



See List of Applications

**APPROVAL LETTER**

Novartis Pharmaceuticals Corp  
Attention: Joyce Ann Sinno  
RA CMC Director, Regulatory Affairs GDD  
One Health Plaza  
Building 337  
East Hanover, NJ 07936-1080

Dear Joyce Ann Sinno:

Please refer to your supplemental New Drug Application(s) (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), and all amendments, for the following products:

<b>Supplemental Application</b>	<b>Product Information</b>	<b>Submit Date</b>	<b>FDA Received Date</b>
NDA 209092/S-025	Kisqali (ribociclib) tablets	May 19, 2025	May 19, 2025
NDA 209935/S-031	Kisqali Femara Co-pack (ribociclib tablets; letrozole tablets)	May 19, 2025	May 19, 2025

These Prior Approval supplemental new drug applications provide for the following:

- Changes in the drug product manufacturing process
- Addition of an in-process control
- Addition of suppliers of primary packaging materials with reference to the Drug Master Files (type III)
- Change to the approved stability protocol
- Change in the drug product storage condition and an extension of the expiration dating period
- Labeling updates

**APPROVAL & LABELING**

We have completed our review of these supplemental applications, as amended. They are 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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, and text for the patient package insert) with the addition of any labeling changes in pending “Changes Being Effectuated” (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 titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via 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 MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, 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).

## **CARTON AND CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 209092/S-025.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, call Stephanie Ngan, Regulatory Business Process Manager,  
at (240) 402 - 5932.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, Ph.D.  
Supervisor  
Division of Product Quality Assessment IV  
Office of Product Quality Assessment I  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure(s):  
Content of Labeling  
Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
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