

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BLA 125586 Information Request - clarification
Date: Wednesday, January 03, 2018 2:02:23 PM
Attachments: [image007.png](#)

Receipt Acknowledged.

Janice Castillo
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From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Wednesday, January 03, 2018 10:09 AM
To: Janice Castillo
Subject: BLA 125586 Information Request - clarification

Hi Janice,

Please see the clarification of our request from Sunday.

Please respond to each of the items listed in the IR from Sunday December 31, 2017, query with specific dates the data was submitted for the investigator assessed AES in the ADAE table. We are specifically asking for investigator assessed AES and irrespective of whether adjudication by the EAC is complete.

Please acknowledge receipt and if you have any additional questions please feel free to contact me.

Sincerely, Jean

Jean F. Gildner MSHS, MT (ASCP)
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