

Date of Approval: June 8, 2004

## **FREEDOM OF INFORMATION SUMMARY**

**Original Abbreviated New Animal Drug Application**

**200-273**

**VETRO-GEN Veterinary Ophthalmic Ointment  
(gentamicin sulfate)**

**Dogs and Cats**

It is indicated for topical treatment of conjunctivitis caused by susceptible bacteria in dogs and cats.

**Sponsored by:  
Altana Inc.  
Melville, NY 11747**

## FREEDOM OF INFORMATION SUMMARY

### 1. GENERAL INFORMATION:

- a. File Number: ANADA 200-273
- b. Sponsor: Altana Inc.  
60 Baylis Rd.  
Melville, NY 11747  
  
Labeler Code: 025463
- c. Established Name: Gentamicin sulfate
- d. Proprietary Name: VETRO-GEN Veterinary Ophthalmic Ointment
- e. Dosage Form: Topical ointment
- f. How Supplied: 3.5 gram (1/8 oz) tubes
- g. How Dispensed: Rx
- h. Amount of Active Ingredients: Each gram contains: gentamicin sulfate (equivalent to 3 mg gentamicin) in a base of mineral oil and white petrolatum.
- i. Route of Administration: Topical
- j. Species/Class: Dogs and cats
- k. Recommended Dosage: Apply approximately 1/2 inch strip of VETRO-GEN Veterinary Ophthalmic Ointment to the affected eye(s) 2 to 4 times a day.

- l. Pharmacological Category: Antibacterial
- m. Indications: VETRO-GEN Veterinary Ophthalmic Ointment is indicated for topical treatment of conjunctivitis caused by susceptible bacteria in dogs and cats.
- n. Pioneer Product: GENTOCIN Ophthalmic Ointment; gentamicin sulfate; NADA 98-989 Schering-Plough Animal Health

## **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 drug 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 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 Guideline, October 9, 2002).

Based upon the formulation characteristics of the generic product, Pharmaderm, Veterinary Division of Altana Inc. was granted a waiver from the requirement for *in vivo* bioequivalence study for VETRO-GEN Veterinary Ophthalmic Ointment (gentamicin sulfate). The generic product is administered as a topical ointment, contains the same active ingredient 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 Ophthalmic Ointment (gentamicin sulfate), the subject of Schering Plough Animal Health's NADA 98-989, was approved on April 2, 1976.

## **3. HUMAN SAFETY:**

This drug is indicated for use in dogs and cats, 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 Warning is provided on the product label as follows:  
“Keep out of reach of children”

**4. AGENCY CONCLUSIONS:**

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that VETRO-GEN Veterinary Ophthalmic Ointment, when used under its proposed conditions of use, is safe and effective for its labeled indications.

**5. ATTACHMENTS:**

Facsimile Generic Labeling and Currently Approved Pioneer Labeling are attached as indicated below:

Generic Labeling for ANADA 200-273

VETRO-GEN Veterinary Ophthalmic Ointment- 3.5 gram (1/8 oz) tube, box and Insert

Pioneer Labeling for NADA 98-989:

GENTOCIN Ophthalmic Ointment- 1/8 oz. tube, box and Insert