



NDA 218347/S-003

APPROVAL LETTER

AbbVie Inc.
Attention: Carl Knable
Director, Regulatory Affairs, CMC
1 North Waukegan Road
Dept PA71/Bldg. AP50
North Chicago, IL 60064

Dear Carl Knable:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 27, 2025, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Rinvoq LQ (upadacitinib) oral solution.

This “Changes Being Effectuated in 30 days” supplemental new drug application provides to cross-reference to NDA (b) (4) Supp (b) (4) (b) (4)

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.

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 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 218347/S-003.**” 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 Erica Keafer, Regulatory Business Process Manager, at (301) 796 – 1435 or erica.keafer@fda.hhs.gov.

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
Center for Drug Evaluation and Research

Enclosure(s):

- Carton and Container Labeling



Vilayat
Sayeed

Digitally signed by Vilayat Sayeed

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