DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-791/S-012

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: M. Daniel Gordin, PhD
Executive Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Gordin:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 29, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Myfortic®(mycophenolic acid) delayed-release tablet, 180 mg and 360 mg.

We also refer to our approval letter dated May 1, 2013, which contained the following errors:

- In the boxed **WARNING** of the highlights section, bullets 2, 3 and 4 were incorrect because they contained the wrong numbers for reference section(s) or subsection(s) of the Full Prescribing Information (FPI) of the attached package insert.
- In the FPI, Table 4 contained these adverse reactions that should have been omitted: abdominal pain lower, blood pressure increased, back pain, tremor, headache and contusion.
- In the FPI, Table 4, these adverse reactions should have been included: urinary retention, pruritus and sepsis.

This replacement approval letter incorporates the corrections of the errors. The effective approval date will remain May 1, 2013, the date of the original approval letter.

We acknowledge receipt of your amendments dated, November 2, 2012 and April 22, 2013.

The November 2, 2012, submission constituted a complete response to our November 9, 2011, action letter.

This prior approval supplemental New Drug Application provides for revisions to the product labeling in response to the, Final Rule titled, R*equirements on Content and Format of Labeling for Human Prescription Drug and Biological Products* (Federal Register Vol. 71, No. 15, 3921-3997). Specifically, this sNDA provides for the conversion of the current approved labeling to the format required by the Physician Labeling Rule in accordance with 21 CFR 201.56 and 201.57.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Ms. June Germain, Acting Safety Regulatory Project Manager, at (301) 796-4024.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, MD
Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling: Package Insert, 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 A BELEN
05/01/2013
Signing on behalf of Dr. Renata Albrecht, Division Director, DTOP