Date of Approval: January 30, 2015

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-576

Gentamicin Sulfate Ophthalmic Solution

(gentamicin sulfate)

Ophthalmic Solution

Dogs and cats

For the topical treatment of conjunctivitis caused by susceptible bacteria in dogs and cats

Sponsored by:

Akorn Animal Health, Inc.

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-576

B. Sponsor

Akorn Animal Health, Inc.
1925 West Field Ct.
suite 300
Lake Forest, IL 60045

Drug Labeler Code: 059399

C. Proprietary Name

Gentamicin Sulfate Ophthalmic Solution

D. Established Name

gentamicin sulfate

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Ophthalmic Solution

G. Amount of Active Ingredient

Gentamicin sulfate equivalent to 3.0 mg gentamicin per mL of solution

H. How Supplied

5 mL bottle

I. Dispensing Status

Rx

J. Dosage Regimen

Instill 1 or 2 drops into the conjunctival sac 2 to 4 times a day.

K. Route of Administration

Ophthalmic

L. Species/Class

Dogs and cats

M. Indication

Gentamicin Sulfate Ophthalmic Solution is indicated for the topical treatment of conjunctivitis caused by susceptible bacteria in dogs and cats.

N. Reference Listed New Animal Drug

GENTOCIN; gentamicin sulfate; NADA 099-008; Intervet Inc.

II. BIOEQUIVALENCE:

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 (reference listed new animal drug (RLNAD)). 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 is required to show that the generic product is bioequivalent to the RLNAD, 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 demonstrating bioequivalence (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Akorn Animal Health, Inc. was granted a waiver from the requirement to demonstrate bioequivalence for the generic product Gentamicin Sulfate Ophthalmic Solution. The generic drug product is a ophthalmic solution, contains the same active ingredient in the same concentration and dosage form as the RLNAD, and contains no inactive ingredients that may significantly affect the bioavailability of the active ingredient. The RLNAD is GENTOCIN (gentamicin sulfate) Ophthalmic Solution, sponsored by Intervet Inc., under NADA 099-008, and it was approved for use in dogs and cats on April 2, 1976.

III. EFFECTIVENESS:

CVM did not require effectiveness studies for this approval.

IV. TARGET ANIMAL SAFETY:

CVM did not require target animal safety studies for this approval.

V. HUMAN FOOD SAFETY:

Data on human food safety, pertaining to drug residues in food, were not required for approval of this application. This drug is approved for use in dogs and cats, which are not food producing animals.

VI. USER SAFETY:

CVM did not require user safety studies for this approval.

VII. AGENCY CONCLUSIONS:

This information submitted in support of this ANADA satisfies the requirements of section 512(n) of the Federal Food, Drug, and Cosmetic Act and demonstrates that Gentamicin Sulfate Ophthalmic Solution, when used according to the label, is safe and effective.