

APPROVED

By Jean Gildner at 3:47 pm, Dec 02, 2016

From: [Amin, Pankaj \(Pete\)](#)
To: [Gildner, Jean](#)
Cc: maquilera@vcel.com; [Thomas, John](#); [Huang, Ellen \(CBER\)](#); [Bobo, Qiao](#)
Subject: Vericel amendment 0017 - need Vericel written statement.
Date: Tuesday, November 29, 2016 12:03:47 PM

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