

From: Maruna, Thomas
Sent: Tuesday, July 12, 2016 11:35 AM
To: 'Janice Castillo'
Cc: Harman, Christine; Ovanesov, Mikhail V.
Subject: 12-Jul-2016 Information Request - BLA 125586.0 - Response required by dates identified below

Importance: High

Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
July 12, 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:

CMC Facility (Response due no-later-than July 22, 2016)

1. Please provide non-conformance report 230315 (Local NCR) /994240 (Corporate PCR) in regards to an (b) (4) OOS result for In-process (b) (4) hold sample during manufacture of batch (b) (4). Additionally, please include more details as to why the (b) (4) method used was deemed inappropriate and where in the process the (b) (4) hold sample is taken for testing.

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

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