

APPROVED

By Jean Gildner at 3:24 pm, Dec 12, 2016

From: [Margarita Aguilera](#)
To: [Gildner, Jean](#)
Cc: [Lorien Armour](#)
Subject: BLA125603 Information Request - November 2, 2016
Date: Thursday, November 03, 2016 4:48:23 PM
Attachments: [image001.png](#)
[Information Request Matricel Supplier Qualification Final 3 November 2016.pdf](#)

Dear Jean,

Enclosed please find Vericel' s response to the information request below regarding supplier qualification.

Thanks in advance for confirming receipt.

Best regards,
Margarita

Margarita Aguilera, M.Sc.
Senior Regulatory Consultant – Vericel Corporation
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Cambridge, MA 02139
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From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Wednesday, November 02, 2016 9:08 AM
To: Margarita Aguilera
Subject: RE: BLA125603 Information Request

Dear Margarita,

Please see the following IR request:

Regarding supplier qualification describe in the BLA (section 3.2.S.2, 3.1 “supplier qualification”), Please provides the most recent vendor audit (supplier qualification) that was performed for the Matricel facility and brief summary of Matricel supplier

qualification. If Vendor audit was not performed, Please provide your rational for not conducting vendor audit and propose timeline.

(Please ask Vericel to response by this Friday).

Please acknowledge receipt of this request.

Sincerely, Jean

Jean F. Gildner MSHS, MT (ASCP), CQA (ASQ)

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