NDA 022068/S-042

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Lori Kneafsey
Senior Global Program Regulatory Manager
One Health Plaza
East Hanover, NJ 07936-1080

Dear Lori Kneafsey:

Please refer to your Supplemental New Drug Application (sNDA) dated February 15, 2024, received February 15, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TASIGNA (nilotinib) capsules.

We also refer to our approval letter dated August 14, 2024, which did not include all the labeling components.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain August 14, 2024, the date of the original approval letter.

This "Changes Being Effected in 30 Days" supplement new drug application provides for the labeling changes in container label artworks to introduce a QR code.

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-042.**" 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 IV
Office of Product Quality Assessment I
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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