FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION **ANADA 200-147 (Supplement)**

ANADA/GENERIC SPONSOR:

Merial Limited
485 Rt 1 South, Bldg. D-210
Iselin, NJ 08830

A.	Established Name:	gentamicin sulfate solution
B.	Trade/Proprietary Name:	GENTA-JECT™
C.	Dosage Form:	Injectable Solution
D.	How Supplied:	GENTAMICIN SULFATE INJECTION 100 mg/mL is supplied in 100 mL vials. Boxes contain twelve vials.
E.	How Dispensed:	OTC
F.	Effect of the Supplement: addition	The supplement provides for the of a new species, turkeys, to the approved label.
G.	Amount of Active Ingredients:	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.	Species	Chickens, Day-old only, Turkeys, One to three day-old

I.	Labeled Dosage and Administration:	Each day-old chicken should be aseptically injected subcutaneously in the neck with a single GENTAMICIN SULFATE INJECTION diluted with sterile, physiologic saline solution to provide 0.2 mg gentamicin in a 0.2 mL dose. Each 1 to 3 day-old turkey should be aseptically injected subcutaneously in the neck with a single GENTAMICIN SULFATE INJECTION diluted with sterile, physiologic saline solution to provide 1 mg gentamicin in a 0.2 mL dose.
I.	Pharmacological Category:	Antibiotic
J.	Indications for Use:	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. Turkeys: as an aid in the prevention of early mortality of 1 to 3 day-old turkeys associated with *Arizona paracolon* infections susceptible to gentamicin sulfate.
K.	Pioneer/NADA #:	Schering Plough, Garasol®, NADA 101-862

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, (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 approval is based on a demonstration that the generic product is bioequivalent to the pioneer product. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (Fifth GADPTRA Policy Letter: 55 FR 24645, June 18, 1990; Bioequivalence Guidance: 61 FR 26182 - 26186, May 24, 1996).

Based upon the formulation characteristics of the pioneer and generic products, Merial Limited was granted a waiver from conducting an *in vivo* bioequivalence study for GENTAMICIN SULFATE INJECTION when the original ANADA was approved on April 10, 1995. Since that approval, the pioneer sponsor which they copied, Schering Plough, has supplemented their application and added turkeys to their label. Merial Limited is supplementing their generic application to add turkeys to their label.

3. HUMAN FOOD SAFETY:

Withdrawal Time

On January 25, 1994, a waiver from the requirement of an *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product. The original waiver was extended to include turkeys on July 29, 1998. For gentamicin sulfate injectable [21 CFR 522.1044 (a) (d) (3)], do not slaughter chickens for food for at least 5 weeks after treatment. Do not slaughter turkeys for food for at least 9 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.

4. AGENCY CONCLUSION:

This is a supplemental Abbreviated New Animal Drug Application (ANADA) filed under section 512(b)(2) of the Federal, Food, Drug and Cosmetic (FFD&C) Act satisfies the requirements of section 512(n) of the act and demonstrates that GENTAMICIN SULFATE INJECTION when used under the proposed use in turkeys, is safe and effective for its labeled indications.

Attachment: Generic labeling