DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-791/S-004

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 and received October 3, 2008, 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 December 9, 2008, and December 10, 2008.

Reference is also made to the FDA letter dated September 4, 2008 invoking our authority under section 505(o)(4) of the Federal Food, Drug and Cosmetic Act (FDCA) that you are required to make safety related labeling changes to the labeling of Myfortic® to address the risk of congenital malformations in offspring of patients exposed to mycophenolate mofetil (MMF) during pregnancy. Following oral or IV administration, MMF is metabolized to mycophenolic acid (MPA), the active ingredient in Myfortic. The required safety related labeling changes are based on new safety information about the risk of congenital malformations identified since the drug was approved.

On October 3, 2008, FDA received your prior-approval labeling supplement that contained your proposed Medication Guide. Section 505(o) requires FDA to promptly review the supplement and if we disagree with the proposed changes, initiate discussions with you on the content of the changes. These discussions are to be completed within 30 days, unless FDA determines that an extension is warranted. On October 30, 2008, we sent you a letter informing you that an extension was warranted for this supplement, extending the discussion period to end on December 2, 2008.

We have completed our review of the Medication Guide. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions "**SPL for approved supplements NDA 50-791/S-004".**

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in SPL format to include the changes approved in these applications.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

We request that this revised labeling approved today be available on your website within 10 days of receipt of this letter and that the revised labeling be reflected in the next printing of the labeling. While you may use labeling already printed as of the date of this letter until May 15, 2009, after that date, we request that the revised labeling accompany any newly shipped product.

Failure to make these changes promptly could make your product misbranded under Sections 201(n) and 502(a) of FDCA.

Please note that you must comply with the Medication Guide Regulations as specified in 21 CFR208. In particular, the carton and container labels must comply with 21 CFR208.24(a)(2)(d). Please submit proposed labels for review within 30 days of receipt of this letter.

LETTERS TO HEALTH CARE PROFESSIONALS

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}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Medication Guide

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

/s/

Renata Albrecht

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