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March 9, 2012

VIA EMAIL Karen.midthun@fda.hhs.gov
AND OVERNIGHT MAIL
Karen Midthun, MD
Director
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852

Re: February 21, 2012 letter of Leigh Turner, University of Minnesota concerning Celltex Therapeutics Corporation

Dear Dr. Midthun:

This firm represents Celltex Therapeutics Corporation ("Celltex"). Celltex has recently learned of a February 21, 2012 letter authored by Leigh Turner, Associate Professor for the University of Minnesota, Center for Bioethics, alleging various misconduct and violations of law by the company. The allegations are false.

Celltex is not in the business of administering stem cells directly to patients; rather, it is a lab that processes stem cells at the behest of independent physicians who diagnose and prescribe to *their* patients. Celltex banks autologous mesenchymal stem cells from adipose tissue. Celltex's process ensures that cells are genetically identical to the original and free from any contaminants. Additionally, Celltex operates lawfully under Texas law and is duly registered with the FDA as a Section 361 facility (referring to Section 361 of the Public Health Services Act). Finally, prospective clinical studies involving Celltex stem cells are being coordinated with the independent Institutional Review Board (IRB) and clinical research organization (CRO) of Texas Applied Biomedical Services ("TABS"). TABS is regularly inspected by FDA as a regulated

IRB and CRO. We have been informed that TABS has no compliance issues related to its functions.

If the agency has any concerns about Celltex, the company welcomes further correspondence and inquiry. Please contact us if you would like to set up a conference call, meeting in your Maryland offices, or an inspection of Celltex's facilities. Attached to this letter is Celltex's inquiry to the University of Minnesota concerning Associate Professor Turner's letter.

Sincerely,

Jonathan W. Emord
Andrea G. Ferrenz

cc: Mary Anne Malarkey, Director, Office of Compliance and Biologics Quality, mary.malarkey@fda.hhs.gov
Rachel Witten, MD, Office of Cellular, Tissue and Gene Therapies, Rachel.witten@fda.hhs.gov
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