

APPROVED

By Patrick S. Riggins at 2:59 pm, Jul 14, 2016

From: [Lorien Armour](#)
To: [Gildner, Jean](#)
Cc: [Riggins, Patrick](#); [Margarita Aguilera](#)
Subject: Vericel MACI BL 125603 - Information for Carolyn Yong Membrane (b) (4) Test
Date: Thursday, July 14, 2016 12:49:30 PM
Attachments: [ACI-Maix Membrane \(b\) \(4\) Testing Update and Proposal.pdf](#)

Dear Jean,

During the inspection and our recent teleconference with FDA on June 29, 2016, reviewer Carolyn Yong welcomed interactions regarding the ACI-Maix membrane and suggested we initiate those through you. Regarding the (b) (4) testing for the membrane, I have attached an update and proposal that I would appreciate be forwarded to Carolyn, along with this email.

Dear Carolyn,

As discussed during the June 29, 2016 teleconference, Vericel and Matricel are working together regarding an appropriate and validated method for (b) (4) testing of the ACI-Maix membrane. I have attached the current proposal and would appreciate your agreement or feedback to ensure we are aligned prior to beginning the proposed work. We welcome feedback via email, or we can be available for a teleconference if you feel a discussion is appropriate (with Vericel and Matricel in Germany).

We anticipate the proposed new methodology would be a post-approval change and, as stated in the proposal, the commitments Vericel made in our 483 response (dated June 6, 2016) regarding the current (b) (4) test methodology and acceptance criteria remain unchanged.

Kind Regards,

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