BLA 125545/S-022

SUPPLEMENT APPROVAL

Hospira Inc.
Attention: Melissa Nguyen, RAC
Senior Manager
275 N. Field Drive
Building H1
Lake Forest, IL 60045

Dear Ms. Nguyen:

Please refer to your supplemental biologics license application (sBLA) dated and received November 22, 2022, and your amendment, submitted under section 351(k) of the Public Health Service Act for Retacrit (epoetin alfa-epbx) injection.

This Prior Approval supplemental biologics license application proposes to include a statement that the drug product is not made with Natural Rubber Latex or Dry Natural Rubber to the Prescribing Information. In addition, the signature line was updated with the most recent company logo on the Prescribing Information, Medication Guide, and Instructions for Use.

APPROVAL & LABELING

We have completed our review of this sBLA, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov[1], that is identical to the enclosed labeling (text for the prescribing information, instructions for use, and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

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/Drugs/GuidanceComplianceRegulatoryInformation/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 BLA, including pending "Changes Being Effected" (CBE) supplements,

for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Kelly Ballard, Senior Regulatory Business Process Manager, at (301) 348 - 3054.

Sincerely,

{See appended electronic signature page}

Susan Kirshner, Ph.D.
Director
Division of Biotechnology Review and Research III
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling

Susan Kirshner

Digitally signed by Susan Kirshner
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