

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BLA 125586 Portola Information Request
Date: Thursday, November 02, 2017 9:54:01 AM
Attachments: [image001.png](#)

Information request received.

Janice

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Thursday, November 02, 2017 6:15 AM
To: Janice Castillo
Subject: BLA 125586 Portola Information Request

Dear Janice,

This IR is in reference to the safety dataset that was submitted October 17, 2017 to the file. Please provide dictionary derived terms, by body systems, high level terms, and organ classifications. Please provide this information by November 6, 2017. If you are not able to meeting this due date please let me know as soon as possible.

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



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.

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.