

From: Cagungun, Nannette  
Sent: Monday, June 27, 2016 1:03 PM  
To: 'jcastillo@Portola.com'  
Subject: Labeling Information Request

Our Reference: BL 125586/0

Dear Ms. Castillo:

We are reviewing your December 17, 2015 biologics license application (BLA) for Coagulation Factor Xa (Recombinant), Inactivated, and have the following request for information:

1. Please submit an updated PI that includes your tradename and any relevant changes to the Indications and Usage, Description, Pharmacology and Clinical Trials sections.

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 response to this information request as an amendment to this file by July 8, 2016 referencing the date of this request. Please include both a red-line strike out and clean copy of the revised package insert in WORD format. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

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

If you have any questions, please contact me at (240) 402-8267 or LT Maruna at (240) 402-8454.

Sincerely,

Nannette Cagungun, MS, PD, RAC  
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