

From: Maruna, Thomas
Sent: Friday, July 15, 2016 11:47 AM
To: 'Janice Castillo'
Cc: Campbell, Karen M; Wang, Hsiaoling; Ovanesov, Mikhail V.
Subject: 15-Jul-2016 Information Request (Reference Standards) - BLA 125586.0 - Response Due 22-July-2016

Importance: High

Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
July 15, 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 require the following information to be submitted to continue our review:

Standards and Quality Control

1. Please provide 3 vials of Andexanet Alfa Reference Standards ((b) (4)) used in your (b) (4) assay (TME-0474) and (b) (4) assay (TME-0584) and its certificate of analysis.

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 July 22, 2016.

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

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