

From: [Janice Castillo](#)  
To: [Gildner, Jean](#)  
Subject: RE: BL125586 Information Request - Response today required and December 11, 2017  
Date: Friday, December 08, 2017 2:35:48 PM  
Attachments: [image007.png](#)

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Receipt of email acknowledged. Confirming with the team now about response for end of day today. I'll get back to you ASAP.

Janice

Janice Castillo  
Senior Vice President, Regulatory Affairs  
Portola Pharmaceuticals, Inc.  
South San Francisco, CA 94080  
Direct Tel: 650-246-7360  
Cell phone: 650-867-6984  
email: [jcastillo@portola.com](mailto:jcastillo@portola.com)

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From: Gildner, Jean [mailto:[Jean.Gildner@fda.hhs.gov](mailto:Jean.Gildner@fda.hhs.gov)]  
Sent: Friday, December 08, 2017 10:23 AM  
To: Janice Castillo  
Subject: BL125586 Information Request - Response today required and December 11, 2017

Dear Janice,

Please see the following information request. We are asking for a response by COB today for on item and mapping the data set no later than December 11 @ COB. Please acknowledge receipt and that you will provide the responses as requested.

**Response by COB today December 8:**

The location in the dataset for data captured in the CRF under Screening assessment Page 2, item 5, Indication for Factor X inhibitor

**Response by COB Monday December 11:**

The Annotated CRFs don't appear to be mapped to the dataset. Could you please map this no later than 12/11? If you have mapped it could you please attach a copy as an email via an attachment as soon as possible.

Sincerely, Jean

*Jean F. Gildner* MSHS, MT (ASCP)  
**Regulatory Project Manager**  
**Center for Biologics Evaluation and Research**

**Office of Tissues and Advanced Therapies**  
**U.S. Food and Drug Administration**

Tel: 240-402-8296

[jean.gildner@fda.hhs.gov](mailto:jean.gildner@fda.hhs.gov)



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