, are attached.

### *B. Statement of grounds*

Under provisions of the Federal Food, Drug, and Cosmetic Act, Section 512(n)(3) –

*If a person wants to submit an abbreviated application for a new animal drug--*

*(A) whose active ingredients, route of administration, dosage form, or strength differ from that of an approved new animal drug, or*

*(B) whose use with other animal drugs in animal feed differs from that of an approved new animal drug,*

*such person shall submit a petition to the Secretary seeking permission to file such an application.*

This ANADA Suitability Petition qualifies under the provisions of the Federal Food, Drug, and Cosmetic Act, Section 512(n)(3)(A) in that permission is sought to change only the concentration of an approved new animal drug.

### *C. Environmental impact*

First Priority, Inc. requests that this petition be considered for categorical exclusion under 21 CFR 25.24.

### *D. Economic impact*

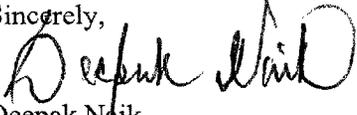
An economic impact analysis will be provided if requested after review of this petition.

### *E. Certification*

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 representative data and information known to the petitioner which are unfavorable to the petition.

If you should have any questions, or need additional information, please contact me at the above address, or at (847) 289-1600. Thank you for your interest in our waiver.

Sincerely,

  
Deepak Naik  
Director of Regulatory Affairs  
First Priority, Inc.

Enclosures

DN:slg

NDC# 58829-308-04

# Priority Care



**INDICATIONS:** For treatment of colibacillosis in neonatal pigs 1-3 days of age.

**DOSAGE:** 1 full pump (equivalent to 5 mg gentamicin) orally per pig one time. One bottle, as filled by the manufacturer, will deliver approximately 100 doses.

**WARNING:** Treated pigs must not be slaughtered for food at least 14 days following treatment.

Read accompanying directions carefully.

## Gentamicin Sulfate Oral Liquid

Pig Pump Solution

Antibacterial

For Oral Administration to Neonatal Pigs Only

For Animal Use Only - Keep Out of Reach of Children

Net Contents: 4 fl oz (120 mL)

ANADA xxx-xxx, Approved by FDA

**ACTIVE INGREDIENT:**

Each ml contains Gentamicin Sulfate Veterinary (equivalent to 4.86 mg Gentamicin)

**STORAGE:** Store at controlled room temperature between 2°-8°C (36°-66°F). Keep container tightly closed when not in use.

Do Not Freeze.

Restricted Drug (California) - Use Only as Directed.

Lot No. Exp. Date

NO VARNISH

Reorder No. AB005PC



Iss. 04-04

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## **Gentamicin Sulfate Oral Liquid**

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Pig Pump Solution  
4.86 mg/mL

**Veterinary**  
Antibacterial  
For Oral Administration to  
Neonatal Pigs Only

**DESCRIPTION:** Each milliliter of Gentamicin Sulfate Oral Liquid contains gentamicin sulfate veterinary, equivalent to 4.86 mg gentamicin.

**WARNING:** For use in neonatal swine only. Pigs treated with the recommended dose of Gentamicin Sulfate Oral Liquid must not be slaughtered for food for at least 14 days following treatment.

**INDICATIONS:** Gentamicin Sulfate Oral Liquid is recommended for the control and treatment of colibacillosis in neonatal pigs 1-3 days of age, caused by strains of *E. Coli* sensitive to gentamicin.

**DOSAGE AND ADMINISTRATION:** Administer orally to baby pigs. Recommended dose is one full pump per pig one time at the first sign of disease. One pump delivers 1.15 mL of gentamicin pig pump solution (5 mg gentamicin).

**CONTRAINDICATIONS:** There are no known contraindications to this drug when used as directed.

**CHEMISTRY:** Gentamicin is a mixture of aminoglycoside antibiotics derived from the fermentation of *Micromonospora purpurea*. Gentamicin sulfate veterinary is a mixture of sulfate salts of the antibiotics produced in this fermentation. The salts are weakly acidic and freely soluble in water. Gentamicin sulfate veterinary is stable in the subject solution under usual storage conditions for periods indicated by the expiration date.

**HOW SUPPLIED:** Gentamicin Sulfate Oral Liquid Pig Pump Solution is available in 4 fl oz (120 mL) bottles (approximately 100 doses) with a pump applicator.

**Store between 2° and 30°C (36° and 86°F).**

**Protect from freezing.**



Iss. 04-04



Manufactured By:  
First Priority, Inc.  
1585 Todd Farm Drive  
Elgin, IL 60123-1146

ANADA xxx-xxx,  
Approved by FDA

**For oral administration to neonatal pigs only.**

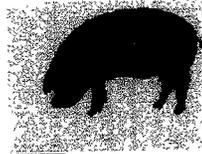
**Indications:** For treatment of colibacillosis in neonatal pigs 1-3 days of age.

**Dose:** 1 full pump (equivalent to 5 mg gentamicin) orally per pig one time; one bottle, as filled by the manufacturer, will deliver approximately 100 doses.

**Warning: Treated pigs must not be slaughtered for food at least 14 days following treatment.**

**Restricted Drug (California) - use only as directed.**

NDC  
0061-0434-08



**Garacin®**  
(GENTAMICIN SULFATE  
VETERINARY)

Pig Pump  
Oral Solution

Antibacterial

NADA #130-464, Approved by FDA.

4 fl. oz. (115 mL)

Schering-Plough Animal Health

**Each mL contains:** gentamicin sulfate veterinary equivalent to 4.35 mg gentamicin.

**Read accompanying directions carefully.**

**Store between 2° and 30°C (36° and 86°F).**

**Do Not Freeze.**

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Control No. 8 NGX 5003

**For oral administration to neonatal pigs only.**  
**Indications:** For treatment of colibacillosis in neonatal pigs 1-3 days of age.  
**Dose:** 1 full pump (equivalent to 5 mg gentamicin) orally per pig one time; one bottle, as filled by the manufacturer, will deliver approximately 100 doses.

**Warning: Treated pigs must not be slaughtered for food at least 14 days following treatment.**  
**Restricted Drug (California) - use only as directed.**

NDC  
0061-0434-08



**Garacin®**  
(GENTAMICIN SULFATE  
VETERINARY)

Pig Pump  
Oral Solution

Antibacterial

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4 fl. oz. (115 mL)

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**Do Not Freeze.**

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Control No. 8 NGX 5003

Enlargement