

APPROVED

By Jean Gildner at 3:52 pm, Dec 12, 2016

From: [Margarita Aguilera](#)
To: [Amin, Pankaj \(Pete\)](#)
Cc: [Thomas, John](#); [Huang, Ellen \(CBER\)](#); [Bobo, Qiao](#); [Gildner, Jean](#)
Subject: RE: Vericel amendment 0017 - need Vericel written statement. BLA 125603
Date: Monday, December 05, 2016 12:09:13 AM
Attachments: [1-12-14 Environmental Assessment Categorical Exclusion \(2\) \(2\).pdf](#)

Dear Pete,

Thank you for your email. This is to let you know that the requested amendment will be filed on Tuesday, December 6. For you information, attached is a copy of the document that is being submitted with the BLA amendment.

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: Amin, Pankaj (Pete) [<mailto:Pete.Amin@fda.hhs.gov>]
Sent: Friday, December 02, 2016 10:14 AM
To: Margarita Aguilera
Cc: Thomas, John; Huang, Ellen (CBER); Bobo, Qiao; Gildner, Jean
Subject: RE: Vericel amendment 0017 - need Vericel written statement.

Hi Margarita,

This is kind reminder to send amendment as per your last email ASAP.

Thanks
Pete

From: Margarita Aguilera [<mailto:maguilera@vcel.com>]

Sent: Tuesday, November 29, 2016 12:24 PM
To: Amin, Pankaj (Pete); Gildner, Jean
Cc: Thomas, John; Huang, Ellen (CBER); Bobo, Qiao
Subject: RE: Vericel amendment 0017 - need Vericel written statement.

Hi Pete,

Thank you for the clarification. We will file an amendment to the BLA and add the additional statement.

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: Amin, Pankaj (Pete) [<mailto:Pete.Amin@fda.hhs.gov>]
Sent: Tuesday, November 29, 2016 12:04 PM
To: Gildner, Jean
Cc: Margarita Aguilera; Thomas, John; Huang, Ellen (CBER); Bobo, Qiao
Subject: Vericel amendment 0017 - need Vericel written statement.

IR _ request for written statement

In reference to Vericel 125603/0 amendment 0017 for withdrawing the Environmental Assessment (dated 03 December 2015) and to amend the BLA application to claim a Categorical Exclusion Environmental Assessment for MACI (autologous cultured chondrocytes on porcine collagen membrane) pursuant to Part 25, Subpart C, Sec 25.31.

Following additional written statement needed from Vericel to request Categorical Exclusion under Part 25, Subpart C, Sec 25.31 .

“To the knowledge of Vericel Inc. no extraordinary circumstances exists.”

Thanks

Pete