

Memorandum

From: Kimberly Benton, Ph.D., Deputy Director, Division of Cellular & Gene Therapies
Raj Puri, M.D., Ph.D., Director, Division of Cellular & Gene Therapies, OCTGT, CBER

Date: December 12, 2016

BLA/ STN#: 125603

Applicant Name: Vericel Corporation

Date of Submission: January 4, 2016

Action Goal Date: January 3, 2017

Proprietary Name/ Established Name: MACI

Non-Proprietary Name: Autologous Cultured Chondrocytes on Porcine Collagen Membrane

Indication: MACI (autologous cultured chondrocytes on porcine collagen membrane) is an autologous cellularized scaffold product indicated for the repair of single or multiple symptomatic, full-thickness cartilage defects of the knee with or without bone involvement in adults.

Product Reviewers: Malcolm Moos, M.D., Ph.D, Carolyn Yong, Ph.D., J. Terrig Thomas, Ph.D.

Branch Chief: Steven Oh, Ph.D.

Material Reviewed/ Consulted: CMC-Device Review dated December 12, 2016, CMC 483 Observation Response Review dated December 12, 2016

I agree with the recommendation for approval as stated in the CMC review memos dated January December 12, 2016, and have no additional comments.

Kimberly Benton, PhD

Raj Puri, MD, PhD