

From: [Janice Castillo](#)  
To: [Gildner, Jean](#)  
Subject: RE: BL 125586/0 Information Request  
Date: Friday, September 15, 2017 4:03:01 PM  
Attachments: [image001.png](#)

**APPROVED**

**By Jean Gildner at 10:49 am, Sep 18, 2017**

I have received your email.

We will also reach out to our vendors and get back to you with a timeline.

Sincerely,  
Janice

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From: Gildner, Jean [mailto:[Jean.Gildner@fda.hhs.gov](mailto:Jean.Gildner@fda.hhs.gov)]  
Sent: Friday, September 15, 2017 12:18 PM  
To: Janice Castillo  
Subject: RE: BL 125586/0 Information Request

Dear Janice,

Please see the response from the requesting reviewer:

***For study 14-505, please submit an updated dataset "adsl" to add two variables: one to identify the subjects in the "complete efficacy population", and the other one to explain the reason of exclusion.***

Please acknowledge receipt of this response and if you have any additional questions please feel free to contact me.

Have a great weekend, 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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From: Janice Castillo [<mailto:jcastillo@Portola.com>]  
Sent: Friday, September 15, 2017 2:12 PM  
To: Gildner, Jean  
Subject: RE: BL 125586/0 Information Request

Dear Jean,

The andexanet team has reviewed the Agency's IR and has the following request for clarification. Portola doesn't have such a variable and requests further clarification/explanation as to what the Agency wants to see.

I look forward to your reply.

Kind Regards,  
Janice

Janice Castillo  
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email: [jcastillo@portola.com](mailto:jcastillo@portola.com)

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From: Gildner, Jean [<mailto:Jean.Gildner@fda.hhs.gov>]  
Sent: Friday, September 15, 2017 4:52 AM  
To: Janice Castillo  
Subject: BL 125586/0 Information Request

Dear Janice,

I have the following information request:

***There is no variable to flag the subjects in the "complete efficacy population" for study 14-505. Please provide this information.***

Please respond as soon as possible. If your response will take longer than a week please let me know.

Please acknowledge receipt of this email.

Sincerely, Jean

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