



RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

June 26, 2015

Patrick Bilbo
Sr. Vice President, Regulatory, Government Affairs and Administration
Organogenesis, Inc.
150 Dan Rd
Canton, MA 02021

RE: Florida Licensure Requirement

Dear Mr. Bilbo,

In accordance with Chapter 765, Part V, Florida Statutes and Chapter 59A-1, Florida Administrative Code, the Agency for Health Care Administration (Agency) regulates entities engaged in the recovery, processing, storage or distribution of cadaveric organs or tissue intended for transplantation. Your communication dated March 18, 2015 indicated that the facility located at 10933 N Torrey Pines Road, Suite 200 in La Jolla, CA manufactures and distributes Dermagraft, a product using human cells originally derived from a non-cadaveric donor source.

Based upon the information provided, Organogenesis Inc is not currently required to obtain or maintain Tissue Bank certification. As such, your organization is not subject to any of the statutes or regulations for certified entities, including those related to medical director requirements.

If you have any questions or need further assistance, please feel free to contact Christopher Stroman at (850) 412-4377 or e-mail at Christopher.Stroman@ahca.myflorida.com.

Sincerely,

Christopher Stroman
Health Services and Facilities Consultant
Laboratory Licensure Unit
Agency for Health Care Administration

Laboratory Licensure Unit
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