

From: Maruna, Thomas  
Sent: Tuesday, May 24, 2016 2:52 PM  
To: 'Janice Castillo'  
Subject: 24-May-2016 Information Request - BLA 125586.0 - Response  
Required  
by 24-June-2016

Importance: High

Portola Pharmaceuticals Inc.  
Attention: Ms. Janice Castillo  
May 24, 2016  
Sent by email

Dear Ms. Castillo:

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

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

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

We have reviewed the following quality assays for the (b) (4) drug product and their validation reports submitted under STN 125586/0, and the additional information you provided in 125586/0.32, and have the following Information Requests:

Direct and Indirect Potency Assays

1. What standard was used to determine the relative potency of Reference Standard, Lot (b) (4) How is the potency of the primary standard established? Please provide data demonstrating how the potency of the primary standard was established for both assays.

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

You are required to submit your responses as an amendment to this file by close-of-business, Friday, June 6, 2016.

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

If you have any questions, please contact me.

Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH  
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