

MEMORANDUM

Wilson W. Bryan, M.D.

**Director (Acting), Division of Clinical Evaluation and Pharmacology / Toxicology
FDA / CBER / OTAT / DCEPT**

BLA 125603

Submission date January 4, 2016
Review date December 13, 2016

CMC Reviewers Malcolm Moos, MD, PhD; Carolyn Yong, PhD; Joseph Nielsen, PhD; Latoya Oliver-Powell; Hyesuk Kong, PhD, J. Terrig Thomas, PhD

Pharm / Tox Reviewer / Team Leader Allen Wensky, PhD / Becky Robinson, PhD

Clinical Reviewer / Team Leader Michael Yao, MD / Bruce Schneider, MD

Statistical Reviewer / Team Leader Stan Lin, PhD / Shiojjen Lee, PhD

Pharmacovigilance Reviewer Meghna Alimchandani, MD

Regulatory Project Manager Jean Gildner

Applicant Vericel Corporation

Product Autologous Cultured Chondrocytes on a Porcine Collagen Membrane (MACI)

Proposed Indication Repair of single or multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement in adults

Recommendation Approval

For details of this submission, please see the pharmacology/toxicology review by Dr. Wensky, the primary clinical review by Drs. Yao and Schneider, the statistical review by Dr. Lin, and the pharmacovigilance review by Dr. Alimchandani. I agree with the conclusions and recommendations of the pharmacology/toxicology review and the clinical review. I also agree with the post-marketing pharmacovigilance plan as recommended in Dr. Alimchandani's review. I recommend approval of BLA 125603.