3. Although you have reported the number of eyes with unintended over-corrections > 2 D at each time point starting at 3 months in response to deficiency 6, it is not clear whether these reports represent different eyes at each visit or whether some of the reports are for the same eye. Please clarify.

4. In response to deficiency 8, you have indicated how you will verify your current accountability for visits that have already past. After your internal audit is complete and you have more insight as to the reasons for any problems with accountability, please directly address the original issue outlined in previous deficiency 8: please describe how you intend to improve subject follow-up and data reporting during the rest of the course of your IDE study.

Please note: In response to a question you asked previously by telephone, eyes that have been enhanced are considered discontinued at the point of enhancement (retreatment). These are then treated the same as the monovision subjects; that is, they are accounted for and analyzed separately. You should not enter subjects into the study that you know you are going to undercorrect or enhance.

This information must be submitted to FDA within 45 days from the date of this letter. It should be identified as an IDE supplement referencing the IDE number above, and must be submitted in triplicate to:

IDE Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

If you do not provide this information within 45 days from the date of this letter, we may take steps to propose withdrawal of approval of your IDE application.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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