NDA 211765/S-002

SUPPLEMENT APPROVAL

Allergan Sales LLC
Attention: Amjad Iqbal, PharmD
Executive Director, Global Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Dr. Iqbal:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 8, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for UBRELVY (ubrogepant) Tablets, 50 mg and 100 mg.

This "Changes Being Effected" supplemental new drug application provides for updates to the carton and container labeling for the 10 count, 16 count, and 30 count presentations of UbrelvyTM (ubrogepant) 50 mg and 100 mg tablets.

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, 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 211765/S-002.**" 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, call Avani Patel, Regulatory Business Process Manager, at (240) 402 - 1845.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief, Branch 2
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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