From:	Janice Castillo
To:	Gildner, Jean
Cc:	Yana Zagorin
Subject:	RE: BLA 125586 Information Request
Date:	Wednesday, December 06, 2017 1:18:29 PM
Attachments:	image007.png

Receipt of email acknowledged.

Janice

Janice Castillo
Senior Vice President, Regulatory Affairs
Portola Pharmaceuticals, Inc.
South San Francisco, CA 94080
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email: jcastillo@portola.com

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Wednesday, December 06, 2017 9:58 AM
To: Janice Castillo
Subject: BLA 125586 Information Request

Dear Janice,

Please find the following information request. Please respond via email and as an amendment to the BLA by COB Friday, December 8th. Please acknowledge receipt of this email.

Please provide the following analyses to the FDA by COB Friday, December 6, for ANNEXA-4 (Study 14-505), based on the 108 efficacy evaluable subjects, in the most recent datasets with the cut-off date of April 20, 2017.

1. *A table of hemostatic efficacy by fXa inhibitor and primary bleed type. Please note that in the figures, each individual subject should have one line, rather than a single line of the median.*
2. *Figures for the time course of anti-fXa activity by fXa inhibitor and primary bleed type. Please note that in the figures, each individual subject should have one line, rather than a single line of the median. To be included in the figures, subjects should have data available for baseline, 5 minutes after bolus, end of infusion, and 4 hour assessment, but are allowed to have a missing measurement for the 8 hour and/or 12 hour assessments.*
3. *Same figures as above (item #2), but stratified by the hemostatic* ***efficacy categories: "excellent/good" or "poor/none".***

Sincerely, Jean

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