NDA 22465/S-29

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Luz Patricia Lee
Sr. Associate Director
Regulatory Affairs GDD
One Health Plaza
East Hanover, NJ 07936-1080

Dear Ms. Lee:

Please refer to your supplemental new drug application dated and received February 3, 2020, and your amendments dated June 12, 2020, July 28, 2020, August 6, 2020, and August 13, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Votrient (pazopanib hydrochloride) tablets.

This Prior Approval supplemental new drug application provides for updates to the following:

- Update to the WARNINGS AND PRECAUTIONS subsection (5.12), retitled Risk of Impaired Wound Healing, to provide recommendations for resumption of Votrient after surgery;
- Updates to the DOSAGE AND ADMINISTRATION subsections (2.1, 2.2, 2.3, and 2.4) to clarify the recommended duration of treatment for renal cell carcinoma and soft tissue sarcoma, and the dosage modification for adverse reactions;
- Updates to the INDICATIONS AND USAGE subsection (1.1 and 1.2) to state that Votrient is indicated for the treatment of adults; and
- Editorial and formatting changes throughout the U.S. package insert for brevity and consistency with current labeling practices.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, and Medication Guide), 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this new drug application (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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

---

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions you may contact Felicia Diggs, Safety Regulatory Project Manager, at (240) 402-4932 or via email at Felicia.diggs@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Meredith K. Chuk, M.D.
Associate Director for Safety
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MEREDITH K CHUK
08/17/2020 08:04:24 AM