

Our STN: BL 125586/0

RESUBMISSION ACKNOWLEDGEMENT
August 17, 2017

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

Dear Ms. Castillo:


We have received your August 3, 2017, resubmission to your biologics license application for Coagulation Factor Xa (Recombinant), Inactivated, on August 4, 2017.

The resubmission contains Chemistry, Manufacturing, and Controls (CMC), and Clinical information that you submitted in response to our August 17, 2016, Complete Response letter.

We consider this a complete, class 2 response to our action letter. Therefore, the user fee goal date is February 03, 2018.

If you have any questions, please contact me at (240) 402-8296 or Jean.Gildner@fda.hhs.gov.

Sincerely yours.

 Jean Gildner, MSHS, MT (ASCP)
Regulatory Project Manager
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research