



NDA 022465/S-031 and S-032

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Kimberly Biango, MS
Global Program Regulatory Manager; Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936

Dear Ms. Biango:

Please refer to your supplemental new drug applications (sNDAs) dated March 24, 2021 (S-031) and June 18, 2021 (S-032), received March 24, 2021 (S-031) and June 21, 2021 (S-032), and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Votrient (pazopanib) tablets.

The Prior Approval Supplement 031 proposed revisions to the Prescribing Information to add [REDACTED] (b) (4) and to change adverse reaction from "anorexia" to [REDACTED] (b) (4) in the Adverse Reactions subsection 6.1.

The FDA disagreed with the Applicant's proposal to add [REDACTED] (b) (4)

The FDA disagreed with the Applicant's proposal [REDACTED] (b) (4)

The FDA considered the Applicant's proposal to change adverse reaction from "anorexia" to [REDACTED] (b) (4) in the Adverse Reactions subsection 6.1 contingent on verification [REDACTED] (b) (4) per CTCAE definition of anorexia.

However, the Applicant agreed to maintain the term "anorexia" throughout the Prescribing Information as some patients have experienced loss of appetite. Additionally, the number of tablets were added to subsection 2.1 to minimize the risk of wrong dosing errors. Editorial and formatting changes throughout the Prescribing Information and Medication Guide were made for consistency with current labeling practices.

The Prior Approval Supplement 032 proposed revisions to the Prescribing Information to add [REDACTED] (b) (4)

The FDA disagreed with the Applicant's proposa (b) (4)

(b) (4) Instead (b) (4)
“(including fatal cases)” was added to subsection 6.2 at the end of “Vascular Disorders: Arterial (including aortic) aneurysms, dissections, and ruption”. The FDA did not agree with the Applicant’s proposal (b) (4)

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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 NDA, including CBE supplements for which the 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 these supplemental applications, 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

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>.

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).

If you have any questions, contact Jessica Kim, Regulatory Project Manager, at 240-402-0883 or Jessica.Kim1@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Laleh Amiri-Kordestani, MD
Director
Division of Oncology 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- 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/

LALEH AMIRI KORDESTANI
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