



FOOD AND DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

MEMORANDUM

To: File (STN BL 125506/0) & Pratibha Rana

From: Mikhail V. Ovanesov, PhD, Visiting Scientist, Laboratory of Hemostasis (LH), Division of Hematology Research and Review (DHRR)/OBRR

Through: Tim Lee, PhD, Acting Chief, LH/DHRR/OBRR

Subject: Classification of BPL's resubmission to BLA for Coagulation Factor X (Human)

1. Executive Summary

On 10 July 2013, Bio Products Laboratory Limited (BPL) submitted an original biologics license application (BLA) for Coagulation Factor X (Human). The FDA granted this product Orphan Drug status (No. 07-2469) on 8 November 2007, Fast Track designation on 12 April 2012, and Priority Review for this BLA on 6 September 2013.

During the first review cycle, the Chemistry, Manufacturing and Controls (CMC) team identified multiple deficiencies in the validations of the manufacturing process including those for cleaning and analytical methods. These deficiencies were also confirmed at the pre-license inspection (PLI) of the BPL facility conducted on 21-25 October of 2013, which were conveyed to BPL as observations in Form FDA 483. As a result, FDA also issued a complete response (CR) letter on 10 March 2014 delineating these deficiencies and the information required to address them.

On 27 April 2015, FDA received BPL's resubmission to BLA STN BL 125506/0. The resubmission contains additional CMC information as a response to the CR letter.

In accordance with SOPP 8405.1 Procedures for Resubmissions of an Application or Supplement, the CMC review team, which consists of Drs. Lokesh Bhattacharyya (OCBQ/DBSQC), Randa Melhem (OCBQ/DMPQ), Ze Peng (OBRR) and Mikhail Ovanesov (OBRR) conducted a cursory review of the resubmission to determine if the amendment constitutes a complete response to the CR letter and its classification. In addition, on 8 May 2015, CBER and BPL held a teleconference to discuss BPL's responses to the observations in the Form FDA 483 issued during the PLI.

Conclusion and recommendation: The CMC review team concludes that BPL's resubmission constitutes a complete, class 2 response to the CR letter, with a PDUFA goal date of 27 October 2015. The quality of the response will be evaluated during the review. Additional information will be requested from BPL to address the outstanding issues.