

From: Maruna, Thomas
Sent: Thursday, February 25, 2016 10:57 AM
To: 'Janice Castillo'
Cc: Faulcon, Lisa; Mahmood, Iftexhar
Subject: Information Request - BLA 125586.0 - Please Respond by March 10. 2016

Importance: High

Portola Pharmaceuticals Inc.
Attention: Ms. Janice Castillo
February 25, 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 determined that the following information is necessary to continue our review:

1. Figure 2.7.2-4, page 29/49, of the *Summary of Clinical Pharmacology Studies* depicts andexanet's effect on anti-FXa activity for the various doses of each anticoagulant evaluated in study 12-502. However, the figures are difficult to interpret due to overlap of data points. To facilitate the review, for each anticoagulant (apixaban, rivaroxaban and edoxaban) please provide separate figures of each dose of andexanet studied, relative to the placebo.
2. For each anticoagulant and dose of andexanet studied in 12-502, please provide a summary of the magnitude and duration of the effect.

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

Please submit your responses as an amendment to this file by March 3, 2016 referencing the date of this request.

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

Senior Regulatory Management Officer

Food and Drug Administration

Center for Biologics Evaluation and Research

Office of Blood Research and Review

10903 New Hampshire Ave.

Silver Spring, MD 20993

thomas.maruna@fda.hhs.gov

O: (240) 402-8454

www.usphs.gov



"THIS MESSAGE, INCLUDING ANY ATTACHMENTS, 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.