

From: Chamrin, Ronald
To: ["Margarita Aguilera"](#)
Subject: RE: BLA 125603\0 (original application) MACI™ (matrix applied characterized autologous cultured chondrocytes) - Site Inspections
Date: Wednesday, March 02, 2016 11:39:00 AM

Hi Margarita,
Vericel should facilitate on-site study records availability for each clinical investigator site designated for FDA inspection, including individual Protocol MACI00206 study sites.

Thanks,

Ron

Ron Chamrin
Regulatory Project Manager
Consumer Safety Officer
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Cellular, Tissue, and Gene Therapies
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From: Margarita Aguilera [mailto:maguilera@vcel.com]
Sent: Wednesday, March 02, 2016 12:27 AM
To: Chamrin, Ronald
Subject: BLA 125603\0 (original application) MACI™ (matrix applied characterized autologous cultured chondrocytes) - Site Inspections

Hi Ron,

This is to inform you that all the clinical study files for the pivotal trial (MACI00206 and MACI00809) supporting this application are located at the Vericel's Ann Arbor office and not at the Cambridge site. I wanted to make that known to you since this information is not in the BLA. This location is not involved with manufacturing or any activities related to MACI. The Vericel's Ann Arbor facility is located at the following address:

Vericel Corporation
Domino's Farms, Lobby K
24 Frank Lloyd Wright Drive
Ann Arbor, MI 48105

I will be the contact for this site.

Please let me know if you have any questions.

Regards,
Margarita

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