NDA 202834/S-018

SUPPLEMENT APPROVAL

Catalyst Pharmaceuticals, Inc.
Attention: Gary Ingenito, MD, PhD
Chief Medical and Regulatory Officer
355 Alhambra Circle
Suite 801
Coral Gables, FL 33134

Dear Dr. Ingenito:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 5, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fycompa (perampanel) tablet.

This "Changes Being Effected" supplemental new drug application provides for updates to the drug product container labeling for the physician's sample kit blister card due to a change in NDA ownership.

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 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 May 5, 2023, 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 202834/S-018.**" 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, please contact Erica Keafer, Regulatory Business Process Manager, at (301) 796 – 1435 or erica.keafer@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, B3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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