

From: Maruna, Thomas
Sent: Monday, June 13, 2016 10:00 AM
To: 'Janice Castillo'
Cc: Ovanesov, Mikhail V.; Tobin, Grainne A.
Subject: 13-Jun-2016 Information Request - BLA 125586.0 - Response Required by 27-June-2016

Importance: High

Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
June 8, 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 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 125586/0.36, and have the following Information Request:

Direct and Indirect Potency Assays

1. With respect to your response received on June 7, 2016, we fail to see how the specificity data provides any information on the qualification of your standard. Since both assays are based on relative potency determinations, the data referred to in Table 4 of both documents you submitted gives information on the potency of the current standard relative to the previous standard. It is therefore imperative that you provide information on the qualification of your primary standard, Lot (b) (4), and how the potency value of this standard was established.

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 June 27, 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

Office of Blood Research and Review

10903 New Hampshire Ave.

Silver Spring, MD 20993

thomas.maruna@fda.hhs.gov

O: (240) 402-8454

www.usphs.gov



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