

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BLA 125586 Information Request
Date: Wednesday, January 03, 2018 3:29:41 PM
Attachments: [image007.png](#)

Receipt acknowledged.

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Wednesday, January 03, 2018 12:21 PM
To: Janice Castillo
Subject: BLA 125586 Information Request

Dear Janice,

A review of the submission from January 2, 2018, shows that Portola's submission from 12/1/17 does not include data (ADAE) for the six subjects listed. In addition, the request is to update all adverse events based on investigator assessment for the 185 subjects.

Submission of a text document or adjudication dossier does not satisfy the request to update the ADAE table, since the analysis tables (ADAE) in this case is used for our analysis. Missing data from the six subjects and investigator assessed AEs are not included in the ADAE dataset.

Therefore, providing an pdf document does not facilitate analysis that the clinical reviewer performs.

Therefore the request from 12/21 remains incomplete. Please provide the ADAE dataset as requested by **tomorrow 12 noon EST**.

Please acknowledge receipt of this email.

Sincerely, Jean

Jean F. Gildner MSHS, MT (ASCP)

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