



Our STN: BL 125603/0.2

PROPRIETARY NAME ACCEPTANCE

Vericel Corporation
Attention: Margarita Aguilera
Senior Regulatory Consultant
64 Sydney Street
Cambridge, MA 02139

March 16, 2016

Dear Ms. Aguilera:

We have reviewed your submission dated January 19, 2016, to your biologics license application (BLA) for autologous cultured chondrocytes on porcine collagen membrane, requesting a proprietary name review. In consultation with the Center for Biologics Evaluation and Research (CBER)'s Advertising and Promotional Labeling Branch we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, MACI, is acceptable.

Please note that the proper name that you proposed, matrix applied characterized autologous cultured chondrocytes, is not acceptable. CBER has designated the proper name of your product as autologous cultured chondrocytes on porcine collagen membrane.

If you have any questions, please contact the Regulatory Project Manager, Ron Chamrin, at (240) 402-8269.

Sincerely yours,

Raj K. Puri, MD, PhD
Director
Division of Cellular and Gene Therapies
Office of Cellular, Tissue, and Gene Therapies
Center for Biologics Evaluation and Research