

**APPROVED**

**By Jean Gildner at 1:19 pm, Sep 06, 2017**

From: [Janice Castillo](mailto:Janice.Castillo@portola.com)  
To: [Gildner, Jean](mailto:Gildner.Jean@fda.hhs.gov)  
Subject: RE: Portola BLA 125586 - Andexxa Information Request  
Date: Wednesday, September 06, 2017 12:46:42 PM  
Attachments: [image001.png](#)

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Dear Jean,

I am acknowledging receipt of this email.

Sincerely,  
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]  
Sent: Wednesday, September 06, 2017 9:42 AM  
To: Janice Castillo  
Subject: Portola BLA 125586 - Andexxa Information Request

Dear Janice,

DBSQC Information Request for STN 125586/0.76

We have reviewed the following assay for drug product and their validation reports submitted under STN 125586/0.76 for the (b) (4) TFPI Inhibition Assay and have the following Information Request

- i. Please provide a representative copy of your SOP, TME-0632 (b) (4) (b) (4) TFPI Inhibition Assay

Please provide the SOP by 9/11/2017.

Please acknowledge receipt of this email.

Please let me know if you are unable to meet the turnaround time.

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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