



Our STN: BL 125586/o

**MAJOR AMENDMENT  
ACKNOWLEDGEMENT**

December 22, 2017

Portola Pharmaceuticals, Inc.  
Attention: Janice Castillo  
270 East Grand Avenue South  
San Francisco, CA 94080

Dear Ms. Castillo:

We received your December 15, 2017 amendment #96 to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Coagulation Factor Xa (Recombinant), Inactivated on December 18, 2017.

We consider your submission a major amendment because your submission contains a substantial amount of new data not previously submitted to or reviewed by the Agency and will add an additional three months to the time by which we should complete our review. Therefore, the action due date is May 4, 2018.

We will contact you regarding your proposed labeling no later than April 4, 2018. If post marketing study commitments (506B) are required, we will contact you no later than April 4, 2018.

If you have any questions, please contact the Regulatory Project Manager, Jean Gildner, at (240) 402-8296.

Sincerely yours,

Ramani Sista, PhD  
Director  
Division of Regulatory Project Management  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research