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Cc: [Riggins, Cindy](#); [narin.ahmed@novartis.com](#)
Subject: BL 125646 DMPQ Information Request
Date: Sunday, August 13, 2017 9:44:32 PM
Attachments: [image001.png](#)

Good evening,

Please see the information request below and provide a response by noon on August 18, 2017. Please submit the information directly in response to this e-mail and follow up by submitting the information as an official amendment to the BLA.

1. Please submit a copy of the unexecuted BMR for the manufacturing process at (b) (4) (commercial version BMR 1159-01)
2. Please submit a copy of the amended deviation GMP778 related to batch (b) (4) and associated BMR.
3. Please submit a copy of INV531-01 (disinfectants used in (b) (4) and INV-309 (clean hold time for cleaned production equipment at (b) (4)

Please confirm receipt of this request.

Thank you,

Erica Giordano

Regulatory Project Manager

Center for Biologics Evaluation and Research

Office of Tissues and Advanced Therapies

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