This approval is being granted on the condition that, within 45 days from the date of this letter, you submit your agreement to:

1. conduct the investigation within the modified limit, i.e., retreatment for myopia or myopic astigmatism only;

2. extend the minimum time between the initial operation and the retreatment to 3 months; and,

3. retreat only eyes which are "white and quiet" and in which refractive stability has been documented with two manifest refractions taken at least 30 days apart with less than 1 diopter of change, confirmed by topography.

This information 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.

We would like to point out that FDA approval of your IDE supplement does not imply that this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597.

You should give serious consideration to the fact that your procedure does not appear to reach stability, as defined by stability of manifest refractions taken 3 months apart: 95% within 1 diopter, mean difference of ≤ 0.1, and a lower confidence limit of 90%. The appearance of instability of manifest refraction may be the result of unreliable or variable refractions having been taken by different persons using different instruments. In addition, you should continue to pursue follow-up on all subjects; it appears that you had 81 subjects eligible for the 3 month visit, yet only 67 were reported to FDA

Prior to your request to modify your protocol to provide hyperopic retreatments, you should submit the following information: