

From: [Riggins, Cindy](#)
To: [Giordano, Erica](#)
Cc: [Patel, Manisha](#); [Ahmed, Narin](#)
Subject: RE: BL 125646/0 Site Information Needed
Date: Friday, February 17, 2017 2:57:02 PM
Sensitivity: Confidential

Hi Erica,

We just received the FEI number for Novartis Morris Plains today.
FEI: 3010353512

I plan to provide this number in the BLA in the next 356h form we submit through the gateway, would that be acceptable? We are still following up with the number for (b) (4)

Take care,
Cindy

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Thursday, February 16, 2017 7:43 PM
To: Riggins, Cindy
Cc: Patel, Manisha; Ahmed, Narin
Subject: RE: BL 125646/0 Site Information Needed
Sensitivity: Confidential

Thank you for providing this information.

Review of the Novartis Morris Plains (NJ, USA) inspection referenced FEI number 999999999. Please provide an update of the FEI for the facility below:

Novartis Morris Plains Facility
220 East Hanover Ave
Morris Plains, NJ 07950

Thank you,
Erica Giordano
Regulatory Project Manager

From: Riggins, Cindy [mailto:cindy.riggins@novartis.com]
Sent: Thursday, February 16, 2017 4:42 PM
To: Giordano, Erica
Cc: Patel, Manisha; Ahmed, Narin
Subject: RE: BL 125646/0 Site Information Needed
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>]
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>]
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>]
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

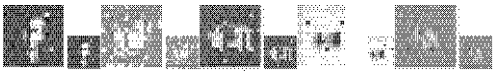
Thank you,

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





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