NDA 022465/S-033

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Beth Purdy
Regulatory CMC Associate Director - Regulatory Affairs
One Health Plaza
Bldg. 337 - B09.4f
East Hanover, NJ 07936-1082

Dear Ms. Purdy:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 13, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Votrient (pazopanib) tablets, 200mg.

This Prior Approval supplemental new drug application provides for:

- Replacement of the (b) (4) film-coat excipient (b) (4) Gray (b) (4) with (b) (4) Pink (b) (4) resulting in change in appearance (color) of the Film-coated tablet.
- Addition of (b) (4) as an alternate site of drug product manufacture and analytical testing and subsequent minor changes in the manufacturing process.
- Change to in-process limits (b) (4)
- Addition of in-process controls
- Replacement of tests and addition of a specification for (b) (4)
- The shelf life for the drug product is proposed to be (b) (4) based on available stability data.

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.

We note that your November 30, 2021, submission includes final printed labeling (FPL) for your prescribing information. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending "Changes Being Effected" (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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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).

CARTON AND CONTAINER LABELS

We acknowledge your August 13, 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

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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