

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BLA125586 Information Request
Date: Thursday, December 28, 2017 2:48:34 PM
Attachments: [image007.png](#)

Receipt of email acknowledged.

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: Thursday, December 28, 2017 7:36 AM
To: Janice Castillo
Subject: BLA125586 Information Request

Dear Janice,

Please see the following information request. Please respond by January 22, 2018. Please let me know if you are not able to meet the deadline. Please acknowledge receipt of this email.

- 1. Regarding the Complete Response Letter, question 3b, please explain the steady increase in the (b) (4) by the (b) (4) which was observed in (b) (4) FDP Batch (b) (4) in real-time and accelerated stability studies. Specifically, please discuss the impact of these findings on the overall conclusions from ANDEXXA stability studies.**
- 2. Regarding the sections 1 and 2 of the document “3.2.R.2 Regional Info: Methods Validation Package”, please relocate the method validation reports for analytical procedures used in release testing andexanet alfa DS and Drug Product (DP) from section 3.2.R.2 to “Validation of Analytical Procedures” sections in 3.2.S.4.3, 3.2.P.4.3 and 3.2.P.5.3. For the methods that are validated for both the DS and DP, the method validation reports can be placed in one “Validation of Analytical Procedures” section, e.g., in 3.2.S.4.3, and referenced in the other, e.g., in 3.2.P.5.3. The existing methods validation document, “3.2.R.2 Regional Info: Methods Validation Package”, contained in section 3.2.R.2, will continue to serve as an overview of where the various**

methods and validation reports exist.

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.