

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



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