

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-183

B. Sponsor

Med-Pharmex Inc.
2727 Thompson Creek Road
Pomona, CA 91767

C. Proprietary Name

Gentavet[®] Otic Solution

D. Established Name

Gentamicin sulfate and betamethasone valerate otic solution

E. Dosage Form

Solution

F. Dosage Regimen

Duration of treatment will depend upon the severity of the condition and the response obtained. The duration of treatment and/or frequency of the dosage may be reduced, but care should be taken not to discontinue therapy prematurely.

Otitis externa- Instill 3 to 8 drops of Gentavet Otic Solution (approximately room temperature) into the ear canal twice daily for seven to fourteen days.

Superficial infected lesions- Apply a sufficient amount of Gentavet Otic Solution to cover the treatment area twice daily for seven to fourteen days.

G. Dispensing Status

Rx

H. Route of Administration

Topical

I. Indication

Gentavet Otic Solution is indicated for the treatment of acute and chronic canine otitis externa and canine and feline superficial infected lesions caused by bacteria sensitive to gentamicin.

J. Pioneer

Gentocin Otic Solution (gentamicin sulfate with betamethasone valerate, NADA 046-821) by Schering-Plough Animal Health Corporation

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988; First GADPTRA Policy Letter), an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). For certain dosage forms, the Agency grants a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter). In lieu of bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based on the formulation characteristics of the generic product, Med Pharmex Inc was granted a waiver July 17, 1990 (photocopy attached) from conducting an *in vivo* bioequivalence study with Gentavet Otic Solution. The generic and pioneer products are solutions with the same inactive ingredients and the same concentrations of the active ingredient. It is intended for topical administration.

III. HUMAN FOOD SAFETY

Human Safety Relative to Food Consumption

Regarding consumption of drug residues in food, human safety data were not required for approval of this ANADA. This drug is labeled for use in dogs and cats only and should not be administered to food-producing animals.

Human Safety Relative to Possession, Handling, and Administration

Labeling contains adequate caution/warning statements.

IV. AGENCY CONCLUSIONS

This is an abbreviated new animal drug application (ANADA) filed under Section 512(b)(2) of the Federal Food, Drug and Cosmetic (FFD&C) Act.

Safety and effectiveness for this generic animal drug, Gentavet Otic Solution, were established by demonstration of chemical equivalence to the pioneer product, Schering-Plough Animal Health Corporation's Gentocin Otic Solution, NADA 046-821). This generic product and the pioneer product have identical labeling indications for use. The route and method of administration of the two drugs are identical. Both drugs are administered topically. The generic and pioneer products are both solutions that contain the same active and inactive ingredients in the same concentrations. Both products have the same pH. Therefore, consistent with FDA policy implementing Section 512(b)(2) of the FFD&C Act, no additional safety, efficacy, or *in vivo* bioequivalency studies were necessary or required.

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that Gentavet Otic Solution is safe and effective for its labeled indications when used under its proposed conditions of use.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.