

From: [Riggins, Cindy](#)
To: [Giordano, Erica](#); [Patel, Manisha](#)
Cc: [Ahmed, Narin](#)
Subject: RE: BL 125646 DMPQ Information Request
Date: Monday, June 26, 2017 11:12:10 AM
Attachments: [image001.png](#)
Sensitivity: Confidential

Hi Erica,
Welcome back. We confirm receipt of this request.
Cindy

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Monday, June 26, 2017 10:09 AM
To: Patel, Manisha
Cc: Riggins, Cindy; Ahmed, Narin
Subject: BL 125646 DMPQ Information Request
Sensitivity: Confidential

Good morning,

Please see the information request below and provide a response by noon on July 3, 2017. As usual please provide a response directly to this e-mail and follow up by submitting the information as an amendment to the BLA.

For the CTL019 vector product operation at (b) (4) facility, please provide a copy of the approved media fill batch record (initiated in (b) (4)) and associated summary report with supporting data results.

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
U.S. Food and Drug Administration
Tel: 240-402-8298
Erica.Giordano@fda.hhs.gov



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