NDA 220613

NDA APPROVAL

Handa Oncology, LLC
Attention: David Quiggle
Vice President, Regulatory Affairs
2025 Gateway Place, Suite 480
San Jose, CA 95110

Dear David Quiggle:

Please refer to your new drug application (NDA) received September 29, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Omcazio (cabozantinib) capsules, 11.5 mg, 23 mg, and 34.5 mg.

We acknowledge receipt of your amendment requesting final approval dated July 30, 2026, following our July 29, 2026, tentative approval letter.

This NDA provides for the use of Omcazio (cabozantinib) capsules for the following indications:

- Treatment of adult patients with advanced renal cell carcinoma
- In combination with nivolumab for the first-line treatment of adult patients with advanced renal cell carcinoma
- Treatment of adult patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib
- Treatment of adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors (epNET).

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.

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 (Prescribing Information and Patient Package Insert) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in guidance for industry *SPL Standard for Content of Labeling Technical Qs and As.*[2]

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 220613**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Omcazio shall be 24 months from the date of manufacture when stored at controlled room temperature, 20°C–25°C (68°F–77° F), with excursions permitted between 15°C–30°C (59°F to 86°F).

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.

The Application contained information supporting the approval of OMCAZIO (cabozantinib) for the treatment of adult and pediatric patients 12 years of age and older

[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.

with previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors (epNET).

We are waiving the pediatric study requirement for patients less than 12 years of age because necessary studies are impossible or highly impracticable due to the rarity of cancers for which investigation of cabozantinib is warranted in this pediatric age group.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[3] Information and Instructions for completing the form can be found at FDA.gov.[4]

REPORTING REQUIREMENTS

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

REQUESTED ENHANCED PHARMACOVIGLIANCE (EPV)

We request that for Omcazio (cabozantinib) capsules, you provide a narrative summary including analysis of all serious and non-serious U.S. cases associated with wrong drug or wrong dose medication errors or describing the potential for a wrong drug or wrong dose error in a report submitted to your NDA as a “Clinical/Clinical Information” submission every 6 months for the period of 3 years following product launch in the U.S. market.

Your narrative summary and analysis should include an interval and cumulative analysis of all serious and non-serious U.S. cases associated with wrong drug or wrong dose errors or describing the potential for these errors, a cumulative line listing of the cases with case narrative, and the search terms used to identify the cases. Your narrative summary, analysis, and line listing should include the following:

- The number of cases associated with a suspected medication error and cases describing the potential for a medication error (i.e., close calls/near misses).

[3] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

- Contributing factors for the error (e.g., proprietary name not displayed in electronic medical record [EMR], bioequivalent dose information not displayed in EMR, formulary changes, etc.).

- Phase of the medication use process where the error originated (prescribing, dispensing, administration, etc.).

- Reporter recommendations or actions taken to prevent future similar errors.

- Adverse events and outcomes associated with the error.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[5].

If you have any questions, contact Alice Lee, Senior Regulatory Project Manager, at (301) 796-8881 or at Alice.Lee@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

ENCLOSURES:
- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
- Carton and Container Labeling

[5] https://www.uspnf.com/

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/

CHRISTY L OSGOOD
09/03/2026 02:34:02 PM
Signing on behalf of Laleh Amiri Kordestani