

APPROVED

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

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

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

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/O.76

We have reviewed the following assay for drug product and their validation reports submitted under STN 125586/O.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



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

This email message is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. If you are the intended recipient, please be advised that the content of this message is subject to access, review and disclosure by the sender's Email System Administrator.