NDA 16-774/SLR-073
NDA 16-775/SLR-041
NDA 16-997/SLR-041

Novartis 15 MAR 2001
Attention: James Rawls, Pharm.D.
Assistant Director, Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936

Dear Dr. Rawls:

Please refer to your supplemental new drug applications dated December 22, 2000, received December 27, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Serentil (mesoridazine besylate) tablets, injection, and oral solution.

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 agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted December 22, 2000).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 16-774/SLR-073, 16-775/SLR-041, 16-997/SLR-041." Approval of these submissions by FDA is not required before the labeling is used.

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