

APPROVED

By Jean Gildner at 12:58 pm, Nov 17, 2017

From: [Janice Castillo](#)
To: [Gildner, Jean](#)
Subject: RE: BL125586 Portola Information Request
Date: Tuesday, November 14, 2017 12:21:37 PM
Attachments: [image001.png](#)

Jean,

I am confirming receipt of the email below. Thank you.

Janice

From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Tuesday, November 14, 2017 8:36 AM
To: Janice Castillo
Subject: BL125586 Portola Information Request

Dear Janice,

Please see the following information request. Please acknowledge receipt of this email.

We have received the MedRA coding file and it is currently under review. The submission asked the FDA if we would want a SAS file with the MedRA codes? The FDA would want the ADAM and SDTM tables updated with the MedRA codes. Please submit this by COB Thursday, November 16, 2017. This submission should be sent through Global Submit as updates to the existing ADAM and SDTM files. The last submission it appears that the files were placed in a separate location. When you place them as updates to the existing files, the Global Submit should report the precursor files as replaced files when the FDA double clicks on it. Please work with CBER data standards team to ensure that the updated files are correctly placed through the gateway.

If you have any questions please feel free to contact me.

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.