

APPROVED

By Patrick S. Riggins at 11:13 a

From: Riggins, Patrick
To: "[Margarita Aguilera](#)"
Cc: [Chamrin Ronald](#)
Subject: RE: Information Request for BLA 125603\0 (original application) MACI™ (matrix applied characterized autologous cultured chondrocytes) Autologous Implantation
Date: Tuesday, January 19, 2016 9:48:00 AM

Margarita,

I have discussed with the Epidemiology reviewer and having the PVP in by January 28 is acceptable.

Regards,

Pat Riggins

Patrick S. Riggins, Ph.D.
Branch Chief
Regulatory Management Staff
Office of Cellular, Tissue, and Gene Therapies
Center for Biologics Evaluation and Research
Food and Drug Administration
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From: Margarita Aguilera [mailto:maguilera@vcel.com]
Sent: Monday, January 18, 2016 4:14 PM
To: Riggins, Patrick
Cc: Chamrin, Ronald
Subject: FW: Information Request for BLA 125603\0 (original application) MACI™ (matrix applied characterized autologous cultured chondrocytes) Autologous Implantation

Dear Patrick,

In Ron's absence could you consider the request below for an extension to submit the PVP by January 28, 2016. Please advise if this new date will be acceptable.

Many thanks in advance.

Regards,
Margarita

Margarita Aguilera, M.Sc.
Senior Regulatory Consultant – Vericel Corporation
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From: Margarita Aguilera
Sent: Monday, January 18, 2016 3:45 PM
To: 'Chamrin, Ronald'
Subject: RE: Information Request for BLA 125603\0 (original application) MACI™ (matrix applied characterized autologous cultured chondrocytes) Autologous Implantation

Dear Ron,

Vericel requires additional time to submit the Pharmacovigilance Plan (PVP). We respectfully request an extension to submit the PVP by January 28, 2016. Please advise if this new date will be acceptable.

Best Regards,
Margarita

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From: Margarita Aguilera
Sent: Wednesday, January 13, 2016 9:56 AM
To: 'Chamrin, Ronald'
Subject: RE: Information Request for BLA 125603\0 (original application) MACI™ (matrix applied characterized autologous cultured chondrocytes) Autologous Implantation

Dear Ron,

The following is to acknowledge receipt of the information request outlined below and to inform you that Vericel will plan to submit a Pharmacovigilance Plan (PVP) by January 22, 2016.

Best Regards,
Margarita

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From: Chamrin, Ronald [<mailto:Ronald.Chamrin@fda.hhs.gov>]

Sent: Tuesday, January 12, 2016 11:28 AM

To: Margarita Aguilera

Subject: Information Request for BLA 125603\0 (original application) MACI™ (matrix applied characterized autologous cultured chondrocytes) Autologous Implantation

Importance: High

Dear Ms. Aguilera:

Information Request for BLA 125603\0 (original application) MACI™ (matrix applied characterized autologous cultured chondrocytes) Autologous Implantation:

We note a document submitted in module 1.16 which discusses your assessment for Risk Evaluation and Mitigation Strategy (REMS). **Please also submit a Pharmacovigilance Plan (PVP) in module 1.16** as per the conventions described in the E2E Pharmacovigilance planning Guidance for Industry

(
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073107.pdf>
).

You may also refer to FDA Guidance for Industry on Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
(<http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126834.pdf>).

Please submit a PVP by **January 22, 2016** or identify a date by which you plan to submit the PVP.

Best,

Ron

Ron Chamrin

Regulatory Project Manager

Consumer Safety Officer

Food and Drug Administration

Center for Biologics Evaluation and Research

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