

**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](#)

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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.  
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Cambridge, MA 02139  
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**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

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**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

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**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