

APPROVED

By Jean Gildner at 2:07 pm, 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](#)

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;
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

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