

**APPROVED**

**By Jean Gildner at 11:16 am, Jul 19, 2016**

**From:** [Margarita Aguilera](#)  
**To:** [Gildner, Jean](#)  
**Cc:** [Riggins, Patrick](#)  
**Subject:** RE: BLA 125603 Information Request  
**Date:** Wednesday, June 01, 2016 4:34:39 PM  
**Attachments:** [Response to FDA Request for Information May 26 2016.pdf](#)

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Dear Jean,

Enclose please find Vericel' s response to FDA' s Information Request of 26 May 2016 below.

Please let me know if you have any questions.

Regards,  
Margarita

Margarita Aguilera, M.Sc.  
Senior Regulatory Consultant – Vericel Corporation  
64 Sidney Street  
Cambridge, MA 02139  
[maguilera@vcel.com](mailto:maguilera@vcel.com);  
Telephone: (617) 588-5661  
Mobile: (224) 659-2129  
Facsimile: (734) 239-7401

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**From:** Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]  
**Sent:** Thursday, May 26, 2016 1:33 PM  
**To:** Margarita Aguilera  
**Subject:** BLA 125603 Information Request

Dear Margarita,

Please review the Information Request below and respond as soon as possible.

***One of Vericel's proposed risk management measures in the pharmacovigilance plan (module 1.16) for MACI is described as a "controlled distribution system." Please elaborate on the following:***

- i. At what stage of distribution of MACI will Vericel determine if healthcare provider (HCP) training was completed?***
- ii. How will Vericel ensure that the HCP received/completed surgical training specific to cartilage biopsy and MACI implantation procedures?***

Sincerely, Jean

*Jean F. Gildner* MSHS, MT (ASCP), CQA (ASQ)

Regulatory Project Manager

FDA/CBER/OCTGT

10903 New Hampshire Avenue

Bldg. 71, RM. 5222

Silver Spring, MD 20993-0002

Phone: (240) 402-8296

Fax: (301) 595-1303

[jean.gildner@fda.hhs.gov](mailto:jean.gildner@fda.hhs.gov)

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