BLA 125545/S-005

SUPPLEMENT APPROVAL

Hospira, Inc.
Attention: Melissa A. Nguyen, BS, RAC
Senior Manager, Global Regulatory Affairs
275 N. Field Drive, Bldg. H1
Lake Forest, IL 60045

Dear Ms. Nguyen:

Please refer to your supplemental biologics license application (sBLA), dated and received December 21, 2018, and your amendments, submitted under section 351(k) of the Public Health Service Act for Retacrit (epoetin alfa-epbx) injection.

We acknowledge receipt of your amendment dated April 30, 2020, which constituted a complete response to our October 21, 2019, action letter.

This Prior Approval supplemental biologics application provides for addition of a new multiple dose vial presentation in the following strengths: 20,000 units/2 mL (10,000 units/mL) and 20,000 units/mL.

APPROVAL & LABELING

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

WAIVER OF HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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,

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved BLA 125545/S-005**." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

3897-1 To conduct (b) (4) bioburden method qualification using two additional batches of Retacrit (b) (4).

The timetable you submitted on April 30, 2020, states that you will conduct this study according to the following schedule:

Final Report Submission: 08/30/2020

3897-2 To perform real time shipping studies to support commercial shipping of Retacrit MDV to Pfizer (b) (4) (b) (4) The studies will evaluate the impact on product quality of handling, shipping route(s), mode(s) of transportation, transport duration, packing configuration (including maximum and minimum load), and shipping containers intended for commercial shipping, including worst-case excursions. The studies will include temperature monitoring and assessment of product quality prior to and after shipment. The study results will be submitted as per 21 CFR 601.12.

The timetable you submitted on April 30, 2020, states that you will conduct this study according to the following schedule:

Final Report Submission: 12/01/2021

Also, we remind you of your prior commitment listed in the original approval letter dated May 15, 2018.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

As required under 21 CFR 601.12(f)(4), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication,

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

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 Charlene Wheeler, MSHS, (Acting) Chief, Project Management Staff at 301-796-1141.

Sincerely,

{See appended electronic signature page}

Ann Farrell, MD
Director
Division of Non malignant Hematology
Office of Cardiology, Hematology,
Endocrinology, & Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use
- Carton and Container Labeling

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ANN T FARRELL
06/30/2020 01:56:12 PM