

APPROVED

By Jean Gildner at 5:00 pm, Dec 02, 2016

From: [Kong, Hyesuk](#)
To: [Gildner, Jean](#)
Cc: [Thomas, John](#); [Kenney, James](#); [Campbell, Karen M](#)
Subject: STN 125603 Information Request for (b) (4) method
Date: Thursday, October 13, 2016 2:45:10 PM
Attachments: [20161012 STN 125603 Information Request for \(b\) \(4\) method.doc](#)

Dear Jean

We have an IR regarding Vericel's response received on 11 October, 2016. The IR was concurred by my supervisors, Dr. James Kenney and Dr. Bill McCormick. Please let Vericel know we expect a quick (1 or 2 day turnaround time).

Thank you.

Hyesuk

-----Original Message-----

From: Gildner, Jean
Sent: Tuesday, October 11, 2016 7:53 PM
To: Kenney, James; Kong, Hyesuk; Kaur, Simleen; Thomas, John; Riggins, Patrick
Subject: FW: DCC Login ID (b) (4) loaded by DCC - DO NOT REPLY

This amendment contains the (b) (4) information that was sent via email a few weeks ago. Please review for completeness and if you have any additional comments that need to be sent to Vericel please let me know.

Thanks,
Jean

-----Original Message-----

From: cbersecure@fda.hhs.gov [<mailto:cbersecure@fda.hhs.gov>]
Sent: Tuesday, October 11, 2016 5:17 PM
To: Davis, Aletha; Tull, Lori; Azari, Mehran; Davidson, Mark; Riggins, Patrick; CBER OCTGT Load Notices; Gildner, Jean; Riggins, Patrick; Elekwachi, Oluchi; CBER RIMS
Cc: CBER IT EDR; CBER IT EDR; Fauntleroy, Michael; CBER DCC EDR
Subject: DCC Login ID (b) (4) loaded by DCC - DO NOT REPLY

This BLA AMENDMENT DCC Login ID (b) (4) is now available in the EDR.

This is an eCTD submission. Select the link to access the .enx file:

(b) (4)

DESCRIPTION:

Applicant: VERICEL CORPORATION / 2010

Product: AUTOLOGOUS CULTURED CHONDROCYTES ON PORCINE COLLAGEN MEMBRANE

Indication: No Information Available

Proprietary Name: MACI

APPLICATION INFORMATION:

Application Number: 125603\0\19

eCTD Sequence Number: 0015

CBER Receipt Date: 11-Oct-2016

If you need additional assistance with this submission, please contact
ERIC Help Desk at 301-827-ERIC (3742).

PLEASE DO NOT REPLY TO THIS EMAIL. This is an automatically generated message.

Technical information for administrators - Process Track ID: (b) (4)

Gateway Core ID: (b) (4)