

APPROVED

By Jean Gildner at 2:57 pm, Jul 19, 2016

From: [Kenney, James](#)
To: [Gildner, Jean](#)
Cc: [Kong, Hyesuk](#); [Kaur, Simleen](#); [Thomas, John](#)
Subject: BLA: 125603 IR Regarding the (b) (4) LOD Study
Date: Thursday, July 14, 2016 10:48:24 AM
Attachments: [STN 125603 Information Request for \(b\) \(4\) .method-EM selection.doc](#)
Importance: High

Dear Jean,

Thank you for Bccing me on the initial IR to Vericel on 29 June at 10:17 AM. Hyesuk was looking in the BLA's file for this communication and was not sure it was sent to the sponsor, as we did not receive a list of their environmental microorganisms as requested.

In lieu of not receiving the list of the sponsors known environmental microorganisms, we found them and formulated the attached follow-up IR for you to send to Vericel.

Please let me know if you have any questions regarding this follow-up IR. In addition, please remember to post this and the previous IR to the file.

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](#)

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