

**From:** Maruna, Thomas  
**Sent:** Wednesday, March 02, 2016 9:30 AM  
**To:** 'Janice Castillo'  
**Cc:** Campbell, Karen M  
**Subject:** Request for Standards, Reagents and Samples for BLA 125586.0 - Please Submit by March 16. 2016

**Importance:** High

Portola Pharmaceuticals Inc.  
Attention: Ms. Janice Castillo  
March 2, 2016  
Sent by email

Dear Ms. Castillo:

We are reviewing your December 17, 2015 biologics license application (BLA) for the following:

<b>STN</b>	<b>Name of Biological Products</b>
125586/0	Coagulation Factor Xa (Recombinant), Inactivated

CBER requests that you provide the following standards, reagents and samples for testing in-support of your BLA submission (STN: 125586) as soon as possible, preferable within 2 weeks of receiving this request (i.e. March 16, 2016). If you are unable to do so, please let us know the date when you will be able to send us the requested materials.

A. Samples - Please provide (b) (4) vials each from (b) (4) lots of your drug product manufactured under full cGMP for in-support testing. If you do not have (b) (4) lots available, please notify CBER for additional information.

B. Reagents

(b) (4) [Redacted]  
(b) (4) [Redacted]  
[Redacted]  
[Redacted]

In addition, please provide,

- A. The quality control test results, if not already included in the BLA for each drug product lot being provided
- B. The assigned values for the reference standards requested if different from document QST-0025.

Ship reagents, standards, controls and drug product samples to the address listed below:

Mark Levi  
Center for Biological Evaluation and Research  
Division of Biological Standards and Quality Control  
10903 New Hampshire Avenue  
WO75, G-662  
Silver Spring, MD 20993-0002

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

The action due date for these files is August 17, 2016.

If you have any questions, please contact me.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH  
Lieutenant, U.S. Public Health Service  
Senior Regulatory Management Officer  
Food and Drug Administration  
Center for Biologics Evaluation and Research  
Office of Blood Research and Review  
10903 New Hampshire Ave.  
Silver Spring, MD 20993  
[thomas.maruna@fda.hhs.gov](mailto:thomas.maruna@fda.hhs.gov)  
O: (240) 402-8454  
[www.usphs.gov](http://www.usphs.gov)



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