DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022068/S-014

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Novartis Pharmaceuticals Corporation
Attention: Katie Chon
Drug Regulatory Affairs Oncology
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Chon:

Please refer to your Supplemental New Drug Application (sNDA) dated September 17, 2012, received September 18, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tasigna® (nilotinib) capsules, 150 mg and 200 mg.

We acknowledge receipt of your amendments dated January 18, 2013, February 22, 2013, March 7, 2013, April 29, 2013, May 31, 2013 and June 6, 2013.

This "Prior Approval" supplemental new drug application provides for updates to the Package Insert (PI) and Medication Guide (MG) based on the data from Study CAMN107A2131:

- Tasigna Prescribing Information, Section 7.3, Drugs that affect Gastric pH
- Medication Guide, What should I tell my doctor before starting Tasigna

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.

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 and 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).

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.

FULFILLMENT OF POSTMARKETING REQUIREMENT

We have received your submissions dated June 27, 2012 and September 17, 2012, containing the final report for the following postmarketing requirement listed in the June 17, 2010 approval letter.

PMR 1650-1 A clinical trial to determine dosing regimens with a) H2 blockers and nilotinib, and b) antacids and nilotinib, that minimize alterations of the pharmacokinetics for nilotinib. You should include steps that dose H2 blockers and antacids at a specified period before nilotinib dosing, as well as at specified periods following nilotinib dosing.

The timetable you submitted on June 4, 2010, states that you will conduct this trial according to the following schedule:

Final Protocol Submission:	June 2011
Trial Completion Date:	January 2012
Final Report Submission:	June 2012.

We have reviewed your submissions and conclude that the above requirement was fulfilled.

This completes all of your postmarketing requirements acknowledged in our June 17, 2010 approval letter.

We remind you that there is a postmarketing requirement listed in the June 3, 2010 approval letter and a postmarketing commitment listed in the October 29, 2007 approval letter that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Patricia Garvey, Regulatory Project Manager, at (301) 796-8493.

Sincerely,

{See appended electronic signature page}

Robert C. Kane, MD
Deputy Director for Safety
Division of Hematology Products
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/

ROBERT C KANE
06/13/2013