DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-791/S-007

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

Dear Dr. Vukelich:

Please refer to your prior approval supplemental new drug application dated June 9, 2009, received on June 11, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Myfortic®(mycophenolic acid) delayed-release tablet, 180 mg and 360 mg.

We also acknowledge receipt of your submission dated July 8, 2009.

This supplemental application provides for the following revisions to the Package Insert and the Medication Guide (additions are noted with underline and deletions noted with ~~strikethrough~~):

1. In the **WARNINGS (SEE BOXED WARNINGS)** section a new subsection "Pure Red Cell Aplasia" is added as follows:

   Pure Red Cell Aplasia

   Cases of pure red cell aplasia (PRCA) have been reported in patients treated with mycophenolate mofetil (MMF) in combination with other immunosuppressive agents. MMF is metabolized to mycophenolic acid (MPA), the active ingredient in Myfortic and the active form of the drug. The mechanism for MMF induced PRCA is unknown; the relative contribution of other immunosuppressants and their combinations in an immunosuppressive regimen are also unknown. In some cases PRCA was found to be reversible with dose reduction or cessation of MMF therapy. In transplant patients, however, reduced immunosuppression may place the graft at risk. Changes to Myfortic therapy should only be undertaken under appropriate supervision in transplant recipients in order to minimize the risk of graft rejection (see ADVERSE REACTIONS, Postmarketing Experience).

2. In the **ADVERSE REACTIONS, Postmarketing Experience** subsection, a third paragraph is added as follows:

   Cases of pure red cell aplasia (PRCA) have been reported in patients treated with mycophenolate mofetil in combination with other immunosuppressive agents (see WARNINGS).

3. In the Medication Guide, under the section entitled, "What are the possible side effects of Myfortic?" the following paragraph is added as follows:

   What are the possible side effects of Myfortic?

   Myfortic can cause serious side effects.

   See "What is the most important information I should know about Myfortic?"

   Stomach and intestinal bleeding can happen in people who take Myfortic. Bleeding can be severe and you may have to be hospitalized for treatment.

   The most common side effects of taking Myfortic include:

   In people with a new transplant:
   - low blood cell counts
     - red blood cells
     - white blood cells
     - platelets
   - constipation
   - nausea
   - diarrhea
   - vomiting
   - urinary tract infections
   - stomach upset

   In people who take Myfortic for a long time (long-term) after transplant:
   - low blood cell counts
     - red blood cells
     - white blood cells
   - nausea
   - diarrhea
   - sore throat

   Your healthcare provider will do blood tests before you start taking Myfortic and during treatment with Myfortic to check your blood cell counts. Tell your healthcare provider right away if you have any signs of infection (see "**What is the most important information I should know about Myfortic**?"), or any unexpected bruising or bleeding. Also, tell your healthcare provider if you have unusual tiredness, dizziness or fainting.

   These are not all the possible side effects of Myfortic. Your healthcare provider may be able to help you manage these side effects.

We have completed our review of this application as amended. This application is approved, effective on the date of this letter, for use as recommended in the package insert and medication guide submitted on July 8, 2009.

As soon as possible, but no later than 14 days from the date of this letter, please submit the 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 to the enclosed labeling text for the package insert and patient package insert. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved supplements NDA 50-791/S-007.**

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.

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

REPORTING REQUIREMENTS

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 June Germain, Regulatory Health Project Manager, at (301) 796-4024.

Sincerely,
{See appended electronic signature page}

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

Enclosure: Package Insert and 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/

Ozlem Belen

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