Our STN: BL 125582/336

SUPPLEMENT APPROVAL
July 23, 2021

CSL Behring Lengnau AG
Attention: Matthew McCaslin
1020 First Avenue
PO Box 61501
King of Prussia, PA 19406

Dear Mr. McCaslin:

We have approved your request submitted January 22, 2021, received January 25, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Coagulation Factor IX (Recombinant), Albumin Fusion Protein, to update the United States Prescribing Information Section 6: ADVERSE REACTIONS and Section 14: CLINICAL STUDIES.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 6 dated July 23, 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 June 25, 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 125582 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)).

FDA Submissions in response to the Coronavirus Disease 2019 (COVID-19)

The Document Control Center (DCC) will not process any submissions received by mail or courier including submissions provided on paper and electronic media (e.g., CDs, USB drives) after Wednesday, April 29, 2020, until further notice. Submission previously submitted by mail can still be sent through the Electronic Submission Gateway (ESG) or in some cases by e-mail. CBER strongly encourages sending submissions (under 10GB) through FDA's preferred secure method of transmission, the ESG. Commercial applicants and sponsors should continue to submit in standard eCTD format using the ESG as described in guidance for industry, Providing Regulatory Submission in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.

For additional information see COVID-19 CBER Regulated Biologics, Letter to CBER Sponsors, Applicants and Regulated Entities on COVID-19.

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

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