DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022334/S-001 **SUPPLEMENT APPROVAL**

Novartis Pharmaceuticals Corporation
Attention: Lincy Thomas, PharmD
Senior Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Thomas:

Please refer to your Supplemental New Drug Application (sNDA) dated July 30, 2009, received July 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Afinitor® (everolimus) 5 mg and 10 mg Tablets.

This Prior Approval supplemental new drug application provides for the replacement of the current food effect statement under Section 12.3, "Based on data in healthy subjects taking 1 mg everolimus tablets, a high fat meal reduced C_{max} and AUC by 60% and 16%, respectively. No data are available with Afinitor 5 mg and 10 mg tablets." with "In healthy subjects, high fat meals reduced systemic exposure to Afinitor 10 mg tablet (as measured by AUC) by 22% and the peak plasma concentration C_{max} by 54%. Light fat meals reduced AUC by 32% and C_{max} by 42%. Food, however, had no apparent effect on the post absorption phase concentration-time profile."

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling text for the package insert and for the patient package insert and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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.

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 Amy Tilley, Regulatory Project Manager, at 301-796-3994.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling and Patient Information

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22334	SUPPL-1	NOVARTIS PHARMACEUTICALS CORP	AFFINITOR

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

/s/

ANTHONY J MURGO

05/13/2010

Anthony J. MD signing for:
Robert L. Justice, M.D., M.S.