

From: [Janice Castillo](#)  
To: [Gildner, Jean](#)  
Subject: RE: BLA 125586 Information Request  
Date: Tuesday, February 06, 2018 4:55:57 AM  
Attachments: [image007.png](#)

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Confirming receipt of email.

Janice

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From: Gildner, Jean [mailto:[Jean.Gildner@fda.hhs.gov](mailto:Jean.Gildner@fda.hhs.gov)]  
Sent: Monday, February 05, 2018 4:49 PM  
To: Janice Castillo  
Subject: BLA 125586 Information Request

Dear Janice,

Please see the following information request. Please respond as soon as possible. Please acknowledge receipt of this email.

***For the ADLB dataset, particularly in relation to the anti-andexanet antibodies, the Applicant has included analysis values (AVALC) that is inputted as “not confirmed”. Could you please reference the location within the “Define” table, where the definition of “Not confirmed” is provided. Alternatively, could you please clarify the definition of “Not confirmed” for example, were samples were not obtained or insufficient for analysis?.***

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**  
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