NDA 022334/S-45
NDA 203985/S-17

CBE SUPPLEMENT –
ACKNOWLEDGEMENT/APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Smita Abbi
Sr. Global Program Regulatory Manager
One Health Plaza
East Hanover, New Jersey 07936

Dear Ms. Abbi:

We have received your supplemental new drug applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER:	022334
SUPPLEMENT NUMBER:	45
PRODUCT NAME:	AFINITOR (EVEROLIMUS) TABLETS
NDA NUMBER:	203985
SUPPLEMENT NUMBER:	17
PRODUCT NAME:	AFINITOR DISPERZ (EVEROLIMUS) TABLETS FOR ORAL SUSPENSION
DATE OF SUBMISSIONS:	DECEMBER 5, 2019
DATE OF RECEIPT:	DECEMBER 5, 2019

These supplemental applications, submitted as a "Changes Being Effected" supplement, proposes revision to Postmarketing Experience (6.2) subsection to include the following: Blood and lymphatic disorders: thrombotic microangiopathy.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-

upon labeling, with minor editorial revisions listed below and reflected in the enclosed labeling.

Capitalized words classifying race throughout the label as listed in FDA Guidance to Industry: *Collection of Race and Ethnicity Data in Clinical Trials*

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), 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. If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for the NDAs, 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 Microsoft Word format, that includes the changes approved in these supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your applications, you are exempt from this requirement.

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 you may contact Felicia Diggs, Safety Regulatory Project Manager, at (240) 402-4932 or via email at Felicia.diggs@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Abhilasha Nair, M.D.
Associate Director for Safety (acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ABHILASHA NAIR
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