NDA 209359/S-007

APPROVAL LETTER

Hospira Inc.
Attention: Craig Hernandez
Associate, Global Regulatory Affairs
275 North Field Drive, Bldg. H1-3S
Lake Forest, IL 60045

Dear Mr. Hernandez:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 4, 2021, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Epinephrine Injection, USP.

This "Changes Being Effected in 30 days" supplemental new drug application provides for [redacted] (b) (4) at Rocky Mount, NC facility for the drug product Epinephrine Injection,USP.

APPROVAL

We have completed our review of this supplemental application, as amended. 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 Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

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

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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