DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205755/S-003
NDA 205755/S-004

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Anne Frederick, Ph.D.
Executive Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, New Jersey 07936

Dear Dr. Frederick:

Please refer to your Supplemental New Drug Applications (sNDAs) for supplement 3, dated January 23, 2015, received January 23, 2015, and for supplement 4, dated March 11, 2015, received March 11, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zykadia (ceritinib), 150 mg capsules.

We acknowledge receipt of your amendments to supplements 3 and 4 dated July 16, July 20, and July 22, 2015.

Supplement 3: This "Prior Approval" supplemental new drug application provides for updates to the DOSAGE AND ADMINISTRATION, Dosage and Administration (2.1), Dose Modification for Adverse Reactions (2.2), WARNINGS AND PRECAUTIONS, Hepatotoxicity (5.2), QT Interval Prolongation (5.4), Hyperglycemia (5.5), and Pancreatitis (5.7), and PATIENT COUNSELING INFORMATION (17) sections of the package insert, and the Patient Information to include an update on pancreatitis.

Supplement 4: This "Prior Approval" supplemental new drug application provides for an update to the WARNINGS AND PRECAUTIONS, Hepatotoxicity (5.2) subsection of the package insert.

APPROVAL & LABELING

We have completed our review of these supplemental applications, 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 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, text for the patient package insert), 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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 application, you are exempt from this requirement.

PROMOTIONAL MATERIALS

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

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. Karen Boyd, Senior Regulatory Project Manager, at (301) 796-7032.

Sincerely,

{See appended electronic signature page}

Jeffery Summers, M.D.
Deputy Director for Safety
Division of Oncology Products 2
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

JEFFERY L SUMMERS
07/22/2015