

**From:** [Patel, Manisha](#)  
**To:** [Giordano, Erica](#)  
**Cc:** [Riggins, Cindy](#); [Ahmed, Narin](#)  
**Subject:** RE: BL 125646 Clinical Information Request  
**Date:** Wednesday, May 10, 2017 11:51:17 AM  
**Attachments:** [image001.png](#)  
[response-fda.pdf](#)  
[Appendix 1.xlsx](#)  
[Appendix 2.xlsx](#)  
[Appendix 3.pdf](#)  
[Appendix 4.pdf](#)  
**Sensitivity:** Confidential

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Dear Erica,

Please find attached a response to the below information request. A copy of the response will be submitted through the gateway.

Kind regards,  
Manisha

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**From:** Giordano, Erica [mailto:[Erica.Giordano@fda.hhs.gov](mailto:Erica.Giordano@fda.hhs.gov)]  
**Sent:** Friday, May 05, 2017 12:04 PM  
**To:** Patel, Manisha <[manisha.patel@novartis.com](mailto:manisha.patel@novartis.com)>  
**Cc:** Riggins, Cindy <[cindy.riggins@novartis.com](mailto:cindy.riggins@novartis.com)>; Ahmed, Narin <[narin.ahmed@novartis.com](mailto:narin.ahmed@novartis.com)>  
**Subject:** BL 125646 Clinical Information Request  
**Sensitivity:** Confidential

Good afternoon,

Please see the information request below and provide feedback by noon on May 10, 2017.

In your CRF, you document that you have collected pharmacokinetic data for tocilizumab and siltuximab. Please tell me where these datasets and analysis are located in the BLA.

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



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