

From: [Riggins, Cindy](#)
To: [Giordano, Erica](#); [Patel, Manisha](#)
Cc: [Ahmed, Narin](#)
Subject: RE: BL 125646 CMC Information Request
Date: Wednesday, April 19, 2017 1:19:16 PM
Attachments: [image001.png](#)
[7008911_ANSW_MC_840_12.pdf](#)
[Appendix 1 - Vector_DS.CSV](#)
[Appendix 2 - Vector_DP.CSV](#)
Sensitivity: Confidential

Dear Erica,

Attached are the responses to the CMC information request received on April 17, 2017, from the previous February 24, 2017 request. There are two associated appendices for these responses in CSV format. We will follow up with a BLA amendment through the gateway of these documents.

Take care,

Cindy

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Monday, April 17, 2017 9:21 AM
To: Patel, Manisha
Cc: Riggins, Cindy; Ahmed, Narin
Subject: BL 125646 CMC Information Request
Sensitivity: Confidential

Good morning,

To facilitate the timely review and reduce the chance of miscalculations due to transcriptional error, please provide the data in sections 3.2.S.4.4 in an electronic format as originally requested on 02.24.2017. Please include the tables for both the vector DS and DP. Please provide this information by 4 pm on April 19, 2017.

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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