cycles per degree (CPD). However, the glare source of 2 lux appears to be too bright, since even the emmetropic subjects have significant reductions (50% to 80%) at all CPD. With this severe degree of impairment in normal subjects, there is very little additional decline, if any, that can be attributed to the study subjects. A small decrease of 10% to 30% with the glare source would show that the glare source was bright enough to affect normals, yet still be able to observe a decrease, if any, in the study subjects. Please re-validate this study using a less intense glare source; perhaps 1.5 lux would be appropriate.

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.

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

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
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