This approval is being granted on the condition that, within 45 days from the date of this letter, you submit information correcting the following deficiency:

Please submit your agreement that you will validate the proposed glare source prior to initiating this substudy. An appropriate validation would be a small control study with 5-10 normal emmetropic subjects. The glare source should just significantly raise contrast thresholds for these subjects. If it does not, the glare is too dim and will not be a sensitive measure of glare effects in LASIK subjects. In that case, the glare source will need to be brightened until it raises normal contrast thresholds.

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 are reminded (see our letter of December 16, 1997) that you may not begin retreatment procedures on subjects treated under this IDE until FDA has reviewed your stability data and approved your retreatment study plan.

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We acknowledge your request in your original IDE (dated March 18, 1997) to conduct a study at one site with 400 eyes low myopia and 590 eyes high myopia for each of two investigators (single site total of 1980 eyes or 990 subjects). We believe that adequate safety information has been provided to allow the initiation of your study with a small expansion of an additional 75 subjects (150 eyes). We will allow you to expand to the full number of subjects for this study (990) after you have received approval of supplements addressing the following deficiency from our letter of October 3, 1997 (enclosed). No additional expansions of your IDE will be granted until supplements containing the following information are approved: