

From: Maruna, Thomas
Sent: Monday, March 21, 2016 12:52 PM
To: 'Janice Castillo'
Subject: Information Request - BLA 125586.0 - Please Respond by March 23. 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:

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

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

CLINICAL – Please respond by close-of-business March 22, 2016

1. For the ongoing confirmatory study, 14-505, FDA has determined that the patient summaries are insufficient to adequately assess the safety of andexanet in bleeding patients. Please provide case report forms for each subject enrolled. In addition, please prove all available adjudication reports.

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 March 23, 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

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