

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

IR received.

Janice

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
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