NDA 10-775/SLR-029
NDA 11-213/SLR-021

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

15 MAR 2001

Dear Ms. Nehring:

Please refer to your supplemental new drug applications dated December 20, 2000, received December 22, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trilafon (perphenazine) tablets and injection.

These "Changes Being Effected" supplemental new drug applications provide for the labeling changes requested in our letter of September 25, 2000, specifically modification of labeling text to more clearly state that these agents are indicated for the treatment of schizophrenia.

We have completed the review of these supplemental applications 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 December 20, 2000). 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,

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