

**From:** [Giordano, Erica](#)  
**To:** [Patel, Manisha \(manisha.patel@novartis.com\)](#)  
**Cc:** ["Riggins, Cindy"; narin.ahmed@novartis.com](#)  
**Subject:** BL 125646 Clinical Information Request  
**Date:** Friday, June 09, 2017 9:19:57 AM  
**Attachments:** [image001.png](#)

---

Good morning,

Please see the information request below and provide a response by COB today, June 9, 2017.

For the 16 enrolled subjects who did not receive tisagenlecleucel – please provide the UPN numbers and your reason for discontinuation. Please include other AEs that may have occurred during the same interval particularly for the manufacturing failures.

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](mailto:Erica.Giordano@fda.hhs.gov)



"THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone."