Our STN: BL 125641/128

SUPPLEMENT APPROVAL
June 20, 2024

Laboratoire Francais du Fractionnement et des Biotechnologies S.A.
Attention: Lionel Murray, PhD
175 Crossing Boulevard
Framingam, MA 01702

Dear Dr. Murray:

We have approved your request received February 22, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for coagulation factor VIIa (recombinant)-jncw [SEVENFACT] to introduce a new 2 mg dosage strength of SEVENFACT drug product manufactured at the (b) (4) , and the co-packaged 3 mL sterile WFI pre-filled glass syringe manufactured at (b) (4) .

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 6, dated June 20, 2024; the draft container label submitted under amendment 1 dated March 7, 2024; and carton labels submitted under amendment 6 dated June 20, 2024

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 20, 2024. 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on June 20, 2024, according to the guidance for

industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125641 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the change approved today.

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

We acknowledge your written commitment as described in your correspondence of May 3, 2024, as outlined below:

1. LFB commits to place the (b) (4) commercial 2 mg dosage SEVENFACT batches manufactured at (b) (4) on routine stability, according to the protocol described in 3.2.P.8.2 POST-APPROVAL STABILITY PROTOCOL AND STABILITY COMMITMENT, and to perform on one of these batches in-use stability study over the shelf-life of the drug product. LFB commits to submit

stability data for this study as part of annual stability data in Annual Report submissions for SEVENFACT.

Final Report Submission: June 1, 2029

We request that you submit information concerning nonclinical and chemistry, manufacturing, and controls postmarketing commitments and final reports to your BLA, STN BL 125641. Please refer to the sequential number for each commitment.

Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Status Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing commitment not subject to the reporting requirements of 21 CFR 601.70, you may report the status to FDA as a **Postmarketing Study Commitment – Status Update**. The status report for each commitment should include:

- the sequential number for each study as shown in this letter;
- the submission number associated with this letter;
- a description of what has been accomplished to fulfill the non-section 506B PMC; and,
- a summary of any data collected or issues with fulfilling the non-section 506B PMC.

When you have fulfilled your commitment, submit your final report as **Postmarketing Commitment – Final Study Report** or **Supplement contains Postmarketing Commitment – Final Study Report**.

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

Sincerely,

Zuben Sauna, PhD
Director
Division of Hemostasis
Office of Plasma Protein Therapeutics
Office of Therapeutic Products
Center for Biologics Evaluation and Research