

**From:** [Riggins, Cindy](#)  
**To:** [Giordano, Erica](#); [Patel, Manisha](#)  
**Cc:** [Ahmed, Narin](#)  
**Subject:** RE: BL 125646 CMC Information Request  
**Date:** Monday, March 20, 2017 5:33:35 PM  
**Attachments:** [QbD1\\_5135B.PDF](#)  
**Sensitivity:** Confidential

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Thank you very much Erica – this helped me out a lot!

We did not provide document QbD1-5135B in the original BLA submission. However, it was provided as one of the attachments for the DMPQ Request for Information received on February 27, 2017. We provided these document to you via email last week on March 15, 2017 (all 71 documents!). QbD1\_5135B was provided in response to Question 6 and I'm attaching it here again for convenience. We are currently working on the gateway submission to the BLA for the March 15, 2017 responses and this document will be included as part of that submission.

Please let me know if you need further clarification.

Take care,  
Cindy

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**From:** Giordano, Erica [mailto:[Erica.Giordano@fda.hhs.gov](mailto:Erica.Giordano@fda.hhs.gov)]  
**Sent:** Monday, March 20, 2017 12:08 PM  
**To:** Riggins, Cindy; Patel, Manisha  
**Cc:** Ahmed, Narin  
**Subject:** RE: BL 125646 CMC Information Request  
**Sensitivity:** Confidential

Hi Cindy,

“QbD1\_5135B” is referenced in Module 3 (3.2.S.2.5 continued-process-verification-plan-cells: pages 6 and 17).

Erica

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**From:** Riggins, Cindy [mailto:[cindy.riggins@novartis.com](mailto:cindy.riggins@novartis.com)]  
**Sent:** Sunday, March 19, 2017 9:10 PM  
**To:** Giordano, Erica; Patel, Manisha  
**Cc:** Ahmed, Narin  
**Subject:** RE: BL 125646 CMC Information Request  
**Sensitivity:** Confidential

Dear Erica,

Can you please clarify in what document of the BLA we referenced QbD1\_5135B? This will help me to track down the location of the appendix.

Thank you!  
Cindy

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**From:** Giordano, Erica [mailto:[Erica.Giordano@fda.hhs.gov](mailto:Erica.Giordano@fda.hhs.gov)]  
**Sent:** Friday, March 17, 2017 6:01 PM

**To:** Patel, Manisha  
**Cc:** Riggins, Cindy; Ahmed, Narin  
**Subject:** BL 125646 CMC Information Request  
**Sensitivity:** Confidential

Good evening,

Please see the information request below and provide a response by noon on March 22, 2017.

You made reference to a study entitled “QbD1\_5135B, Process risk assessment (Drug product QbD1)” for evaluation of the manufacturing process and control for CTL019. We are unable to locate the study report in the BLA. Please let us know where exactly the study report is located in the BLA modules or provide a copy of the study report by March 22, 2017.

Please confirm receipt of this request.

*Thank you,*

**Erica Giordano**

*Regulatory Project Manager*

Center for Biologics Evaluation and Research

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