Our STN: BL 125641/67

SUPPLEMENT APPROVAL
PMR FULFILLED
November 22, 2022

Laboratoire Francais du Fractionnement
et des Biotechnologies S.A. (LFB S.A.)
Attention: Melissa Green
175 Crossing Boulevard
Framingham, MA 01702

Dear Ms. Green:

We have approved your request received May 25, 2022, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for coagulation factor VIIa (recombinant)-jncw to update Section 8.4, Pediatric Use, of the U.S. Prescribing Information in order to fulfill the Pediatric Research Equity Act (PREA) Post-Marketing Requirement.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment #3, dated November 17, 2022.

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 November 17, 2022. 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 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)).

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 April 1, 2020, approval letter for BLA STN BL 125641/0 for coagulation factor VIIa (recombinant)-jncw. The requirement addressed in this submission is as follows:

STN: BL 125641/0
PMR #1: Deferred pediatric study under PREA for “A phase III Study on the Safety, Pharmacokinetics, and Efficacy of Coagulation Factor VIIa (Recombinant) in Congenital Hemophilia A or B Patients from birth to <12 years old with Inhibitors to Factor VIII or IX.”

Final Protocol Submission: Completed

Completed Study Completion Date: Completed

Final Report Submission: July 10, 2020

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.

We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for this application.

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