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**Subject:** BL 125646 Clinical Information Request  
**Date:** Thursday, June 01, 2017 1:16:19 PM  
**Attachments:** [image001.png](#)

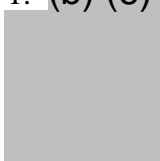
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Good afternoon,

Please see the information request below and provide a response by COB on June 2, 2017 and follow-up by submitting the information as an official amendment to the BLA.

Please provide the IRC overall assessment used for the efficacy analysis for the following subjects:

1. (b) (6)



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

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