

APPROVED

By Jean Gildner at 3:09 pm, Dec 12, 2016

From: [Lorien Armour](#)
To: [Gildner, Jean](#)
Cc: [Margarita Aguilera](#)
Subject: Re: BLA 125603 Information Request - (b) (4) validation EM selection
Date: Friday, July 22, 2016 3:26:27 PM
Attachments: [STN 125603 Information Request for \(b\) \(4\) .method-EM selection.doc](#)

Dear Jean,

The Vericel team has the following proposal in response to the IR received on July 14th regarding the (b) (4) validation, which provided additional information (EM selection) to the FDA request received on June 29th.

Vericel no longer has facility (b) (4) . The only facility (b) (4) remaining in our (b) (4) are (b) (4) . We propose to use these (b) (4) in the limit of detection study ((b) (4)) instead of the additional (b) (4) used in the (b) (4) that FDA requested in the July 14th request.

Furthermore, Vericel wishes to clarify that we plan to perform the limit of detection study by (b) (4) . Vericel also wishes to clarify that we interpret the MACI drug substance sample configuration requested by FDA to be the "Pre-release" sample described in 3.2.S.4 Section 2.3.3 of the BLA.

Vericel looks forward to a timely response so that work can begin in order to meet the October 1, 2016 deadline.

Kind Regards,

Lorien Armour, RAC
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Fax: 734-239-7401

From: Gildner, Jean [<mailto:Jean.Gildner@fda.hhs.gov>]
Sent: Thursday, July 14, 2016 12:00 PM
To: Margarita Aguilera
Subject: BLA 125603 Information Request

Dear Margarita,

Please find attached an IR. Please review this request carefully as there is a suspense date involved.

Please acknowledge receipt of this request.

Sincerely, Jean

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

Regulatory Project Manager

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