DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-758 / S-056

Novartis Pharmaceuticals Corp.
Attention: Roy Dodsworth
One Health Plaza
East Hanover, NJ 07936

Dear Mr. Dodsworth:

Please refer to your supplemental new drug application (supplement) dated May 31, 2005, received June 1, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clozaril (Clozapine HCl) Tablets.

This "Changes Being Effected" supplement provides revised labeling in response to the Division's letter of April 11, 2005. Our letter requested that all manufacturers of atypical antipsychotic drugs add a Boxed Warning and a Bolded Warning section to the product labeling stating that elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death.

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 May 31, 2005 (attached).

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

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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