



NDA 022068/S-037

## APPROVAL LETTER

Novartis Pharmaceuticals Corporation  
Attention: JoyceAnn Sinno  
Regulatory CMC Director- Regulatory Affairs GDD CMC  
One Health Plaza  
Bldg. 337 - B09.3C  
East Hanover, NJ 07936

Dear Dr. Sinno:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 18, 2021, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TASIGNA® (nilotinib) capsules.

This “Changes Being Effected in 30 days” supplemental new drug application provides for the following:

- Addition of [REDACTED] (b) (4) as an alternative primary and secondary packaging site.
- Addition of 60 cc round shaped bottles with 33 mm [REDACTED] (b) (4) closure for Tasigna 50 mg [REDACTED] (b) (4) capsules.

### **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.

### **CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 022068/S-037.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Chelsea Bostic, Regulatory Business Process Manager, at (301) 796 - 8862.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, PhD  
Chief, Branch I  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
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