

**From:** [Riggins, Cindy](#)  
**To:** [Giordano, Erica](#); [Patel, Manisha](#)  
**Cc:** [Ahmed, Narin](#)  
**Subject:** RE: BL 125646 CMC Information Request  
**Date:** Thursday, April 13, 2017 12:15:03 PM  
**Attachments:** [image001.png](#)  
[7008911\\_ANSW\\_MC\\_840\\_9.pdf](#)  
**Sensitivity:** Confidential

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Dear Erica,

Attached are the responses to the vector information questions received on April 6, 2017. There are no associated appendices for these responses. We will follow up with a BLA amendment through the gateway of these documents.

Take care,  
Cindy

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**From:** Giordano, Erica [mailto:[Erica.Giordano@fda.hhs.gov](mailto:Erica.Giordano@fda.hhs.gov)]  
**Sent:** Thursday, April 06, 2017 9:14 AM  
**To:** Patel, Manisha  
**Cc:** Riggins, Cindy; Ahmed, Narin  
**Subject:** BL 125646 CMC Information Request  
**Sensitivity:** Confidential

Good morning,

Please see the information request below and provide a response by 4pm on April 13, 2017. Please e-mail your response directly to me and follow-up by submitting the information as an official amendment to the BLA.

Please provide more information on the processes and equipment used when (b) (4) and when freezing (b) (4) DP at (b) (4). Is there any control of the freezing rate? Have there been any validation studies of the (b) (4) DP freeze processes? Are QC retain samples frozen simultaneously with the (b) (4) DP, using the same freezers?

Vector section 3.2.S.2.2 (vector manufacturing process and controls), table 5-7, lists a (b) (4) but the use of (b) (4) is not described elsewhere. Please explain how (b) (4) is used.

Also in 3.2.S.2.2, step 13, it is mentioned that the (b) (4), but there is no mention of any (b) (4) limit in the process parameters in table 6-2, nor in the (b) (4) document PE-16-0001. Is there a specified maximum (b) (4), and what will trigger a decision to switch from the (b) (4) to the (b) (4)?

Please confirm receipt and let me know if you have any questions.

Thank you,

**Erica Giordano**

*Regulatory Project Manager*  
Center for Biologics Evaluation and Research  
Office of Tissues and Advanced Therapies  
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