



NDA 202806/S-021

APPROVAL LETTER

Novartis Pharmaceuticals Corp
Attention: Andrew Bridge
Regulatory CMC Associate Director - Regulatory Affairs GDD CMC
One Health Plaza
Building 337 - 04/B19L1-08
East Hanover, NJ 07936-1080

Dear Mr. Bridge:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 5, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tafinlar (dabrafenib) capsules.

This Prior Approval supplemental new drug application provides for:

1. Expansion of manufacturing activities at a currently approved site Lek Ljubljana (FEI: 3002807460) to include drug product manufacturing, quality control and stability testing.
2. A change to the drug product manufacturing process as used at the Lek, Ljubljana site (FEI: 3002807460)

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

We acknowledge your October 5, 2021, submission containing final printed carton and container labeling.

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 Laya Keyvan, Regulatory Business Process Manager, at (240) 402 - 4598.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Branch Chief, B1
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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