NDA 211280/S-006

APPROVAL LETTER

Eli Lilly and Company
Attention: Mitchell R. Cunningham, PharmD
Consultant, Global Regulatory Affairs - NA
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Dear Dr. Cunningham:

Please refer to your Supplemental New Drug Application (sNDA) dated September 30, 2021, and received October 1, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Reyvow (lasmiditan) Tablets.

This Prior Approval supplemental new drug application provides for updates to the currently registered (b) (4) manufacturing process (b) (4) including the following:

(b) (4)

APPROVAL

We have completed our review of this supplemental application. This supplement is approved.

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 Nikole Ayala-Agosto, Regulatory Business Process Manager, at Nikole.Ayala-Agosto@fda.hhs.gov or (240) 402 - 2723.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Branch Chief, Branch 3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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