NDA 209092/S-020
NDA-209935/S-028

APPROVAL LETTER

Novartis Pharmaceuticals Corporation
Attention: Masha Berkhin, PharmD
Senior Global Program Regulatory Director
One Health Plaza
Building 337
East Hanover, NJ 07936-1080

Dear Dr. Berkhin:

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:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 209092/S-020	KISQALI (ribociclib) tablets	March 22, 2024	March 22, 2024
NDA-209935/S-028	KISQALI FEMARA COPACK (ribociclib tablets; letrozole tablets)	March 22, 2024	March 22, 2024

These "Changes Being Effected in 30 days" supplemental new drug applications provide for the following:

- Addition of (b) (4) as an alternate site for manufacture, quality control, and (b) (4) This change is associated with (b) (4)
- Addition of (b) (4) as an alternate site for manufacture, quality control and (b) (4).
- Addition of (b) (4) as an alternate site for the manufacture, quality control, and storage for the drug substance, storage of the drug substance stability samples and stability testing.

- Addition of [redacted] as an alternate site for quality control and stability testing of the [redacted] and storage of stability samples.
- Addition of [redacted] and [redacted] as alternate sites for the quality control and stability testing of the drug substance [redacted]
- Addition of [redacted] as alternate storage sites for [redacted] the drug substance.

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) 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.

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 NDAs, 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 and carton and container labels submitted on March 22, 2024, 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-020 and NDA-209935/S-028.**" 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.

If you have any questions, contact Utkarsh Desai, Regulatory Business Process Manager, at Utkarsh.Desai@fda.hhs.gov.

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):
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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