
Valencia, Iliana

From: Valencia, Iliana
Sent: Friday, June 24, 2016 5:26 PM
To: jcastillo@portola.com
Subject: FW: BLA 125586/0 Coagulation Factor Xa (Recombinant), Inactivated - Follow up to Information Request of April 6, 2016
Attachments: BLA 125586 stat IR April 6.pdf
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

"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."

