

APPROVED

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

From: [Lorien Armour](#)
To: [Moos, Malcolm](#)
Cc: [Margarita Aguilera](#); [John Duguid](#); [Riggins, Patrick](#); [Gildner, Jean](#)
Subject: Follow up to June 17th Teleconference MACI BL 125603
Date: Friday, June 17, 2016 6:03:24 PM
Attachments: [MACI BLA 125603 Response from March 9 telecon.pdf](#)

Dear Malcolm,

We appreciate the time you took this afternoon to address outstanding questions/comments you had regarding the comparability protocol in 3.2.R as well as (b) (4), which was previously discussed during a March 9th teleconference.

As agreed, Vericel will formally withdraw 3.2.R Comparability Protocol from the BLA next week.

The attached document is the response follow up we sent via email to FDA regarding outstanding questions from the March 9th teleconference, which discusses (b) (4). Please do not hesitate to contact us if this response does not answer your question. As agreed, Vericel will include this response in a formal amendment to the BLA.

Kind Regards,

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