NDA 209463/S-013

APPROVAL LETTER

Hikma International Pharmaceuticals LLC
c/o Hikma Pharmaceuticals USA Inc
Attention: J. Kalis
Sr. Director, Regulatory Affairs
2 Esterbrook Lane
Cherry-Hill, NJ 08003-4002

Dear J. Kalis:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 26, 2021, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pantoprazole Sodium for Injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for use of (b) (4) in the drug product manufacturing process. The proposed (b) (4) is (b) (4) manufactured by (b) (4) (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, call Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

{See appended electronic signature page}

David Lewis,PhD.
Branch Chief, B2
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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