DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 10-775 / S-031
NDA 11-213 / S-024

Schering Corporation
Attention: Mary Jane Nehring
Sr. Director, Marketed Products Support
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Nehring:

Please refer to your supplemental new drug applications of September 28, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trilafon (perphenazine) Tablets and Injection.

We acknowledge receipt of your submission dated April 19, 2002, which constituted a complete response to our October 18, 2001 action letter.

These supplemental new drug applications provide for revisions to the OVERDOSAGE section of the labeling. The revisions update the description of signs, symptoms, and laboratory findings of acute overdosage and general principles of treatment. (We note that these submissions also provide final printed labeling (FPL), relevant to geriatric use, which was approved in our letter of October 18, 2001, to NDA 10-775 / S-030 and NDA 11-213 / S-022. A separate letter will acknowledge and retain the FPL to these supplements.)

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted April 19, 2002 - copy attached). Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Steven D. Hardeman, R.Ph., Senior Regulatory Project Manager, at (301) 594-5525.

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

attachment

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
5/10/02 08:06:04 AM