

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BLA 125586 Information Request
Date: Thursday, December 07, 2017 1:46:57 PM
Attachments: [image007.png](#)

Receipt 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: Thursday, December 07, 2017 4:46 AM
To: Janice Castillo
Subject: BLA 125586 Information Request

Dear Janice,

Please see the following information request. Please respond as soon as possible not later than December 13, 2017. Please acknowledge receipt of this email.

- 1. In reference to the data included in validation report VAL-30238.02.01 for the (b) (4) [REDACTED] used for (b) (4) [REDACTED] and (b) (4) [REDACTED] processes (provided in IR response received as Amendment 80 Oct 6, 2017), please set an alert limit for (b) (4) [REDACTED] at (b) (4) [REDACTED].**

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.