

From: [Patel, Manisha](#)
To: [Giordano, Erica](#)
Cc: [Riggins, Cindy](#); [Ahmed, Narin](#)
Subject: RE: BL 125646 Clinical Information Request
Date: Tuesday, May 09, 2017 10:00:32 AM
Attachments: [image001.png](#)
Sensitivity: Confidential

Hi Erica, below is the list of patients who manufactured at Fraunhofer (Germany) and included in the safety set:

CCTL019B2202_ (b) (6)
CCTL019B2202_
CCTL019B2202_
CCTL019B2202_
CCTL019B2202_

Kind regards,
Manisha

From: Patel, Manisha
Sent: Tuesday, May 09, 2017 9:51 AM
To: 'Erica.Giordano@fda.hhs.gov' <Erica.Giordano@fda.hhs.gov>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: RE: BL 125646 Clinical Information Request
Sensitivity: Confidential

Hi Erica, I confirm receipt of this request.

Kind regards,
Manisha

From: Giordano, Erica [<mailto:Erica.Giordano@fda.hhs.gov>]
Sent: Tuesday, May 09, 2017 9:49 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 see the information request below and provide a response as soon as possible, ideally by COB today.

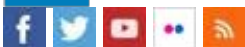
Please provide the UPN numbers for the 5 subjects manufactured in Germany who are in the Safety Data set for 2202 and not the EAS updated efficacy pool.

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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