NDA 021164/S-001

SUPPLEMENT APPROVAL

Fabre Kramer Pharmaceuticals Inc.
Attention: Stephen J. Kramer, MD
Chief Executive Officer
5847 San Felipe
Suite 2000
Houston, TX 77057

Dear Dr. Kramer:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 9, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Exxua (gepirone) extended-release tablets.

This Prior Approval supplemental new drug application provides for revision of the proprietary name logo(s) on the container labels for each approved strength (i.e., 18.2 mg, 36.3 mg, 54.5 mg, and 72.6 mg) respectively.

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 container labels that are identical to enclosed container labels and container labels submitted on May 9, 2025, and May 19, 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 021164/S-001.**" 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 Teshara G. Bouie, Senior Regulatory Business Process Manager, at (301) 796 - 1649.

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:

Container Labeling

Vilayat Sayeed

Digitally signed by Vilayat Sayeed
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