16. For your follow-up visit schedule, the text on page 20 of the protocol appears to be inconsistent with the chart on page 43 of the protocol. In addition, please justify your statement on page 20 that measurement of corneal topography will be at the discretion of the investigator.

On page 93 of your submission you give the name and address of your Institutional Review Board (IRB). You are advised that your IRB should be composed and conducted in accordance with 12 CFR Part 56 and that members of the IRB should conform to 21 CFR 56.107 (e): "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB."

If you submit information correcting the deficiencies, we will reevaluate your application. The information should be identified as an IDE amendment 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

Alternatively, you may request a regulatory hearing regarding the disapproval of your IDE application. The enclosure "Procedures to Request a Regulatory Hearing" describes how to submit such a request. The procedures governing a regulatory hearing are described in the regulations at 21 CFR Part 16.

If you prefer not to request a regulatory hearing, you may nevertheless request that this decision be reviewed by the IDE Review Committee within the Office of Device Evaluation (ODE). The enclosure entitled, "IDE Review Committee and Procedures to Request Review" discusses the purpose and operation of the Committee as well as how to submit such a request to the Committee.