DEPARTMENT OF HEALTH & HUMAN SERVICES

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

JUL 11 2014

Via UPS Delivery

Bei-Hung Chang, Sc.D.
VA Boston Healthcare System
150 S. Huntington Avenue
Boston, MA 02130

Re: Submission of Clinical Trial Information Pursuant to 42 U.S.C. § 282(j)
Reference Number: FDA-2014-107 (NCT00545623)

Dear Dr. Chang:

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 NCT00545623. 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, you appear to be the responsible party for NCT00545623 and 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)). You should review this record and determine whether you 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 September 2011 to ClinicalTrials.gov.

FDA intends to conduct a further review and assessment of the above-referenced clinical trial beginning 30 days after the date you receive this letter. If a further review and assessment of the record related to NCT00545623 results in a determination, at that time, that you are not in compliance with all applicable requirements of section 402(j) of the PHS Act (42 U.S.C. § 282(j)), you 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 NCT00545623 clinical trial record 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. Responses to this letter should be addressed to:

Patrick J. McNeilly, Ph.D.
Food and Drug Administration
WO 32, Rm 5169
10903 New Hampshire Ave.
Silver Spring, MD 20993

Please have the reference number provided above available when you call and include it with any written communications.

Sincerely,

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