

APPROVED

By Jean Gildner at 3:03 pm, Jun 22, 2016

From: [Margarita Aguilera](#)
To: [Gildner, Jean](#)
Cc: [Riggins, Patrick](#)
Subject: RE: BLA 125603 Request for information
Date: Wednesday, May 25, 2016 5:08:31 PM
Attachments: [MACI00206_CSR_Table_30_25May2016..pdf](#)

Dear Jean,

The purpose of this email is to provide a response to your Request for Information received via email on 19 May 2016.

FDA Request for Information

When discussing treatment by site interaction in your study report, Section 11.2.2.4, the report states that microfracture was associated with a greater improvement in KOOS pain scores at 3 sites including Site# 17. However, we see only 11 sites listed in Table 30 and Site# 17 is not on this list. Please clarify the number of sites as well as the absence of Site# 17. The following is a response to FDA Request for Information below.

Vericel Response

Table 30 in the MACI00206 study report is incomplete. Five sites were inadvertently not included in the table: Sites 4, 6, 17, 19, and 29. The missing information was the result of a programming issue. Please note that subject data from ALL sites was included in the planned efficacy and safety analyses included in the BLA.

Table 30 has been revised to include information for all sites. Please note that the conclusion stated in Section 11.4.2.4: Multicenter Studies of the MACI00206 CSR remain unchanged. Enclosed please find a revised Table 30. Please note that an official submission will be made to the BLA to include a Study Report Addendum (2) to MACI00206 (Module 5.3.2.1) with a revised Table 30.

We trust that this addressed your question.

Regards,
Margarita

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From: Gildner, Jean [<mailto:Jean.Gildner@fda.hhs.gov>]
Sent: Thursday, May 19, 2016 1:50 PM
To: Margarita Aguilera
Subject: BLA 125603 Request for information

Dear Margarita,

Please review the following information request from our review team.

When discussing treatment by site interaction in your study report, section 11.2.2.4., the report states that microfracture was associated with a greater improvement in KOOS pain scores at 3 sites including site#17. However, we see only 11 sites listed in Table 30 and site#17 is not on this list. Please clarify the number of sites as well as the absence of site#17.

Please response as soon as possible (or Wednesday, May 25, 2016) via email to me and with an official submission to the BLA.

Sincerely, Jean

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

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