Date of Approval: July 30, 2015

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-553

Neomycin and Polymyxin B Sulfates, and Bacitracin Zinc Ophthalmic Ointment, USP

Neomycin and polymyxin B sulfates, and bacitracin zinc

Ointment

Dogs and cats

For the treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to organisms susceptible to one or more of the antibiotics contained in the ointment

Sponsored by:

Akorn Animal Health Inc

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I. GENERAL INFORMATION:

A. File Number

ANADA 200-553

B. Sponsor

Akorn Animal Health Inc
1925 West Field Court
Suite 300
Lake Forest, IL 60045

Drug Labeler Code: 059399

C. Proprietary Name

Neomycin and Polymyxin B Sulfates, and Bacitracin Zinc Ophthalmic Ointment, USP

D. Product Established Name

Neomycin and polymyxin B sulfates, and bacitracin zinc

E. Pharmacological Category

Antimicrobial

F. Dosage Form

Ointment

G. Amount of Active Ingredient

Each gram of ointment contains: polymyxin B sulfate 10,000 units, bacitracin zinc 400 units, and neomycin sulfate 5 mg (equivalent to 3.5 mg neomycin base).

H. How Supplied

3.5 g tube

I. Dispensing Status

Rx

J. Dosage Regimen

Properly cleanse area to be treated. Foreign bodies, crusted exudates and debris should be carefully removed. Express a small quantity of ointment into the conjunctival sac beneath the lower eyelid three or four times daily. After application hold the eyelids shut for a short time so that a thin film of ointment covers the cornea.

K. Route of Administration

Ophthalmic

L. Species/Class

Dogs and cats

M. Indications

For the treatment of superficial bacterial infections of the eyelid and conjunctiva of dogs and cats when due to organisms susceptible to one or more of the antibiotics contained in the ointment.

N. Reference Listed New Animal Drug

NEOSPORIN; neomycin and polymyxin B sulfates, and bacitracin zinc; NADA 065-485; 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 period 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 Neomycin and Polymyxin B Sulfates, and Bacitracin Zinc Ophthalmic Ointment, USP. The generic drug product is a topical ophthalmic ointment, 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 NEOSPORIN (neomycin and polymyxin B sulfates, and bacitracin zinc) Ophthalmic Ointment, sponsored by Intervet, Inc. under NADA 065-485 and, was approved for use in dogs and cats on February 3, 1981.

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.

The product labeling contains the following information regarding safety to humans handling, administering, or exposed to Neomycin and Polymyxin B Sulfates, and Bacitracin Zinc Ophthalmic Ointment, USP:

Not for Human Use. Keep out of reach of children.

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 Neomycin and Polymyxin B Sulfates, and Bacitracin Zinc Ophthalmic Ointment, USP, when used according to the label, is safe and effective.