NDA 212728/S-025

CORRECTED SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Ira Do, PharmD, MBA
Senior Director, Pfizer Global Regulatory Sciences
66 Hudson Boulevard East
New York, NY 10001

Dear Dr. Do:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 21, 2024, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nurtec ODT (rimegepant) tablet, orally disintegrating.

We also refer to our approval letter dated December 12, 2024, which contained the following error: Incorrect "12/2024" revised date for the Prescribing Information (PI) and Patient Package Insert (PPI). The "revised" date has been updated to "4/2023" for the PI and PPI to reflect the PI and PPI submitted with the April 26, 2023 annual report.

This corrected action letter incorporates the correction of the error. The effective action date will remain December 12, 2024, the date of the original letter.

This "Changes Being Effected" supplemental new drug application provides for the following changes to the carton labeling, dimensions, and packaging configuration for the professional sample:

- Revised professional sample carton labeling and dimensions to align with the existing trade carton labeling (for the trade carton containing eight orally disintegrating tablets).
- Removal of the inner and outer wallet from the sample secondary packaging which does not affect the drug substance nor the drug product specifications or primary blister packaging or blister labeling.
- Changing the sample packaging configuration from 1 carton x 4 (inner and outer) wallets with two orally disintegrating tablets per blister pack (8 tablets total per carton) to 1 carton x 1 blister pack with two orally disintegrating tablets (2 tablets total per carton).

APPROVAL & LABELING

We have completed our review of this supplemental 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 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 Patient Package Insert) 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/Drugs/GuidanceComplianceRegulatoryInformation/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 this supplemental application, 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 label that are identical to enclosed carton label and carton label submitted on June 21, 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 212728/S-025.**" Approval of this submission by FDA is not required before the labeling is used.

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 Erica Keafer, Regulatory Business Process Manager, at (301) 796 – 1435 or erica.keafer@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Joyce Crich, Ph.D.
Senior Pharmaceutical Quality Assessor

For:
Gurpreet Gill-Sangha, Ph.D.
Supervisor
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
- Carton Labeling

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/

JOYCE Z CRICH
12/30/2024 12:02:37 PM