Our STN: BL 125317/231

SUPPLEMENT APPROVAL/
PMR FULFILLED
June 4, 2021

CSL Behring GmbH
Attention: Matthew McCaslin
CLS Behring, LLC
1020 First Avenue
P.O. Box 6150
King of Prussia, PA 19406

Dear Mr. McCaslin:

We have approved your request submitted and received on August 5, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Fibrinogen Concentrate (Human) (RiaSTAP™) to provide results of Study BI3023_4003, a Phase IV post marketing required (PMR) study intended to verify clinical benefit of RiaSTAP™.

We approved BLA 125317/125 on September 9, 2016, under 21 CFR 601 Subpart E for Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses. Approval of this supplement fulfills the postmarketing requirements for PMR #1: Postmarketing Study Requirement Final Study Report BI3023_4003 made under 21 CFR 601.41:

FULFILLED ACCELERATED APPROVAL REQUIRED STUDIES

1. CSL Behring will conduct phase 4 study BI 3023_4003 to verify the clinical benefit by comparing the hemostatic efficacy of RiaSTAP™ to historical control. The completion dates are listed below:

   Final Protocol Submission: May 8, 2014
   Study/Trial Completion: December 31, 2017
   Final Report Submission: June 30, 2018

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT02427217.

LABELING

We hereby approve the draft content of labeling for the Package Insert submitted under amendment 9 dated June 4, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via 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 Package Insert submitted on May 12, 2021. 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* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125317/0 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes this change.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing requirement PMR #1 identified in the January 16, 2009 original approval letter for BLA STN BL 125317 and in the September 9, 2016 release from the accelerated approval postmarketing requirement and new accelerated approval postmarketing requirement letter for BL 125317/121 and BL 125317/125 for Fibrinogen Concentrate (Human). The requirement addressed in this submission is as follows:

1. CSL Behring will conduct phase 4 study BI 3023_4003 to verify the clinical benefit by comparing the hemostatic efficacy of RiaSTAP™ to historical control.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because the biological product for this indication has an orphan drug designation, you are exempt from this requirement.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research