DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Pre Notice of Non-Compliance

March 9, 2016

Via UPS Delivery

Thomas S. Tooma, M.D.
NVISION Laser Eye Centers
3501 Jamboree Road, Suite 1100
Newport Beach, CA 92660

Re: Submission of Clinical Trial Information Pursuant to 42 U.S.C. § 282(j)

Dear Dr. Tooma:

In reviewing records of the Food and Drug Administration (FDA), FDA has identified potential non-compliance with certain clinical trial information related to your trial entitled "Study of the Safety and Efficacy of the Photochemically Induced Collagen Cross-linking at Irradiance of 18mW/cm^2." 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 the above mentioned trial and it appears that the records for the referenced clinical trial may be missing clinical trial registration information required to be submitted to ClincialTrials.gov under section 402(j)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. § 282(j)(2)). You should review your records and determine whether you submitted the required information. If you determine that information should be submitted, please submit the information promptly.

FDA intends to conduct a further review and assessment of the above-referenced clinical trial beginning 30 days after the date of receipt of this letter. If a further review and assessment of the record related to the above-referenced trial 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.

Please review your records and make any necessary submissions of clinical trial information as required under section 402(j)(2) of the PHS Act (42 U.S.C. § 282(j)(2)). If you have any questions about this letter, please contact Patrick McNeilly, Ph.D., at 301-796-2941; facsimile 301-847-8640 or email Patrick.Mcneilly@fda.hhs.gov.

Sincerely,

David C. Burrow, Pharm.D., J.D.
Acting Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration