

From: [Giordano, Erica](#)
To: [Patel, Manisha \(manisha.patel@novartis.com\)](#)
Cc: [Riggins, Cindy](#); [narin.ahmed@novartis.com](#)
Subject: BL 125646 CMC Information Request
Date: Thursday, July 06, 2017 10:22:18 AM
Attachments: [image001.png](#)

Good morning,

Please see the information requests below and provide a response by the time indicated in each request. As usual please respond directly to this e-mail and follow up by submitting the information as a formal amendment to the BLA.

Please provide the following information as follow up to the pre-license inspections at (b) (4)

1. The batch master records (BMR) at both facilities lacked adequate processing and hold time ranges for unit operations. In response to the 483 observations, the BMRs will be updated. Please submit the updated BMRs and a table detailing the changes (template below):

Facility	Target BMR update date	Please submit by:
(b) (4)	June 30, 2017	July 10,2017
(b) (4)	July 28, 2017	July 28, 2017

Template for BMR changes:

unit operation	CPP (Y/N)	lower limit	upper limit	directions for operator if limits are exceeded

2. Please provide the validation of the vector appearance testing by July 14, 2017 at 9 am.
3. During pre-license inspection, you indicated that you were developing the continued process verification (CPV) as part of the overall validation study for the vector manufacturing process. Please provide the continued process verification protocol for the vector manufacturing process by July 14, 2017 at 9 am.

Please confirm receipt of this request.

Thank you,

Erica Giordano

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