NDA 020648/S-024

APPROVAL LETTER

Bausch Health US, LLC
Attention: Sunny Bhardwaj
Associate Director, Global Regulatory Affairs, CMC
400 Somerset Corporate Boulevard
Bridgewater, NJ 08807

Dear Sunny Bhardwaj:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 17, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Diastat (diazepam) gel.

This Prior Approval supplemental new drug application provides for the following changes:

- (b) (4) the acceptance criterion for the "pH" test parameter in the drug product specifications for all three Diastat presentations (2.5 mg, 10 mg, and 20 mg) from (b) (4)" to "(b) (4)"

- a reduction in the shelf-life from 48 months to 22 months for the 2.5 mg Diastat presentation

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, call Onyekachukwu (Onyeka) Ihezie, PharmD, Regulatory Business Process Manager, at (240) 402 - 2480.

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

David Lewis

Digitally signed by David Lewis
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