

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BLA125586 Portola Label
Date: Tuesday, May 01, 2018 8:20:26 PM
Attachments: [image013.png](#)
[image019.png](#)

Receipt of email acknowledged.

Janice

Janice Castillo
Senior Vice President, Regulatory Affairs
Portola Pharmaceuticals, Inc.
South San Francisco, CA 94080
Direct Tel: 650-246-7360
Cell phone: 650-867-6984
email: jcastillo@portola.com

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Tuesday, May 01, 2018 5:15 PM
To: Janice Castillo
Subject: RE: BLA125586 Portola Label

Dear Janice,

Please see the following comments from the Clinical reviewer:

The final protocol submission date of April 17, 2018 is based on the submission to the IND (and therefore not the BLA). So if the plan is to submit the final protocol submission date of April 17, 2018 under SN0135 of the BLA that is fine. Please include the dates for the rest of the milestones so the revised milestones should read as:

- **Final protocol submission date: April 17, 2018**
- First patient enrolled: January 31, 2019
- Completion Date of Patient Accrual: September 30, 2022
- Study Completion Date: October 31, 2022
- Date of Final Study Report Submission: April 30, 2023

Please acknowledge receipt of this email.

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



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From: Janice Castillo [<mailto:jcastillo@Portola.com>]
Sent: Tuesday, May 01, 2018 7:24 PM
To: Gildner, Jean <Jean.Gildner@fda.hhs.gov>
Subject: RE: BLA125586 Portola Label

Hi Jean,
Receipt acknowledged.

Also, can you please respond to my email question on the RCT milestone date.

Janice

From: Gildner, Jean [<mailto:Jean.Gildner@fda.hhs.gov>]
Sent: Tuesday, May 01, 2018 3:16 PM
To: Janice Castillo
Subject: BLA125586 Portola Label

Dear Janice,

Please see attached the final label. There are 3 comments for you. Please revise and send back via

email and as an amendment as soon as possible.
Please confirm receipt of this email.

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
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