

APPROVED

By Jean Gildner at 2:57 pm, Dec 12, 2016

From: [Lorien Armour](#)
To: [Yong, Carolyn](#)
Cc: [Margarita Aguilera](#); [Gildner, Jean](#); [Riggins, Patrick](#)
Subject: MACI BL125603 - Follow up 483 Response for Observation 3 (Design Controls)
Date: Thursday, August 18, 2016 7:18:50 PM
Attachments: [Follow up Response Obs 3 Form 483 MACI Inspection.pdf](#)

Dear Dr. Yong,

Vericel will be submitting a follow up 483 response from the MACI Pre-License Inspection in May 2016 to DMPQ (the Division listed on the Form 483) for Observation #3 regarding Design Controls. Given the timing of our teleconference tomorrow and to facilitate the BLA review, we are sending you a copy of this response in preparation for any discussion regarding the Design Controls or Design History File. The attached file provides:

- Follow up response to 483 Observation #3
- SOPs we committed to in the June 6, 2016 original 483 response
- Completed sections of the in-progress DHF to provide an interim update prior to the September 20, 2016 deadline (i.e., TOC, Design Intent Document, Traceability Matrix)

We look forward to speaking with you tomorrow.

Kind Regards,

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