DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 208692/S-001

SUPPLEMENT APPROVAL

Exelixis, Inc.
Attention: Lisa Sauer
Vice President, Regulatory Affairs and Quality Assurance
210 East Grand Avenue
South San Francisco, CA 94080

Dear Ms. Sauer:

Please refer to your Supplemental New Drug Application (sNDA) dated July 13, 2017, received July 13, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cabometyx® (cabozantinib) tablets, 20 mg, 40 mg, and 60 mg.

This "Changes Being Effected" supplemental new drug application proposes the following change:

- A modified bottle label for the 60 mg strength only to add the statement, "Professional Sample-Not For Sale" and include a different NDC number

APPROVAL & LABELING

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

CARTON AND IMMEDIATE CONTAINER LABELS

Submit the final printed immediate container label that is identical to the immediate container label submitted on July 13, 2017, as soon as it is available, but no more than 30 days after it is printed. Please submit this label electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Immediate Container Label for approved NDA 208692/S-001**." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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).

If you have any questions, contact Rajesh Venugopal, Senior Regulatory Project Manager, at (301) 796-4730.

Sincerely,

{See appended electronic signature page}

Julia Beaver, MD
Director
Division of Oncology Products 1
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

ENCLOSURE:
Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JULIA A BEAVER
11/16/2017