

July 16, 2001

Ms. Jenifer Merritt
Tissue Bank Director
Bio-Tissue
8780 SW 92 Street, Suite 211
Miami, FL 33176

Dear Ms. Merritt:

The documentation you submitted regarding services provided by Bio-Tissue have been reviewed to determine whether or not Bio-Tissue 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 Bio-Tissue uses only tissue from healthy pregnant women at the time of an elective Cesarean section delivery. The Agency regulates tissue banks that procure, process, store, or distribute tissues from cadaveric donors only. The services provided by Bio-Tissue do not require tissue bank certification by the Agency.

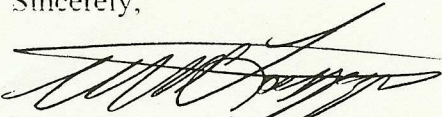
You may wish to have this literature reviewed by the Agency's laboratory unit to determine if a laboratory license is required. The contact person would be:

Ms. Pat James, Unit Manager
Laboratory Unit, Mail Stop 32
2727 Mahan Drive, Tallahassee, 32308.

Ms. James can be contacted by telephone at (850) 487-3109.

If you have questions or need assistance regarding tissue bank requirements, please contact Jo Ann Linch by telephone at (850) 487-2717, by fax at (850) 922-4351, or by e mail at linchj@fdhc.state.fl.us.

Sincerely,



Mary Loepp, Unit Manager
Hospital & Outpatient Services Unit

