

**From:** Maruna, Thomas  
**Sent:** Tuesday, May 03, 2016 2:17 PM  
**To:** 'Janice Castillo'  
**Subject:** Information Request - BLA 125586.0 - Please Respond by May 17. 2016

**Importance:** High

Portola Pharmaceuticals Inc.  
Attention: Ms. Janice Castillo  
March 21, 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 |

We determined that the following information is necessary to continue our review:

1. In the validation report No. VAL-30235-02, you scaled the viral clearance step for (b) (4) of the full scale. To support the evaluation of the qualification for the other (b) (4) viral removal steps, i.e., (b) (4) please provide the same information on the scale (b) (4) factor for these (b) (4) steps.
2. In the viral clearance studies on the steps of (b) (4) you used (b) (4) for each run for each virus (i.e., (b) (4)). Please specify the (b) (4) used in each run.

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

Please submit your responses as an amendment to this file by **May 17, 2016** referencing the date of this request.

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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