DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 1-546/S-011

Schering Corporation
Attention: Mary Jane Nehring
Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated March 29, 1988, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Guanidine HCl 125 mg tablets.

Supplemental application S-011, submitted under "Changes Being Effected", provides for the following changes:

1. The addition of "acute interstitial nephritis" in the **ADVERSE REACTIONS-Renal** section of labeling as requested in an Agency letter dated December 18, 1987,
2. The deletion of the statement in labeling "Caution: Federal Law Prohibits Dispensing Without a Prescription",
3. The addition of the NDC number and a storage statement in the **HOW SUPPLIED** section,
4. Updated address of drug manufacturer.

We have completed the review of this supplemental application, S-011, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted March 29, 1988/Label Code I007407). Accordingly, this supplemental application is approved effective on the date of this letter.

We additionally request, at the next printing, that you replace the presently used storage recommendations under the **HOW SUPPLIED** section of labeling as well as the container labels with the following statement:

> "Store at 25°C (77°F); excursions permitted to 15 - 30°C (59 - 86°F) [see USP Controlled Room Temperature]. "

This change may be reported in your next annual report.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Russell Katz
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