DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-758 / S-057

Novartis Pharmaceuticals Corporation
Attention: Ira Do, Pharm.D.
Drug Regulatory Affairs
One Health Plaza
East Hanover, New Jersey 07936-1080

Dear Dr. Do:

Please refer to your supplemental new drug application dated June 3, 2005, received June 6, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clozaril (clozapine).

This "Changes Being Effected" supplemental new drug application provides for changes in the product labeling under PRECAUTIONS, Drug Interactions, Pharmacokinetic-Related Interactions to add ciprofloxacin to the list of drugs that may increase plasma levels of Clozaril, potentially resulting in adverse effects.

We have completed our review of this supplemental new drug application and it is approved effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 3, 2005.

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 LT Keith Kiedrow, Pharm.D., Regulatory Project Manager, at (301) 796-1924.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry 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/

Thomas Laughren

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