NDA 011719/S-135

SUPPLEMENT APPROVAL

Hospira, Inc.
Attention: Emily K. Schmidt
Manager, Pfizer Global Regulatory Affairs
275 North Field Drive Bldg H1
Lake Forest, IL 60045

Dear Ms. Schmidt:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 2, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Methotrexate Injection, USP 25 mg/mL.

This "Changes Being Effected" supplemental new drug application provides for changes to the drug product labeling as specified by the Agency's supplement request letter dated October 3, 2021.

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

We acknowledge your March 18, 2022, submission containing final printed carton and container labeling.

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, call Laya Keyvan, Regulatory Business Process Manager, at (240) 402 - 4598.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Branch Chief, B1
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
Date: 5/02/2022 03:55:16PM
GUID: 502d0913000029f375128b0de8c50020