NDA 203756/S-09

**SUPPLEMENT APPROVAL**

Exelixis, Inc.
Attention: Lisa Sauer
Senior Vice President, Regulatory Affairs and Quality Assurance
1851 Harbor Bay Parkway
Alameda, CA 94502

Dear Ms. Sauer:

Please refer to your supplemental new drug application dated and received June 15, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cometriq (cabozantinib) capsules.

This "Changes Being Effected" supplemental new drug application provides changes to the U.S. prescribing information for Cometriq (cabozantinib), consistent with our May 21, 2020, request to update Adverse Reactions, subsection 6.2 (Post Marketing Experience) to include: Arterial (including aortic) aneurysms, dissections, and rupture.

## 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.

- Removed the comma after "(including aortic)" under the subheading *Vascular* in subsection 6.2.
- Updated the date at the end of the Highlights of Prescribing Information to "Revised: 10/2020".

## 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 via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at FDA.gov[1] that is identical to the enclosed labeling (text for the Prescribing Information), and include any labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements**.** If the content of labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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(s) 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).

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[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, call Jana L. Highsmith Regulatory Health Project Manager, at 301-348-1823, or via email at Jana.Highsmith@fda.hhs.gov.

Sincerely,

*{See appended electronic signature page}*

Shaily Arora, Pharm.D.
Associate Director for Safety (Acting)
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

APPEARS THIS WAY ON ORIGINAL

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**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.**

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/s/

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SHAILY ARORA
10/22/2020 06:51:12 PM