DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 14-713/S-031/S-032

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

Dear Ms. Nehring:

Please refer to your new drug application, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Etrafon (perphenazine and amitriptyline hydrochloride) 2/10, 2/25, and 4/25 Tablets.

Reference is also made to an Agency letter dated October 31, 2001, providing for the approval of supplemental application 14-713/S-031 and requesting 20 copies of final printed labeling (FPL) as well as requesting additional labeling revisions.

We acknowledge receipt of your submission dated April 19, 2002, providing for 20 copies of FPL as well as providing for revisions to the **CLINICAL PHARMACOLOGY-Pharmacokinetics** section of labeling as requested in the Agency letter dated October 31, 2001. We note that these changes, supplemental application S-032, were submitted under "Changes Being Effected".

We have completed the review of this supplemental application, NDA 14-713/S-032, 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 April 19, 2002). Accordingly, this supplemental application is approved effective on the date of this letter.

Additionally, the 20 copies of FPL contained in your April 19, 2002, adequately addresses our request made in the approval letter for S-031 dated October 31, 2001.

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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