



NDA 022068/S-035/S-036

**SUPPLEMENT APPROVAL/  
FULFILLMENT OF POSTMARKETING  
REQUIREMENTS**

Novartis Pharmaceuticals Corporation  
Attention: Shreyas Gupte, MS, RAC  
Senior Global Program Regulatory Manager  
One Health Plaza  
East Hanover, NJ 07936-1080

Dear Mr. Gupte:

Please refer to your supplemental new drug application (sNDA) dated March 26, 2021, received March 26, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tasigna (nilotinib) capsules.

These Prior Approval supplemental new drug applications provide for the extension of the CML-AP indication in adults to the pediatric population 1 year and older, and updates to the USPI based upon the final clinical study report for CAMN107A2203 "A multi-center, open label, non-controlled phase II study to evaluate efficacy and safety of oral nilotinib in pediatric patients with newly diagnosed Ph+ chronic myelogenous leukemia (CML) in chronic phase (CP) or with Ph+ CML in CP or accelerated phase (AP) resistant or intolerant to either imatinib or dasatinib."

**APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

**WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS**

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 FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide), with the addition of any labeling changes in pending “Changes Being Effectuated” (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 *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in this 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).

## **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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

## **FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)**

We have received your submission dated March 26, 2021, containing the final reports for the following postmarketing requirements listed in the March 22, 2018, approval letter.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

- 3359-1 To characterize the long-term safety of treatment with Tasigna in pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase, submit annual interim and final reports and integrated analysis datasets from Study CAMN107A2203 until at least 5 years of follow-up.
- 3359-2 To characterize the effect of treatment with Tasigna on growth and development in pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase, submit the final report and analysis datasets that include long-term follow-up of patients enrolled on CAMN107A2203. For prepubertal patients and those who have not completed pubertal development, include growth parameters, sexual maturation, bone metabolism parameters, and endocrine and reproductive toxicities in the safety evaluation. The growth and development safety data should include patients with at least 5 years of follow-up or until pubertal development is complete, in at least 90% of patients, whichever is longer.

We have reviewed your submission and conclude that the above requirements were fulfilled.

This completes all of your postmarketing requirements acknowledged in our March 22, 2018, supplement approval letter.

### **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.<sup>3</sup>

You must submit final promotional materials and Prescribing Information, 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 FDA.gov.<sup>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</sup>

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<sup>3</sup> For the most recent version of a guidance, check the FDA guidance web page at

<https://www.fda.gov/media/128163/download>.

<sup>4</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>5</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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 labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

## **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, contact Brad McKenzie, Regulatory Project Manager, at [bradley.mckenzie@fda.hhs.gov](mailto:bradley.mckenzie@fda.hhs.gov) or (301) 796-2583.

Sincerely,

*{See appended electronic signature page}*

R. Angelo de Claro, MD  
Division Director  
Division of Hematologic Malignancies I  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

### **ENCLOSURE(S):**

- Content of Labeling
  - Prescribing Information
  - Medication Guide

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**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.**  
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/s/  
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