

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

From: Gildner, Jean [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



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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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Cell phone: 650-867-6984
email: jcastillo@portola.com

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
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Office of Tissues and Advanced Therapies
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