

BLA 125603
MF 16742

Vericel & Matricel CMC/Device Teleconference
19AUG2016 1:30-2:30pm

Agenda:

1. Vericel Proposal for (b) (4) Testing for the ACI-Maix Membrane
Information emailed to Jean Gildner on July 14, 2016 by Lorien Armour
 - Proposed methodology discussion:
 - a. Sampling Plan, Reportable Value, Calculation of (b) (4) – OK
 - b. Test item dimensions
(b) (4)
 - c. Incubation conditions
Rationale: Same as implemented for (b) (4) product
Manufacturer committed to incorporate in their validation studies conditions that mimic the manufacturing process of the final product, i.e. (b) (4). If no significant change from (b) (4), then (b) (4) is justified.
 - d. (b) (4)
(b) (4) : based on scientific literature for surgical materials and clinical application
Analyzed (b) (4) – no significant affect seen. Recommended that manufacturer implement worst case scenario conditions, (b) (4)
 - e. Testing parameters
Discussion on (b) (4) as final product specification:
Sponsor provided rationale that due to issues with (b) (4), correlation was made between (b) (4). This is the rationale for (b) (4) specification. FDA advised sponsor to consider (b) (4). FDA indicated that no formal response to this inquiry was required.
 - Acceptance criteria for proposed methodology
Acceptable
2. Current Methodology and Acceptance Criteria (for Lot Acceptance by Vericel)
Commitment for revision and implementation confirmed by sponsor for September 20th.
Proposal anticipated as post-approval change. Sponsor committed to providing FDA with a timeline or estimate for implementation.
3. QS Documentation
 - a. MACI
Commitments for SOPs provided – still on track to submit complete documentation by 9/20.

Late stage draft – any significant revisions will be sent as tracked-changed documents

b. ACI-Maix Membrane

FDA informed sponsor that QS information is under review and anticipate that any IR requests, if any would be submitted in approximately 2 weeks.

Follow-up to Matricel:

FDA will confirm that 483 responses should be sent as amendments to the file
Sponsor proposes to submit as Quality Informational Amendments – Module 1.11.1