

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BLA 125586 Information Request
Date: Monday, March 26, 2018 10:14:12 AM
Attachments: [image007.png](#)

Good morning Jean,

Email received. I'll check with the team shortly regarding the response date and get back to you.
Janice

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Monday, March 26, 2018 4:46 AM
To: Janice Castillo
Subject: BLA 125586 Information Request

Dear Janice,

Please see the following information request. Please respond by COB Wednesday March 28, 2018.
Please acknowledge receipt of this email and the ability to meet the requested deadline.

The IR request pertains to the following subjects

Subj ID: (b) (6)

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***Please identify whether these subjects received the Gen 2 product or Gen 1 product.
Could Portola confirm that 70 subjects received the Gen 2 product as of approximately
3/24/18? I wasn't sure if the 70 subjects included subjects from another study...***

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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