

From: [Gildner, Jean](#)  
To: ["Janice Castillo"](#)  
Subject: RE: BLA 125586 Portola Label First round of edits - Excel spreadsheet attached.  
Date: Tuesday, April 03, 2018 1:07:14 PM  
Attachments: [To send to Portola - Subject IDs for FDA assessed TEE, isch events and death.xlsx](#)

---

Hi Janice,

Please see the excel spreadsheet that needs to be filled out as per instructions in a comment bubble associated with the label. Please acknowledge receipt of this email.

Thanks,  
Jean

---

**From:** Janice Castillo [mailto:jcastillo@Portola.com]  
**Sent:** Tuesday, April 03, 2018 12:44 PM  
**To:** Gildner, Jean <Jean.Gildner@fda.hhs.gov>  
**Subject:** Re: BLA 125586 Portola Label First round of edits

Draft label received.  
Janice

Sent from my iPhone

On Apr 3, 2018, at 9:36 AM, Gildner, Jean <[Jean.Gildner@fda.hhs.gov](mailto:Jean.Gildner@fda.hhs.gov)> wrote:

Hi Janice,

Can you acknowledge receipt of the label?

Thanks,  
Jean

---

**From:** Gildner, Jean  
**Sent:** Tuesday, April 03, 2018 7:50 AM  
**To:** Janice Castillo ([jcastillo@Portola.com](mailto:jcastillo@Portola.com)) <[jcastillo@Portola.com](mailto:jcastillo@Portola.com)>  
**Subject:** BLA 125586 Portola Label First round of edits

Dear Janice,

Please find attached the first round of edits from the FDA. Please provide your version of the label by Thursday April 4<sup>th</sup> at Noon EST. Please ensure that any comments from you are not anonymized so that we know it clearly from Portola (not specifically who they are just that it is an edit from you).

Please acknowledge receipt of this label and the ability to meet the requested deadline.

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)

[<image001.png>](#)

[<image002.jpg>](#) [<image003.jpg>](#) [<image004.jpg>](#) [<image005.jpg>](#)  
[<image006.jpg>](#)

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.

<BLA 125586\_20180403\_Label\_FDAV2.docx>

This email message is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original message. If you are the intended recipient, please be advised that the content of this message is subject to access, review and disclosure by the sender's Email System Administrator.

USUBJID

14-505 (b) (6)

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505

14-505