

APPROVED

By Jean Gildner at 3:27 pm, Dec 12, 2016

From: [Margarita Aguilera](#)
To: [Gildner, Jean](#)
Cc: [Lorien Armour](#)
Subject: BLA125603 Information Request - October 27, 2016
Date: Tuesday, November 01, 2016 3:28:57 PM
Attachments: [image001.png](#)
[1-11-1_October 27 Request CAPA related SOPs.pdf](#)

Dear Jean,

Attached please find Vericel' s response to Question 2 (CAPA Related SOPs) of the information request received on October 27, 2016. A separate email addressing Question 1 was sent earlier.

Please let me know if you have any questions.

Best Regards,
Margarita

Margarita Aguilera, M.Sc.
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From: Gildner, Jean [mailto:Jean.Gildner@fda.hhs.gov]
Sent: Thursday, October 27, 2016 9:42 AM
To: Margarita Aguilera
Cc: Lorien Armour
Subject: RE: BLA125603 Information Request

Dear Margarita,

Please find below an information request. Please respond by COB Tuesday November 1, 2016. If you cannot meet that suspense date please let me know.

1. In a single document, please provide a procedure summarizing purchasing controls with

the following information. As referenced in 21 CFR 820.50, the procedure should describe your firm's supplier evaluation process and describe how it will determine type of and extent of control it will exercise over suppliers. Please define how your firm maintains records of acceptable suppliers and how it addresses the purchasing data approval process. Please explain how your firm will balance purchasing assessment and receiving acceptance to ensure that products and services are acceptable for their intended use. Please explain how your firm will ensure that changes made by contractors/suppliers will not affect the final combination product. Please describe how your firm applied the purchasing controls to the suppliers/contractors involved in the manufacturing of the combination product or provide evidence of the application. (Please ensure to provide purchasing control procedures specific to the manufacturing of the MACI product, i.e., for the device constituent acquired from Matricel, and referenced sections of procedures or SOPs.)

2. *In Amendment 14, received by CBER on September 14, 2016, you provided Quality Manual QA1-010 that describes Corrective and Preventive Actions (CAPA). Please provide all QA documents that are referenced in Section 7.16 of this document for review. Please ensure that this information addresses how your firm's procedure analyzes sources of quality data to identify existing and potential cause of nonconforming practices and products; investigation of the cause of nonconformities, identification of actions needed to correct and prevent recurrence of non-conformances; and, verification or validation of the actions.*

Please be advised that the review of the Quality Systems information pertaining to the final combination product is ongoing and additional information requests may be made.

Please acknowledge receipt of this email.

Sincerely, Jean

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

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