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

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

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Friday, May 05, 2017 12:04 PM
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 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

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