

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-147

B. Sponsor

Sanofi Animal Health, Inc.
7101 College Boulevard-Suite 610
Overland Park, KS 66210

C. Proprietary Name

GENTAMICIN SULFATE INJECTION

D. Established Name

gentamicin sulfate solution

E. Pharmacological Category

Antibiotic

F. Dosage Form

Injectible solution

G. Amount of Active Ingredient

Each mL contains gentamicin sulfate equivalent to 100 mg gentamicin base; 3.2 mg sodium metabisulfite; 0.1 mg edetate disodium; 4.5 mg sodium acetate anhydrous; 3.0 mg glacial acetic acid; 0.8 mg methylparaben and 0.1 mg propylparaben as preservatives.

H. How Supplied

GENTAMICIN SULFATE INJECTION 100 mg/mL is supplied in 100 mL vials. Boxes contain twelve vials.

I. Dispensing Status

OTC

J. Species/Class

Chickens, Day-old only

K. Indication

GENTAMICIN SULFATE INJECTION is indicated for use in the prevention of early mortality in day-old chickens caused by *Escherichia coli*, *Salmonella typhimurium*,

and *Pseudomonas aeruginosa* susceptible to gentamicin sulfate.

L. Reference Listed New Animal Drug

Garasol®, NADA 101-862

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). 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, 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, Sanofi Animal Health, Inc. was granted a waiver from conducting an *in vivo* bioequivalence study for GENTAMICIN SULFATE INJECTION. The generic and pioneer products are injectable solutions with the same active ingredient and no differences in the inactive ingredients which would affect absorption of the active ingredient.

III. HUMAN FOOD SAFETY

Withdrawal Time

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product.

For gentamicin sulfate injectable [21 CFR 522.1044 (a) (d) (3)], do not slaughter treated animals for food for at least 5 weeks after treatment.

Regulatory Method

The analytical method for the determination of gentamicin in tissues uses a microbiological assay procedure. This method is found in the *Antibiotic Residues in Milk, Dairy Products, and Animal Tissues: Methods, Reports, and Protocols*, revised October 1968, National Center for Antibiotic and Insulin Analysis, FDA, Washington, D.C. 20204.

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 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.