

From: [Patel, Manisha](#)
To: [Giordano, Erica](#)
Cc: [Riggins, Cindy](#); [Ahmed, Narin](#); [Azevedo Santos, Joana](#)
Subject: RE: BL 125646 Clinical Information Request
Date: Wednesday, April 26, 2017 12:40:33 PM
Attachments: [image001.png](#)
[response-fda.pdf](#)
Sensitivity: Confidential

Dear Erica,

Please find attached a response to the below request for information. I will submit an archival copy through the gateway.

Kind regards,
Manisha

From: Giordano, Erica
Sent: Friday, April 21, 2017 9:51 AM
To: 'Patel, Manisha'
Cc: Riggins, Cindy; Ahmed, Narin
Subject: RE: BL 125646 Clinical Information Request
Sensitivity: Confidential

Thank you Manisha.

Yes, all of these subjects are on study B2202.

Thanks
Erica

From: Patel, Manisha [<mailto:manisha.patel@novartis.com>]
Sent: Friday, April 21, 2017 9:30 AM
To: Giordano, Erica
Cc: Riggins, Cindy; Ahmed, Narin
Subject: RE: BL 125646 Clinical Information Request
Sensitivity: Confidential

Dear Erica,

I acknowledge receipt of this request. Are all of these subjects on study B2202?


Kind regards,
Manisha

From: Giordano, Erica [<mailto:Erica.Giordano@fda.hhs.gov>]
Sent: Friday, April 21, 2017 9:29 AM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: BL 125646 Clinical Information Request
Sensitivity: Confidential

Good morning,

Please provide the manufacturing site for the following subjects:

(b) (6)



If product was not produced, please provide an explanation. Please provide this information by noon on April 26, 2017.

Please confirm receipt of this request.

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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