

From: [Gildner, Jean](#)  
To: [Janice Castillo \(jcastillo@Portola.com\)](mailto:jcastillo@Portola.com)  
Subject: BLA 125586 Information Request  
Date: Thursday, December 21, 2017 9:24:57 PM  
Attachments: [image001.png](#)

---

Dear Janice,

Please see the following information request. Please respond to this request by 9am EST 12/22/17. If you are unable to respond to this deadline please let me know ASAP. Please acknowledge receipt of this email.

**1) Specifically respond to the request as to the reason for the discrepancy between the data table provided on 12/1/17 and the IR response from December 14th.**

**2) You state "In the ADAE dataset that was provided to the FDA in SN0083, detailed data were provided on 55 patients in ANNEXA-4. However, it should be noted that this dataset only contains information on patients enrolled on or before 29 May 2016. The updated dataset (SN0091) provides a list of adverse events that is concordant with the 185-patient data cut performed on 20 April 2017."**

**We note that the updated data set that you refer to above, relates to the Submission from 12/1/17. No updated ADAE datasets were provided in response (submitted on 12/21/17) to the IR request of 12/19/17. Per the ADSL dataset Subjects with the following ID- (b) (6)**

**(b) (6) were included in the 185 subjects (referenced in your response as excerpted above). These subjects (with Subject IDs provided to you) were noted in your December 14th, 2017 response, to have experienced a thrombotic event but not recorded in the ADAE dataset from 12.1.17. However your response from 12.21.17 to the IR request from December 19, does not include an updated ADAE dataset. Please provide updated ADAE data table with the data for all subjects in the ADSL who experienced any AE (Irrespective of EAC adjudication and based on investigator assessment) during the study follow up period.**

**3) Please provide source documents, including investigator's clinical notes related to the thrombotic events and any reports of imaging or other diagnostic tests performed to diagnose the thrombotic event(s) for the subjects noted in Item 2 above and for Subject (b) (6) .**

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)**





THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.