

**From:** [Giordano, Erica](#)  
**To:** [Patel, Manisha \(manisha.patel@novartis.com\)](#)  
**Cc:** "Riggins, Cindy"; [narin.ahmed@novartis.com](#)  
**Subject:** BL 125646 Clinical Information Request  
**Date:** Monday, August 07, 2017 8:12:01 PM  
**Attachments:** [image001.png](#)

---

Good evening,

Please see the information request below and provide a response by noon on August 8, 2017. As usual please provide this information directly to this e-mail and follow-up by submitting the information as an official amendment to the BLA.

1. Please provide information on all subjects intubated for CRS to include Subject ID number, duration, median and mean time of intubation, study start date and study end date for intubations
2. Please clarify if (b) (6) was intubated and if so when and for how long

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."