Dear Dr. Chon:

Please refer to your Supplemental New Drug Application (sNDA) dated March 22, 2013, received March 22, 2013, 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 June 13, 27, September 27, October 11, November 13, 21, 25, December 10, 20 and 24, 2013 and January 16 and 22, 2014.

This Prior Approval supplemental new drug application updates the Tasigna® (nilotinib) Capsules labeling based on the interim report at 48 months for the use of nilotinib in adult patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia in chronic phase (CML-CP), Study CAMN107A2303 titled “A Phase III Multi-Center, Open-Label, Randomized Study of Imatinib Versus Nilotinib in Adults Patients with Newly Diagnosed Philadelphia Chromosome Positive (Ph+) Chronic Myelogenous Leukemia in Chronic Phase (CML-CP).”

APPROVAL & LABELING

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.

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

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
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
CM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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,
defered, or inapplicable.

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

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

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 or by fax to 301-847-8444.

**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, please contact Patricia Garvey, Senior Regulatory Project Manager, at (301) 796-8493.

Sincerely,

{See appended electronic signature page}

Edvardas Kaminskas, M.D.
Deputy Director
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/

ANN T FARRELL
01/22/2014
Farrell for Kaminskas