

Approval Date: July 31, 2006

FREEDOM OF INFORMATION SUMMARY

**ORIGINAL ABBREVIATED NEW ANIMAL
DRUG APPLICATION**

ANADA 200-395

**Gentamicin Sulfate Solution
(gentamicin sulfate)**

**Recommended for the control of bacterial infections of the uterus
(metritis) in horses and as an aid in improving conception in
mares with uterine infections caused by bacteria sensitive to
gentamicin**

Sponsored by:

Sparhawk Laboratories, Inc.

Table of Contents

1.	GENERAL INFORMATION:.....	1
2.	TARGET ANIMAL SAFETY AND DRUG EFFECTIVNESS:.....	2
3.	HUMAN SAFETY:	2
4.	AGENCY CONCLUSIONS:.....	2
5.	ATTACHMENTS:	3

I. GENERAL INFORMATION:

- a. File Number: ANADA 200-395
- b. Sponsor: Sparhawk Laboratories, Inc.
12340 Santa Fe Trail Dr.
Lenexa, KS 66215
- Drug Labeler Code: 058005
- c. Established Name: Gentamicin sulfate
- d. Proprietary Name: Gentamicin sulfate solution
- e. Dosage Form: Intra-uterine injection
- f. How Supplied: 100 mL vial
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: 100 mg gentamicin sulfate/mL
- i. Route of Administration: Intra-uterine injection
- j. Species/Class: Horses
- k. Recommended Dosage: 2.0 – 2.5 grams per day for 3 to 5 days during estrus. Each dose should be diluted with 200 – 500 mL of sterile physiological saline before aseptic uterine infusion
- l. Pharmacological Category: Aminoglycoside antimicrobial
- m. Indications: Recommended for the control of bacterial infections of the uterus (metritis) in horses and as an aid in improving conceptions in mares with uterine infections caused by bacteria sensitive to gentamicin.
- n. Pioneer Product: GENTOCIN Solution Veterinary;
gentamicin sulfate; NADA 046-724;
Schering-Plough Animal Health Corp.

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 09, 2002).

Based on the formulation characteristics of the generic product Sparhawk Laboratories, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Gentamicin Sulfate Solution. The generic product is administered as an intra-uterine injection in horses, contains the same 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. The pioneer product, GENTOCIN Solution Veterinary, the subject of Schering-Plough Animal Health Corp., NADA 046-724, was approved on October 14, 1972.

3. HUMAN SAFETY:

This drug is intended for use in horses, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

Human Warnings are provided on the product label as follows: Do not use in horses intended for human consumption.

4. AGENCY CONCLUSIONS:

This 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 Gentamicin Sulfate Solution, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile labeling is attached as indicated below:

Generic animal drug labeling for ANADA 200-395

Gentamicin Sulfate Solution; vial label and package outsert

Pioneer animal drug labeling for NADA 046-724

GENTOCIN Solution Veterinary; vial label; container label; package insert