

From: Cagungun, Nannette
Sent: Monday, June 27, 2016 12:42 PM
To: Janice Castillo
Cc: Valencia, Iliana; Maruna, Thomas (Thomas.Maruna@fda.hhs.gov)
Subject: RE: BLA 125586/0 Coagulation Factor Xa (Recombinant),
Inactivated - Follow
up to Information Request of April 6, 2016

Dear Ms. Castillo:

Please refer to the email string below.

Please provide your response to our April 6, 2016 statistical information request by Friday, July 1, 2016.

Please contact me if you are not able to respond by this date or if you have any questions.

Sincerely,

Nannette Cagungun, MS, PD, RAC
Regulatory Project Manager
OBRR/CBER/FDA
10903 New Hampshire Ave
WO71-4258

Silver Spring, MD 20993-0002
Tel: (240) 402-8267
Fax: (301) 595-1128

Email: nannette.cagungun@fda.hhs.gov

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sender immediately by e-mail or phone.

From: Valencia, Iliana
Sent: Monday, June 27, 2016 8:25 AM
To: Janice Castillo
Cc: Cagungun, Nannette
Subject: RE: BLA 125586/0 Coagulation Factor Xa (Recombinant),
Inactivated - Follow up to Information
Request of April 6, 2016

Dear Ms. Castillo,
This email is to acknowledge receipt of your response.

Iliana

240.402.8444
Iliana.valencia@fda.hhs.gov

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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