

APPROVED

By Jean Gildner at 2:17 pm, Jul 19, 2016

From: [Margarita Aguilera](#)
To: [Yao, Michael \(CBER\)](#)
Cc: [Schneider, Bruce](#); [Gildner, Jean](#)
Subject: BLA 125603 Request for Information - Dated June 3 2016
Date: Tuesday, June 07, 2016 12:15:20 PM
Attachments: [Response to FDA Request for Information dated 3 June 2016.pdf](#)

Dear Dr. Yao,

Attached please find responses to the questions raised in your email dated June 3, 2016.

Please let me know if additional information or clarification is needed.

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

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.

From: Yao, Michael (CBER) [mailto:Michael.Yao@fda.hhs.gov]
Sent: Friday, June 03, 2016 4:50 PM
To: Margarita Aguilera
Cc: Schneider, Bruce; Gildner, Jean; Yao, Michael (CBER)
Subject:
Importance: High

Hi Margarita,

Thanks for providing me information regarding SSPs. Now I have other questions for you.

Given that the enrollment of SUMMIT extension study was elective, and 2 study sites, 16 subjects (7 subjects in MACI group and 9 subjects in microfracture group), did not participate in the SUMMIT Extension study. Could you please provide following information for us:

Could you please provide information to identify 2 sites (where?) that did not participate in SUMMIT extension study?

Could you please provide reasons or explanations why those 2 sites did not participate in SUMMIT extension study?

Thank you very much.

Michael