Approval Date: March 24, 1997

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-191

B. Sponsor

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

C. Proprietary Name

Gentasol (gentamicin sulfate solution)

D. Established Name

gentamicin sulfate

E. Dosage Form

Solution to be diluted in water for egg dipping

F. Amount of Active Ingredient

50 mg/mL

G. How Supplied

2-2/3 fl oz (80 mL) bottle

H. Dispensing Status

OTC

I. Dosage Regimen

A concentration of 500 ppm is recommended. To make a solution of approximately 500 ppm gentamicin activity, mix one bottle of Gentasol Solution for turkey egg dipping to each 2 gallons water.

J. Route of Administration

Dip

K. Species/Class

Turkey eggs

L. Indication

For the reduction or elimination of the following organisms from turkey hatching eggs: *Arizona hinshawii* (paracolon), *Salmonella st. paul*, *Mycoplasma meleagridis*.

M. Pioneer Product

Garasol® Solution (Gentamicin Sulfate Veterinary) (Schering, NADA 092-523)

II. 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 and the Center's first policy letter (53 FR 50460, December 15, 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 data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety data, drug effectiveness, and human food safety data in the pioneer's new animal drug application. Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer. If bioequivalence is demonstrated through a clinical end-point study, then a tissue residue study to establish the withdrawal time for the generic product is also required. For certain dosage forms, the Agency will grant a waiver from conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, April 1990).

Based upon the formulation characteristics of the generic product, Med-Pharmex, Inc. was granted a waiver from conducting an in vivo bioequivalence study for gentamicin sulfate solution. The generic and pioneer products contain the same active and inactive ingredients in the same concentration and are solutions.

III. HUMAN FOOD SAFETY

Tolerance

The tolerances established for the pioneer product apply to the generic product. Since eggs that have been dipped in gentamicin sulfate solutions are not intended for use as food, a tolerance for residues has not been established.

Withdrawal Time

When a waiver of the in vivo bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. Since the drug is to be used in the dipping treatment of turkey hatching eggs only, and since the eggs dipped in the solution are not intended for food, there is no withdrawal time assigned to the solution.

Regulatory Method for Residues

Since eggs that have been dipped in gentamicin sulfate solutions are not intended for use as food, a regulatory method for residues has not been established.

IV. 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 gentamicin sulfate solution when used under the proposed conditions of use, is safe and effective for its labeled indications.

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.