

From: [Ahmed, Narin](#)
To: [Giordano, Erica](#); [Patel, Manisha](#)
Cc: [Riggins, Cindy](#)
Subject: RE: BL 125646 Information Request
Date: Tuesday, August 22, 2017 12:38:53 AM
Sensitivity: Confidential

Hi Erica,

I confirm receipt.

Best regards,
Narin

Narin Ahmed (Hussain), Pharm.D.
Sr. Associate Director, Regulatory Affairs

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From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Monday, August 21, 2017 3:42 PM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: BL 125646 Information Request
Sensitivity: Confidential

Good afternoon,

Please see the information request below and provide a response by noon tomorrow, August 22, 2017 with your response to the revised PMR. Please submit this information directly in response to this e-mail and follow up by submitting the information as an amendment to the BLA.

With the updated protocol submission for B2401, the PMR registry, submit the final protocol submission date, the study completion date, and final report submission date with both a month and year.

Please confirm receipt.

Thanks
Erica