

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> 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) <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 4th 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

[<image001.png>](#)

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

[<image006.jpg>](#)

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<BLA 125586_20180403_Label_FDAV2.docx>

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