From:	Patel, Manisha
To:	Giordano, Erica
Cc:	Riggins, Cindy; Ahmed, Narin; Redd, Naomi; Auth, Doris; LaCivita, Cynthia
Subject:	RE: BL 125646 DRISK Information Request
Date:	Tuesday, May 09, 2017 11:23:14 AM
Attachments:	image001.png response-fda.pdf Appendix_1.pdf Appendix_2.pdf Appendix 3.pdf
Sensitivity:	Confidential

Dear Erica,

Please find attached a response to the information request in the email below.

A copy of the response will also be submitted through the gateway.

Kind regards,
Manisha

From: Giordano, Erica [mailto:Erica.Giordano@fda.hhs.gov]
Sent: Tuesday, May 02, 2017 11:04 AM
To: Patel, Manisha <manisha.patel@novartis.com>
Cc: Riggins, Cindy <cindy.riggins@novartis.com>; Ahmed, Narin <narin.ahmed@novartis.com>; Redd, Naomi <Naomi.Redd@fda.hhs.gov>; Auth, Doris <Doris.Auth@fda.hhs.gov>; LaCivita, Cynthia <Cynthia.LaCivita@fda.hhs.gov>
Subject: BL 125646 DRISK Information Request
Sensitivity: Confidential

Good afternoon,

Please see the information request below and provide the requested information by noon on May 9, 2017. As usual please provide the information in response to this e-mail and follow up by submitting the information as an official amendment to the BLA.

In your IND and on page 16 of the proposed pharmacovigilance plan you state that you will train and certify hospitals to be able to prescribe and administer tisagenlecleucel:
Treatment site training:

- Novartis will train and certify hospitals to be able to prescribe and administer tisagenlecleucel-T
- Novartis will accept product request/orders only from certified sites and prescribers
- Novartis will certify only a limited number of sites
- Novartis will train on the FDA approved USPI with particular focus on:
    - Appropriate patients as per FDA approved indication
    - Safety management (CRS, neurological and psychiatric events and other AEs)
    - Process and patient management

- Chain of identity
- REMS

It is unclear if the training that you refer to in the IND are the same materials submitted with your proposed REMS. In order to evaluate and better understand what training was provided in the IND, submit the IND training and certification materials for prescribers and hospitals.

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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