DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-791/S-006

Novartis Pharmaceuticals Corporation
Attention: Sabine Vukelich, Ph.D.
Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Vukelich:

Please refer to your supplemental new drug application (NDA) dated January 14, 2009 and received January 15, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Myfortic® (mycophenolic acid) Delayed-release Tablets.

We acknowledge receipt of your submission dated March 23, 2009.

This supplemental new drug application provide for the following changes to the labels:

Container Labels:
Addition of the statement: "Dispense the accompanying Medication Guide to each patient."

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels).

As soon as possible, but no later than 14 days from the date of this letter, please submit the final printed immediate container and carton labels. For administrative purposes, please designate these submissions, "**Carton and Container Labels for approved supplements NDA 50-791/S-006".**

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA

(21 CFR 314.80 and 314.81).

If you have any questions, call Hyun Son, Pharm.D., Acting Safety Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, M.D., MPH
Deputy Director for Safety
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Ozlem Belen

3/27/2009 11:27:45 AM