

From: [Janice Castillo](#)  
To: [Gildner, Jean](#)  
Subject: RE: BLA 125586 Information Request  
Date: Tuesday, December 05, 2017 11:23:29 AM  
Attachments: [image007.png](#)

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Email received.

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: Tuesday, December 05, 2017 6:53 AM  
To: Janice Castillo  
Subject: BLA 125586 Information Request

Dear Janice,

Please see the following information request. Please respond December 18, 2017. Please acknowledge receipt of this email.

***With reference to your report entitled “(b) (4) Binding Interactions of  
(b) (4) of Andexanet Alfa” (# NC-17-0799-R0001), please provide (b) (4), potency assessment and other available analytical evidence to demonstrate the structural and functional degradation of the (b) (4) sample (b) (4).***

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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