From:	Patel, Manisha
To:	Giordano, Erica
Cc:	Riggins, Cindy; Ahmed, Narin
Subject:	RE: BL 125646 Information Request
Date:	Wednesday, July 26, 2017 1:45:10 PM
Attachments:	image001.png
Sensitivity:	Confidential

Thanks for clarifying.

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Wednesday, July 26, 2017 12:42 PM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>
Subject: RE: BL 125646 Information Request
Sensitivity: Confidential

Hi Manisha,

The Medication Guide in general is not compliant. For more information, see the guidance listed.

I hope this helps,
Erica

From: Patel, Manisha [mailto:manisha.patel@novartis.com]
Sent: Wednesday, July 26, 2017 12:31 PM
To: Giordano, Erica
Cc: Riggins, Cindy; Ahmed, Narin
Subject: RE: BL 125646 Information Request
Sensitivity: Confidential

Hi Erica, I confirm receipt of this request.

Regarding bullet 1, can you clarify if there are specific requirements of 21 CFR 208.20 which FDA believes the proposed medication guide does not meet? Or, are requests 2, 3, and 4 intended to be sub-bullets of bullet 1?

Kind regards,
Manisha

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Wednesday, July 26, 2017 12:18 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 4 pm on July 28, 2017. As usual please respond directly to this e-mail and follow-up by submitting the information as an amendment to the BLA.

The Medication Guide is a strictly formatted document with required regulatory language. We have the following comments on the proposed Medication Guide:

1. Revise the proposed Medication Guide to be consistent with the requirements of 21 CFR 208.20. For additional information, see "Guidance: Medication Guides — Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS)" at https://www.fda.gov/downloads/Drugs/.../Guidances/UCM244570.pdf

2. To enhance readability, use active voice and plain language in the revised Medication Guide.

3. Cross-referencing within the Medication Guide is discouraged as it reduces the readability and comprehension. Delete internal cross-references except as indicated in the Guidance listed above.

4. Throughout the Medication Guide, the terms "white blood cells" and "immune cells" are used interchangeably. For consistency and clarity, use one term to describe the cells.

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