

**From:** [Riggins, Cindy](#)  
**To:** [Giordano, Erica](#); [Johnson, Joan \(CBER\)](#); [Ahmed, Narin](#); [Patel, Manisha](#)  
**Cc:** [Melhem, Randa](#)  
**Subject:** RE: Novartis BLA 125646/0 Request for Manufacturing Schedule for March through August  
**Date:** Thursday, February 23, 2017 4:35:43 PM  
**Attachments:** [7008911\\_ANSW\\_MC\\_840\\_1.docx](#)  
**Sensitivity:** Confidential

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Dear Erica and Joan,

Please find attached the response with the requested manufacturing schedules for Novartis Morris Plains, (b) (4), and (b) (4) (see response to Question 3 in this document).

Please note that this document includes the responses for all 3 requests received on February 15, 16, and 17, 2017. I have already sent the responses to Questions 1 and 2 to Erica by email and this document is intended to capture all three questions for submission to the BLA through the electronic gateway. Our submission through the gateway is targeted for Friday this week or Monday next week.

Take care,  
Cindy

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**From:** Giordano, Erica [mailto:[Erica.Giordano@fda.hhs.gov](mailto:Erica.Giordano@fda.hhs.gov)]  
**Sent:** Wednesday, February 22, 2017 2:08 PM  
**To:** Johnson, Joan (CBER); Riggins, Cindy; Ahmed, Narin; Patel, Manisha  
**Cc:** Melhem, Randa  
**Subject:** RE: Novartis BLA 125646/0 Request for Manufacturing Schedule for March through August  
**Sensitivity:** Confidential

Good afternoon,

I wanted to make sure you received the request below and confirm that you will be able to provide this information by noon on Friday February 24, 2017, if not sooner?

*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](mailto:Erica.Giordano@fda.hhs.gov)



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**From:** Johnson, Joan (CBER)  
**Sent:** Friday, February 17, 2017 11:14 AM  
**To:** Riggins, Cindy; Ahmed, Narin; Patel, Manisha  
**Cc:** Melhem, Randa; Giordano, Erica  
**Subject:** RE: Novartis BLA 125646/0 Request for Manufacturing Schedule for March through August

Good Morning All,

To coordinate with the pre-license inspection activities, please provide a detailed manufacturing schedule (with daily activities, process steps and locations) for the months from March to August for each of the following three facilities as soon as possible or by next Friday 2/24/17 the latest:

(b) (4)

Novartis Morris Plains, NJ facility

Once we receive the manufacturing schedule, the Lead inspectors will communicate directly with the facility contacts you provided on inspection related activities.

Thank you,  
Joan

**Joan Johnson**

*Consumer Safety Officer*

**Center for Biologics Evaluation and Research**  
**Office of Compliance and Biologics Quality**  
**U.S. Food and Drug Administration**  
Tel: 240-402-7392  
[joan.johnson1@fda.hhs.gov](mailto:joan.johnson1@fda.hhs.gov)

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