NDA 211675/S-029

APPROVAL LETTER

AbbVie Inc.
Attention: Deepak Mehta
Associate Director, Regulatory Affairs CMC
1 N. Waukegan Road
Dept. PA72, Bldg. AP50
North Chicago, IL 60064

Dear Deepak Mehta:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 27, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RINVOQ (Upadacitinib) extended-release tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for

- To add (b) (4) as an alternate site for the (b) (4) (b) (4)
- (b) (4) (b) (4)

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 submitted agreed-upon labels.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to carton and container labels submitted on February 27, 2025, 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 211675/S-029.**" 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 Rajani Ranga, Regulatory Business Process Manager, at Rajani.Ranga@fda.hhs.gov or 2404025041

Sincerely,

{See appended electronic signature page}

Vilayat Sayeed, Ph.D.
Director, Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality

Vilayat Sayeed

Digitally signed by Vilayat Sayeed
Date: 8/12/2025 10:30:26AM
GUID: 508da70600028a7aad41a1cc455d8261