

From: Chamrin, Ronald
To: "Margarita Aguilera"
Subject: Information Request for BLA 125603\0 (original application) MACI™ (matrix applied characterized autologous cultured chondrocytes) Autologous Implantation
Date: Tuesday, January 12, 2016 11:27:00 AM
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

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