

**From:** [Riggins, Cindy](#)  
**To:** [Giordano, Erica](#)  
**Cc:** [Patel, Manisha](#); [Ahmed, Narin](#)  
**Subject:** RE: BL 125646/0 Site Information Needed  
**Date:** Thursday, February 16, 2017 4:43:16 PM  
**Attachments:** [7008194\\_ANSW\\_MC\\_840\\_1\\_final.docx](#)  
**Sensitivity:** Confidential

---

Dear Erica,

Please find our response to the request for site contact information. We will follow up with an electronic gateway submission of this document to the BLA.

Take care,  
Cindy

---

**From:** Giordano, Erica [mailto:[Erica.Giordano@fda.hhs.gov](mailto:Erica.Giordano@fda.hhs.gov)]  
**Sent:** Thursday, February 16, 2017 2:09 PM  
**To:** Patel, Manisha  
**Cc:** Riggins, Cindy  
**Subject:** RE: BL 125646/0 Site Information Needed  
**Sensitivity:** Confidential

Please let me know when you plan to send this information.

Thanks  
Erica

---

**From:** Patel, Manisha [mailto:[manisha.patel@novartis.com](mailto:manisha.patel@novartis.com)]  
**Sent:** Wednesday, February 15, 2017 11:18 AM  
**To:** Giordano, Erica  
**Cc:** Riggins, Cindy  
**Subject:** RE: BL 125646/0 Site Information Needed  
**Sensitivity:** Confidential

Dear Erica,

Novartis acknowledges receipt of your email, and will provide the information requested.

Kind regards,  
Manisha

---

**From:** Giordano, Erica [mailto:[Erica.Giordano@fda.hhs.gov](mailto:Erica.Giordano@fda.hhs.gov)]  
**Sent:** Wednesday, February 15, 2017 10:54 AM  
**To:** Patel, Manisha  
**Subject:** BL 125646/0 Site Information Needed  
**Sensitivity:** Confidential

Good afternoon,

Please provide the contact information (including title, phone number, and email address ) for the personnel currently responsible for regulatory inspections and US FDA compliance at the

following sites:

(b) (4)

Novartis Morris Plains, NJ facility

*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)



"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."