



Mr. James Saunders, Vice President
New England Institutional Review Board
85 Wells Avenue, Suite 107
Newton, MA 02456

Dear Mr. Saunders:

Between August 19, 2011 and August 25, 2011, Ms. Paraluman Leonin, representing the Food and Drug Administration (FDA), inspected the Institutional Review Board (IRB) at New England Institutional Review Board. The purpose of this inspection was to determine whether the IRB procedures for the protection of human subjects complied with Title 21 of the Code of Federal Regulations (CFR), parts 50 and 56. These regulations apply to clinical investigations of products regulated by FDA.

From our review of the establishment inspection report and the documents submitted with that report, we conclude that the IRB adhered to the applicable statutory requirements and FDA regulations governing the protection of human subjects.

For helpful information on human subject protections, please visit the following FDA web page:

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm>

We appreciate the cooperation shown to FDA Investigator Leonin during the inspection. Should you have any questions or concerns regarding this letter or the inspection, please contact me by letter at the address given below.

Sincerely,

{See appended electronic signature page}

Patrick J. McNeilly, Ph.D.
Acting Branch Chief, Human Subject Protection Branch
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Bldg 51, Room 2266
10903 New Hampshire Avenue
Silver Spring, MD 20993

cc: Ms. Erin Bower, Director of Operations
New England Institutional Review Board
85 Wells Avenue, Suite 107
Newton, MA 02456

Ms. Mary Oster, IRB Chair
New England Institutional Review Board
85 Wells Avenue, Suite 107
Newton, MA 02456

Dr. Martha Gilpatrick, IRB Chair
New England Institutional Review Board
85 Wells Avenue, Suite 107
Newton, MA 02456

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/s/

PATRICK J MCNEILLY
12/21/2011