

**APPROVED**

**By Jean Gildner at 2:40 pm, Dec 12, 2016**

**From:** [Lorien Armour](#)  
**To:** [Gildner, Jean](#)  
**Cc:** [Margarita Aguilera](#)  
**Subject:** MACI BL125603 SN0014 - 483 Responses for Design Controls and Membrane (b) (4) Test  
**Date:** Wednesday, September 21, 2016 11:10:52 AM

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Dear Jean,

A BLA amendment (BL 125603 SN0014) was submitted this morning to provide responses to 483 Observation #1 (ACI-Maix Membrane (b) (4) Test/Criteria) and Observation #3 (Design Controls and Design History File). We understand Dr. Carolyn Yong is awaiting these responses and wanted to ensure the review team is aware of this submission.

Kind Regards,

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