

**APPROVED**

By Jean Gildner at 2:37 pm, Dec 12, 2016

**From:** [Lorien Armour](#)  
**To:** [Gildner, Jean](#)  
**Cc:** [Margarita Aguilera](#)  
**Subject:** FW: BLA125603 IR for (b) (4)  
**Date:** Monday, October 17, 2016 2:40:44 PM  
**Attachments:** [Attachment 2 GTR-168-03-01-A-2.pdf](#)

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Dear Jean,

In response to the request below, I am providing Attachment 2 to validation report GTR-168-03-01-A. Due to the very large file size of Attachment 1 (96MB), I am unable to send it via email. A BLA amendment is being submitted tomorrow (Tue 10/18), which will include a replacement GTR-168-03-01-A with both of these attachments.

Kind Regards,

Lorien Armour, RAC  
CMC Regulatory Consultant  
Vericel Corporation  
Office: 919-450-0802  
Fax: 734-239-7401

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**From:** Gildner, Jean [<mailto:Jean.Gildner@fda.hhs.gov>]  
**Sent:** Thursday, October 13, 2016 3:12 PM  
**To:** Margarita Aguilera  
**Subject:** BLA125603 IR for (b) (4)

Dear Margarita,

Please find the following information request regarding the (b) (4) Validation. Please send a response by COB, Monday October 17, 2016. If you have a problem meeting this timeframe please let me know ASAP.

***Information Request for MACI (STN 125603/0) Regarding Vericel's Response received on 11 October, 2016 for Sterility using (b) (4) Validation testing***

***Please provide attachments #1 and #2 for your validation report (GTR-168-03-01-A), which contain MACI batch production records for sample configuration and challenge strain inoculum preparation records for confirmatory (b) (4), respectively.***

Please acknowledge receipt of this email.

Sincerely, Jean

*Jean F. Gildner* MSHS, MT (ASCP), CQA (ASQ)

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