DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 23, 2006

By Certified Mail - Return Receipt Requested

Peter K. Law, Ph.D.
[redacted]

Notice of Disqualification to Receive Investigational New Drugs

Dear Dr. Law:

On November 1, 2002, the Food and Drug Administration (FDA) sent to [redacted] your attorney, a Notice of Opportunity for a Hearing (NOOH, attached) to determine whether you would remain entitled to receive investigational new drugs [Title 21 of the Code of Federal Regulations (CFR) Parts 16 and 312.70 (21 CFR 16, 312.70)]. In your response to the NOOH dated November 19, 2002, you stated that you do not request a hearing at this time. FDA considers this to be a refusal of the offer for a hearing and, therefore, no hearing will be held [21 CFR § 16.22(b)].

On the basis of all information available to FDA, I have determined that you have repeatedly and deliberately failed to comply with pertinent regulations governing the conduct of clinical investigators and the use of investigational new drugs. These violations occurred in the following clinical studies sponsored by Cell Therapy Research Foundation:

Protocol 93-5 – "Myoblast Transfer Therapy as an Experimental Treatment for Duchenne Muscular Dystrophy;"

Protocol 95-1 – "Whole Body Myoblast Transfer Therapy (MTT) as an Experimental Treatment for Duchenne Muscular Dystrophy (DMD) - Pivotal Trial;" and

Protocol 95-2 – "Whole Body Myoblast Transfer Therapy as an Experimental Treatment for Becker Muscular Dystrophy."

Specifically:

1. You violated 21 CFR § 312.60 by failing to fulfill the general responsibilities of an investigator by failing to protect the rights, safety, and welfare of study subjects.

2. You violated 21 CFR § 312.60 by failing to conduct the studies in accordance with the approved protocols.

3. You violated 21 CFR § 312.60 by failing to ensure that informed consent was obtained and documented in accordance with 21 CFR Part 50.

4. You violated 21 CFR § 312.66 by providing incomplete or inaccurate information to the IRB, which the IRB used as the basis for its initial and continuing review and approval decisions.

5. You violated 21 CFR §312.62(b) by failing to maintain adequate and accurate case histories designed to record all data observations pertinent to the investigation.

In accordance with 21 CFR Parts 16 and 312.70, you are hereby advised that you are no longer entitled to receive investigational new drugs. All such products in your possession should be promptly returned to their suppliers. Furthermore, you may not administer investigational myoblast cells manufactured at Cell Therapy Research Foundation to human subjects in the United States.

FDA will notify the sponsors of the clinical studies of investigational drugs in which you participated as an investigator that you are no longer entitled to receive investigational products. The notifications will include the basis for your disqualification, and the steps the sponsors should take.

FDA will make this notice available to interested parties under the Freedom of Information Act (FOIA). Your name will also be added to the list of clinical investigators who have been disqualified that is available under FOIA and posted on FDA's Internet website.

Sincerely,

Andrew C. von Eschenbach, M.D.
Acting Commissioner of Food and Drugs

Attachment - Copy of NOOH to Dr. Law, dated November 1, 2002