



CHARLIE CRIST
GOVERNOR

HOLLY BENSON
SECRETARY

August 7, 2008

Ms. Cheryl McManamin-L'Heureux, CQM
Tissue Bank Director
Organogenesis, Inc.
150 Dan road
Norfolk, MA 02021

Dear Ms. McManamin-L'Heureux,

The documentation you submitted regarding services provided by Organogenesis, Inc. have been reviewed to determine whether or not Organogenesis, Inc. must become certified by the Agency for Health Care Administration (Agency) to operate as a tissue bank in Florida. In reviewing the literature submitted it appears that Organogenesis, Inc. uses only tissue from healthy infant males at the time of an elective circumcision. The Agency regulates tissue banks that procure, process, store or distribute tissues from cadaveric donors only. The services provided by Organogenesis, Inc. do not require tissue bank certification by the Agency.

If you have questions or need assistance regarding tissue bank requirements, please contact Ken Arnold by telephone at (850) 414-0359, by fax at (850) 410-1511 or by e-mail at arnoldk@ahca.myflorida.com.

Sincerely,

Jeffrey N. Gregg, Chief
Bureau of Health Facility Regulation
Agency for Health Care Administration
2727 Mahan Drive, MS 28A
Tallahassee, Florida 32308
(850) 922-0791
(850) 413-7955 (fax)

