



NDA 202806/ S-026

## **SUPPLEMENT APPROVAL**

Novartis Pharmaceuticals Corporation  
Attention: Stanislaw Kuruc  
Global Program Regulatory Manager  
Regulatory Affairs  
One Health Plaza  
East Hanover, NJ 07936-1080

Dear Mr. Kuruc:

Please refer to your supplemental new drug application (sNDA) dated and received November 29, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tafenlar (dabrafenib), capsule.

This Prior Approval sNDA provides for updates to the Tafenlar (dabrafenib) Prescribing Information (PI), to add hemophagocytic lymphohistiocytosis (HLH) in Section 5, WARNINGS AND PRECAUTIONS with associated revisions to the Medication Guide (MG). Additional minor edits were made throughout the PI and MG to align with Mekinist labeling.

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. 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.<sup>1</sup> 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.

---

<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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*.<sup>2</sup>

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 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).

## **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 Kristin Jarrell, Pharm.D., Regulatory Health Project Manager, at (301) 796-0137.

Sincerely,

*{See appended electronic signature page}*

Steven Lemery, MD, M.H.S.  
Director  
Division of Oncology 3  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

## **ENCLOSURES:**

- Content of Labeling
  - Prescribing Information
  - Medication Guide

---

<sup>2</sup> 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>.

-----  
**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/  
-----

STEVEN J LEMERY  
05/26/2023 03:03:17 PM