Our STN: BL 125582/484

SUPPLEMENT APPROVAL
June 16, 2023

CSL Behring Lengnau AG
Attention: Harsh Patel
CSL Behring LLC
1020 First Avenue
P.O. Box 61501
King of Prussia, PA 19406

Dear Harsh Patel:

We have approved your request received December 16, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Coagulation Factor IX (Recombinant), Albumin Fusion Protein [IDELVION] to update its Prescribing Information to include information on previously untreated patients from study CSL654-3003 in Sections 5.1 Warnings and Precautions, 6 Adverse Reactions (6.1 Clinical Trials Experience, 6.2 Immunogenicity), and Patient-Directed Labeling.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 3, dated June 15, 2023.

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 15, 2023. 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)).

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,

Celia M. Witten, MD, PhD
Acting Director
Division of Clinical Evaluation Hematology
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research