

From: Maruna, Thomas
Sent: Wednesday, June 01, 2016 1:51 PM
To: 'Janice Castillo'
Cc: Ovanesov, Mikhail V.; Bhattacharyya, Lokesh
Subject: 01-Jun-2016 Information Request (DBSQC) - BLA 125586.0 - Response Required by 15-June-2016

Importance: High

Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
June 1, 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 determined that the following information is necessary to continue our review:

1. We do not agree that your Moisture by (b) (4) method can be considered a compendial method for your product as the cited method, (b) (4), is not described in sufficient detail to allow replication and there is no monograph for your product in (b) (4). In addition to the data you provided in validation report VAL-60150-03 and in Amendment 33 (dated May 26, 2016), please provide accuracy data, as we requested in our previous IR dated 12 May 2016.

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 15, 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
Lieutenant, U.S. Public Health Service

Senior Regulatory Management Officer
FDA/CBER/OBRR/IO
thomas.maruna@fda.hhs.gov
Office: (240) 402-8454