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To: [Patel\\_Manisha \(manisha.patel@novartis.com\)](#)  
Cc: ["Riggins\\_Cindy"; narin.ahmed@novartis.com](#)  
Subject: BL 125646 CMC Information Request  
Date: Friday, July 28, 2017 8:31:16 AM  
Attachments: [image009.png](#)  
[image015.png](#)  
[image016.png](#)  
[image017.png](#)  
[image018.png](#)

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Good morning,

Please see the information request below and provide a response by 4 pm on July 31, 2017. As usual please respond directly to this e-mail and follow-up by providing the information as an official amendment to the BLA.

We have reviewed your recent supplemental validation studies (Amendment #32). We have following recommendations and comments.

1. In amendment #32 (serial#31) submitted on June 16, 2017, you have not revised any CPPs (b) (4) starting viable WBC, static culture viable WBC seeding number, and Positive selection starting viable WBC) that may be too broad. We recommend the following:

- a. The lower limit of (b) (4) may be more appropriate for the (b) (4) starting viable WBC to exclude the lower 3 terminated/rejected batches. See figure 2-7.

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- b. The lower limit of (b) (4) may be more appropriate for the static culture viable WBC seeding number to exclude the lower terminated batch. See figure 2-31

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- c. A tighter lower limit for the Positive selection starting viable WBC may be more appropriate. See figure 2-12.

(b) (4)

2. You provided the ranges process time based on historical ranges for CTL019 unit operations (Table 6-4).

(b) (4)

You classified the process time range as “historical ranges,” but not as CPPs. Please clarify if a deviation will be triggered if a unit operation exceeds a historical range of the process time limit.

Please confirm receipt of this request.

*Thank you,*

**Erica Giordano**

*Regulatory Project Manager*

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