From:	Kumar, Vasantha
To:	"jcastillo@Portola.com"
Cc:	Maruna, Thomas (Thomas.Maruna@fda.hhs.gov)
Subject:	FW: BLA 125586/0 Coagulation Factor Xa (Recombinant), Inactivated - Follow up to Information Request of April 6, 2016
Date:	Tuesday, July 05, 2016 10:24:00 AM
Importance:	High

Hi Ms. Castillo,

I am writing on behalf of Thomas Maruna.

This is regarding the stat information request that was originally sent to you on April 6, followed by a reminder by Ms. Cagungun on June 27 to provide a response to the information request by July 1, 2016. We still have not heard back from you. Could you please treat this as urgent and provide your response by the COB today.

Thanks
Vasantha

Vasantha Kumar, Ph.D.
U.S. Food & Drug Administration
CBER/OBRR
10903 New Hampshire Ave.
White Oak Building 71, Rm 4206
Silver Spring, MD 20993-0002
Phone: (240) 402-8413
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From: Janice Castillo [mailto:jcastillo@Portola.com]
Sent: Sunday, June 26, 2016 7:14 PM
To: Valencia, Iliana
Subject: RE: BLA 125586/0 Coagulation Factor Xa (Recombinant), Inactivated - Follow up to Information Request of April 6, 2016

Dear Iliana,

Unfortunately, I don't have a record of having received this request on 6 April. April was a very busy month for RFIs and perhaps this one was missed. We did provide responses regarding Dr Lam and termination report query on April 20th.
Portola will provide responses as soon as possible.

Janice

From: Valencia, Iliana [mailto:Iliana.Valencia@fda.hhs.gov]
Sent: Friday, June 24, 2016 2:26 PM
To: Janice Castillo
Subject: FW: BLA 125586/0 Coagulation Factor Xa (Recombinant), Inactivated - Follow up to Information Request of April 6, 2016

Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
June 24, 2016
Sent by email

Dear Ms. Castillo:

We are reviewing your December 17, 2015 biologics license application (BLA) for 125586/0 Coagulation Factor Xa (Recombinant), Inactivated. We are unable to find the response(s) to the request (attached for reference) in your submitted amendments. Could you please point us to its location? the sequence number will be most helpful. Please let us know as soon as possible.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

The action due date for this file is August 17, 2016.

Sincerely,

Iliana Valencia, MS, MCPM
Chief, Regulatory Project Management Staff
FDA/CBER/OBRR/IO 240-402-
8444
iliana.valencia@fda.hhs.gov

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