



NDA 011719/S-136

APPROVAL LETTER

Hospira, Inc.
Attention: Emily Schmidt
Senior Manager, Pfizer Global Regulatory Sciences
275 North Field Drive, Bldg. H1-3S
Lake Forest, IL 60045

Dear Emily Schmidt:

Please refer to your supplemental New Drug Application (sNDA) dated and received April 27, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Methotrexate Injection, USP.

We acknowledge receipt of your amendment dated July 27, 2023, which constituted a complete response to our August 26, 2022, action letter.

This Prior Approval supplemental new drug application provides for updates to the prescribing information for the preservative-free formulation regarding the use time and storage conditions.

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.

We note that your November 24, 2023, submission includes final printed labeling (FPL) for your prescribing information. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, please contact me at email: Janell.Artis@fda.hhs.gov, or (301) 796 – 6309.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief
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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