

From: [Gildner, Jean](#)  
To: [Janice Castillo \(jcastillo@Portola.com\)](mailto:jcastillo@Portola.com)  
Subject: BLA 125586 Portola - Advice  
Date: Tuesday, May 01, 2018 11:11:20 AM  
Attachments: [image001.png](#)

---

Dear Janice,

Please see the following advice from the FDA:

- 1) Please revise the milestone provided under the BLA on 26<sup>th</sup> April 2018 for the RCT protocol as follows:  
Submission of the Study Protocol: June 2018 to **Final Protocol Submission Date: April 17, 2018**
- 2) At this time the UCC and the ANNEXA 4 study are not under consideration as a PMR or PMC study. The RCT study is the only study under OTAT's consideration as a PMR. Please acknowledge.

Please acknowledge receipt of this email and please respond by COB (5pm EST) today that you are in agreement.

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.

