DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

MAR 0 7 2014

Via UPS Delivery

Landon S. King, M.D.
Executive Vice Dean, School of Medicine
The Johns Hopkins Hospital
600 N. Wolfe Street
Hospital Main Entrance - Sheikh Zayed Tower
Baltimore, MD 21287

Re: Submission of Clinical Trial Information Pursuant to 42 U.S.C. § 282(j)
Reference Number: FDA-2014-101 (NCT00617097)

Dear Dr. King:

In reviewing certain records contained in the ClinicalTrials.gov data bank, operated by the National Institutes of Health/National Library of Medicine (NIH/NLM), and records of the Food and Drug Administration (FDA), FDA has identified potential non-compliance with certain clinical trial information related to NCT00617097. Clinical trial registration and results submission requirements are described in section 801 of the Food and Drug Administration Amendments Act of 2007. Based on an initial review, your institution appears to be the responsible party for NCT00617097and it appears that the records for the referenced clinical trial may be missing clinical trial results information required to be submitted under section 402(j)(3) of the Public Health Service Act (PHS Act) (42 U.S.C. § 282(j)(3)). Your institution should review this record and determine whether it submitted all required information. If you determine that corrections, updates, or additional information should be submitted, please submit them promptly.

Our preliminary review of records suggests that there may be clinical trial results which should have been submitted in May 2010 to ClinicalTrials.gov.

FDA intends to conduct a further review and assessment of the above-referenced clinical trial beginning 30 days after you receive this letter. If a further review and assessment of the record related to NCT00617097 results in a determination, at that time, that your institution is not in compliance with all applicable requirements of section 402(j) of the PHS Act (42 U.S.C. § 282(j)), your institution may receive from FDA a notice under section 402(j)(5)(C)(ii) of the PHS Act (42 U.S.C. § 282(j)(5)(C)(ii)). After FDA sends such a notice to a responsible party, FDA could initiate an administrative action seeking a civil monetary penalty against the responsible party. Failure to submit clinical trial information required under section 402(j) of the PHS Act (42 U.S.C. § 282(j)) is a prohibited act under section 301(jj)(2) of the Federal Food,

Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. § 331(jj)(2)). Pursuant to section 303(f)(3)(A) of the FD&C Act (21 U.S.C. § 333(f)(3)(A)), "[a]ny person who violates section 301(jj) shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding."

Moreover, section 303(f)(3)(B) of the FD&C Act (21 U.S.C. § 333(f)(3)(B)) provides that "[i]f a violation of section 301(jj) is not corrected within the 30-day period following receipt of a [notice issued] under section 402(j)(5)(C)(ii) [of the PHS Act (42 U.S.C. § 282(j)(5)(C)(ii))], the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected."

In addition to civil monetary penalties, violations of section 301(jj) of the FD&C Act (21 U.S.C. § 331(jj)) also could result in other regulatory action without further notice, such as injunction and/or criminal prosecution.

As requested, please review your institution's clinical trial record for NCT00617097 at http://www.clinicaltrials.gov and make any necessary submissions or corrections of clinical trial information as required under section 402(j)(3) of the PHS Act (42 U.S.C. § 282(j)(3)). If you have any questions about this letter, please call Patrick J. McNeilly, Ph.D., at (301) 796-2941 or email patrick.mcneilly@fda.hhs.gov. Please have the reference number provided above available when you call and include it with any email communications.

Sincerely,

Douglas Stearn
Director
Office of Enforcement and Import Operations
Office of Regulatory Affairs