NDA 022068/S-040

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Joyce Ann Sinno, Ph.D.
RA CMC Director
One Health Plaza
Building 337
East Hanover, NJ 07936-1080

Dear Dr.Joyce Ann Sinno:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 30, 2023, 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 changes:

1) Addition of Novartis d.o.o., Ljubljana, Slovenia (FEI # 3013358387) as a drug Product manufacturing and quality control testing site
2) Consequential batch size decrease, minor changes to the manufacturing process of the drug product and changes to secondary packaging material of the bulk drug product
3) Addition of (b) (4) (b) (4) as storage and warehousing site
4) Addition of (b) (4) microbiological testing site for drug product release
5) Change in the name and address (postal code) of a currently registered packaging site located in (b) (4) to Novartis d.o.o.

APPROVAL & LABELING

We have completed our review of this supplemental application. 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-040." Approval of this submission by FDA is not required before the labeling is used.

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 Dahlia A. Walters, Regulatory Business Process Manager, at (301) 796 - 8427.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Supervisor
Division of Product Quality Assessment lV
Office of Product Quality Assessment l
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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