

**APPROVED**

**By Jean Gildner at 11:45 am, Aug 18, 2016**

**From:** [Kenney, James](#)  
**To:** [Gildner, Jean](#)  
**Cc:** [Thomas, John](#); [McCormick, William](#); [Kong, Hyesuk](#); [Kaur, Simleen](#); [Campbell, Karen M](#)  
**Subject:** IR for MACI - BLA 125603/0; IR response reply for (b) (4) Validaiton  
**Date:** Wednesday, June 29, 2016 1:02:01 PM  
**Attachments:** [201606229\\_STN 125603 2ed Information Request for \(b\) \(4\) \\_method.doc](#)  
**Importance:** High

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Dear Jean,

Attached is the IR response reply for Vericel regarding the validation of their (b) (4) as an alternate sterility test method.

I added the last paragraph to document Vericel's verbal commitment during today's external midcycle meeting to send the FDA a list of their current known environmental microorganisms from their Cambridge facility to determine which should be included in the requested validation.

As stated during this meeting – I promised them this IR response by COB today, so the prompt processing of this request would be greatly appreciated. With that said, Terrig and I determined it was a miscommunication between us as to why Vericel did not have this information to read over before today's meeting.

Please let me know if you have any questions or concerns regarding this request.

Best regards,

**James L. Kenney, D.Sc.**

Commander, [USPHS](#), Regulatory Review Officer  
Chief, Laboratory of Microbiology, *In-vivo* Testing and Standards

[Division of Biological Standards & Quality Control](#)

[Office of Compliance & Biologics Quality](#)

[Center for Biologics Evaluation & Research](#)

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