

From: [Janice Castillo](#)  
To: [Gildner, Jean](#)  
Subject: RE: BLA 125586 Information Request  
Date: Monday, January 29, 2018 10:59:13 AM  
Attachments: [image007.png](#)

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IR received.

Janice

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From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]  
Sent: Monday, January 29, 2018 4:53 AM  
To: Janice Castillo  
Subject: BLA 125586 Information Request

Dear Janice,

Please see the following information request. Please acknowledge receipt of this request and the ability to meet the deadline of January 30, 2018.

**Of the 18 screen failures, 4 were related to the investigator's decision and 1 for other causes. Could you please provide the specific reasons that investigator's decided against enrolling a subject and for the 1 subjects who was not enrolled for "other" causes.**

If you have any questions please feel free to contact me.

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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