



**MEMORANDUM**

**Date:** September 19, 2017

**From:** Marie J. Anderson  
Division of Biological Standards and Quality Control (DBSQC)  
Office of Compliance and Biologics Quality (OCBQ)  
Center for Biologics Evaluation and Research (CBER)  
Food and Drug Administration (FDA)

**To:** Biologics License Application Submission Tracking Number # 125641

**Subject:** Status of the CBER Laboratory Quality Product Testing Plan (TP) for Coagulation Factor VIIa (Recombinant)

**Through:** James Kenney, D.Sc., Acting Director DBSQC/OCBQ/CBER/FDA  
Suzanne Carter, Chief, QAB/DBSQC

**Cc:** Mikhail Ovanesov, PhD, Chair, BLA Review Chairperson, HB/DPPT/OTAT/CBER/FDA  
Mark Levi, PhD, RPM, RPMBII/DRPM/OTAT/CBER/FDA

**Applicant:** Laboratoire Francais du Fractionnement et des Biotechnologies S.A. (LFB S.A.)

**Product:** Coagulation Factor VIIa (Recombinant)

## **1 General Information**

### **1.1 CMC Review Identifiers and Dates**

**1.1.1 Biologics License Application (BLA) Submission Tracking Number (STN) #: 125641**

**1.1.2 Submission received by CBER:** October 13, 2016

**1.1.3 Review completed:** September 19, 2017

#### **1.1.4 Material Reviewed:**

BLA 125641

#### **1.1.5 Related Master File, INDs and BLAs:**

None reviewed

**2 Executive Summary:** The TP for Coagulation Factor VIIa (Recombinant) is in draft form as the BLA 125641 will be subject to a complete response letter.

## **3 Review**

### **3.1 Documents Written and Reviewed**

TP for Coagulation Factor VIIa (Recombinant)

### **3.2 Review**

The TP for BLA 125641 Coagulation Factor VIIa (Recombinant) is currently under review by DPPT and DBSQC reviewers. The review will continue upon response by the applicant to the complete response letter.

### **3.3 Conclusions**

The TP for BLA 125641 Coagulation Factor VIIa (Recombinant) is currently under review by DPPT and DBSQC reviewers. The review will continue upon response by the applicant to the complete response letter.