Approval Date: March 28, 1996

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

NADA 101-862

B. Sponsor

Sponsor NameSchering-Plough Animal Health
Schering-Plough Corporation
PO Box 529
Kenilworth, New Jersey 07033

C. Proprietary Name

GARASOL® Injection

D. Established Name

gentamicin sulfate veterinary

E. Dosage Form

GARASOL® Injection diluted with sterile, physiological saline solution

F. Dispensing Status

OTC

G. Dosage Regimen

1 day old Chickens0.2 mg gentamicin in a 0.2-mL dos1 to 3 days old Turkeys1.0 mg gentamicin in a 0.2-mL dose

H. Route of Administration

Subcutaneously

I. Indication

For day-old chicks, GARASOL® Injection is indicated for the prevention of early mortality associated with *Escherichia coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa* infections susceptible to gentamicin sulfate.

For 1- to 3-day-old turkeys GARASOL® Injection is indicated as an aid in the prevention of early mortality associated with *Arizona paracolon* susceptible to gentamicin sulfate.

J. Effect of Supplement

This supplement provides for adding the previously approved turkey claims under NADA 47-486 to the labeling of NADA 101-862. The excipients in the formulations are identical, although the quantities are slightly different.

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

For effectiveness and animal safety information relative to turkeys, refer to the FOI for GARASOL® Injection (NADA 47-486). The data, summaries and conclusions which support this approval are now filed in NADA 101-862.

For effectiveness and animal safety information relative to chickens, refer to the FOI for GARASOL® Injection (NADA 101-862).

III. HUMAN FOOD SAFETY

When GARASOL® Injection (50 or 100 mg/mL) is diluted as described in labeling, the concentration of gentamicin is not different, while the concentration of the excipients (non-therapeutic ingredients) are much lower than those concentrations in the 5-mg/mL formulation, as dosed to turkeys. These differences are inconsequential to safety and efficacy. NADA 101-862 contains sufficient information, such that further studies are not required.

For human safety information relative to turkeys, refer to the FOI for GARASOL® Injection (NADA 47-486). The data, summaries, and conclusions which support this approval are now filed in NADA 101-862.

IV. AGENCY CONCLUSIONS

The data submitted in support of this supplement to the NADA satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and support the request to add the claims for GARASOL® Injection (5 mg/mL) approved for turkeys (NADA 47-486) to GARASOL® Injection (50 and 100 mg/mL) approved for chickens (NADA 101-862).

This action will provide for an animal drug to be marketed under the same conditions as a previously approved animal and, therefore, qualifies for categorical exclusion under 21 CFR 25.24(d)(iii). No change in the dose and indications of GARASOL® Injection provided to chickens and turkeys is permitted by this action

The patent has expired, and approval of this supplement does not affect exclusivity.

V. ATTACHMENTS

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

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.