

From: Hooban, Christopher
Sent: Thursday, June 30, 2016 4:05 PM
To: jcastillo@portola.com
Subject: BLA 125586/0 - Information Request - Please Respond by July 11, 2016

We are reviewing your December 18, 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. Please provide summary data or report for the andexanet alfa (b) (4) shipping validation protocol VAL-80003-01.

2. Please provide summary data or report for the hold time study performed per Process Hold Time Study Protocol VAL-30234-01.

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 July 11, 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 Thomas Maruna.

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