



NDA 205422/S-013

SUPPLEMENT APPROVAL

Otsuka Pharmaceutical Co Ltd.
Attention: Dana Cahill, PhD
Senior Director, Global Regulatory Affairs
2440 Research Boulevard
Rockville, MD 20850

Dear Dr. Cahill:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 11, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for REXULTI (brexpiprazole) tablets.

This Prior Approval supplemental new drug application to seeks FDA approval for changes that are being proposed to the REXULTI (brexpiprazole) packaging (cartons). The proposed changes include updates to text placement and prominence in order to accommodate the placement of a new security seal.

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 November 25, 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 205422/S-013.**” 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).

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If you have any questions, call Teshara G. Bouie, Senior Regulatory Business Process Manager, at (301) 796 - 1649.

Sincerely,

{See appended electronic signature page}

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

Enclosures:
Carton Labeling



Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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