From: Maruna, Thomas
Sent: Tuesday, August 15, 2017 9:53 AM
To: 'Janice Castillo'; Dana Redhair (dredhair@Portola.com)
Cc: Chun, Haecin; McDowell, Erin; Cato, Dennis (Dennis.Cato@fda.hhs.gov); Gildner, Jean; Ovanesov, Mikhail V.
Subject: 15-Aug-2017 Information Request (BIMO) - BLA 125586.0 - Response
Due 29-Aug-2017

Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
August 15, 2017
Sent by email

Dear Ms. Castillo:

We are reviewing your August 4, 2017, biologics license application (BLA) resubmission 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:

1. The tabulation data in your resubmission indicates that study subjects were enrolled for Protocol 14-505 from various study sites. Portola did not identify the clinical investigators who were associated those study sites. Please provide a complete listing of all study site information for Protocol 14-505; each study site should be identified with the following information:

a. Clinical Investigator name
b. Address
c. Telephone number
d. Study site number/other unique site identifier

Please also include this information in the IND.

2. Please provide the financial disclosure information for all clinical investigators and their subinvestigators who participated in the conduct of Protocol 14-505.

Please submit your responses as an amendment to this file by August 29, 2017. If you are unable to provide responses by August 29th, please propose an alternative date.

The action due date for these files is February 2, 2018.

If you have any questions, please contact Ms. Jean Gildner (Jean.Gildner@fda.hhs.gov).

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH
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